

# **Raghavendra Institute of Pharmaceutical Education and Research (RIPER)-Autonomous**

Accorded under Sections 2 (f) and 12 (B) of UGC act 1956 and Accredited by NBA (UG)  
& NAAC-A Grade, Approved by PCI & AICTE, New Delhi

**Academic regulations (AR-21)**

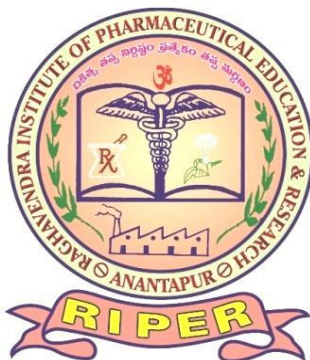
**Program structure**

**&**

**Syllabus**

**Effective from ACY 2021-2022**

**Bachelor of Pharmacy**



(Applicable for the batch admitted from 2021 -2022)

**: Awarding University:**

**Jawaharlal Nehru Technological University Anantapur (JNTUA)**

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## Introduction to the Document

The guidelines published in this document are official guidelines by the Board of studies (BoS) and Academic council of Raghavendra Institute of Pharmaceutical Education and Research (RIPER) - Autonomous, sponsored by Raghavendra Educational and Rural Development Society (RERDS), Anantapur, Andhra Pradesh. The document is a fusion product based on recommendations and guidelines stipulated for syllabus structure by UGC, AICTE, PCI, New Delhi.

- Academic regulations stipulated by Jawaharlal Nehru Technological University Anantapur (JNTUA), Ananthapuramu, Andhra Pradesh.
- Experts' opinion from the Board of Studies, Academic Council constituting approved Advisory boards members includes both academicians and researchers from reputed organizations at national and international levels.
- Suggestions and inputs from members of academic council and Board of studies.
- Recommendations based on feedback from alumni, employers, faculty, students, parents and other experts from allied area.

This *academic regulations, Program structure & Syllabus document* has been prepared to ensure quality system in teaching and learning process, examination, assessment, and functioning of other academic related matters to the satisfaction of stakeholders, such as students, parents, alumni, employers, faculty, etc. This document provides core principles of academic regulations duly approved by academic council and board of studies of this institution. The Implementation of these academic regulations shall lead to be considered in the institute and thereby enrich the quality of education and research in the field of pharmaceutical sciences. The guidelines shall aid the transparency and accountability in the administration set up. The list of objectives for implementing academic regulations and course structure through these guidelines are listed below,

- To improve the academic regulations and course structure.
- To strengthen the Industry-Institute interaction.
- To comply with rules and regulations of regulatory bodies like UGC, JNTUA, PCI, AICTE etc.,
- To meet the requirements of accreditation council and board.

- To enhance the quality of teaching-learning process and assessments.
- To provide career support programs, training for enhancing quality in placements and higher education.
- To place improved systems for feedback, self-appraisal of faculty and staff.
- To create bench marking with other institutes of repute.

### **Preamble**

The regulations stated herein below shall be called as a document of “**Academic regulations, Program structure & Syllabus for B. Pharm**” for Raghavendra Institute of Pharmaceutical Education and Research (RIPER)-Autonomous.

- These regulations shall be in force from the batch admitted from 2021 -2022 by the date of ratification by the Academic council and Board of studies (BoS) of the institute.
- In the event of any doubt about the interpretation of these regulations, the matter shall be referred to Board of studies (BoS) and Academic council and their decision shall be final.
- The Board of studies (BoS) and Academic council shall have the authority to modify, amend and repeal any of the provisions of these regulations from time to time.

## Definitions

- i. **“College”** means “Raghavendra Institute of Pharmaceutical Education & Research (RIPER) - Autonomous, Anantapur, Andhra Pradesh”.
- ii. **“Student”** means a candidate who has taken admission into B. Pharm course of this college as per the guidelines stipulated from time to time by the regulations of State Government of Andhra Pradesh and the Government of India for admissions into various courses of study and the affiliating university, i.e., Jawaharlal Nehru Technological University, Anantapur (JNTUA), Ananthapuramu, Andhra Pradesh.
- iii. **“Academic Council”** means the Academic council constituted as per the guidelines of UGC.
- iv. **“Board of Studies”** means Board of Studies constituted in each department as per the guidelines of UGC.
- v. **“Principal”** means the Head of the institution
- vi. **“Head of the Department”** means the Head of an Academic Department of the College.
- vii. **“Faculty member”** means the teacher (Assistant/Associate/Professor) working on regular or ad-hoc basis in any of the Academic Departments of the College.
- viii. **“Program”** means a candidate who has chosen to avail degree of B. Pharm of this college as per the marks/ rank awarded by the National/ University/ State common entrance tests, India.
- ix. **“Course”** *individual subjects described with content for instructions to the students.*
- x. **“Assessment”** means evaluation process for the outcome and grading in term of the marks.
- xi. **“Credit”** means a weight to the time requirements of the academic course in the institute.

## **Quality Policy**

To formulate quality graduate through quality teaching and training in regard to versatile development of professional skills for their higher learning and career.

## **Program Specific Outcomes**

**PSO 1:** Accomplish a successful professional career in pharmaceutical industries, health care sector and health system research.

**PSO 2:** Adopt their higher learning for innovative and widening horizons in pharmaceutical and health care system to global standards.

**PSO 3:** Facilitate support to design and manufacture of pharmaceuticals and community services to public health.

**PSO 4:** Possess team based and multidisciplinary approach to broaden social contact and to resolve and manage issues in relation to public health.



## **Program Outcomes**

**PO1: Pharmacy Knowledge** – Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioural, social, and administrative pharmacy sciences; and manufacturing practices.

**PO2: Planning abilities** – Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

**PO3: Problem Analysis** – Utilize the principles of scientific enquiry, thinking analytically, clearly, and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate, and apply information systematically and shall make defensible decisions.

**PO4: Modern Tool Usage** – Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.

**PO5: Leadership skills** – Understand and consider the human reaction to change, motivation issues, leadership and team building when planning changes required for fulfilment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.

**PO6: Professional Identity** – Understand, analyze and communicate the value of their professional roles in society (e.g., health care professionals, promoters of health, educators, managers, employers, employees).

**PO7: Pharmaceutical Ethics** – Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behaviour that recognizes cultural and personal variability in values, communication, and lifestyles. Use ethical

frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

**PO8: Communication** – Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

**PO9: The Pharmacist and Society** – Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

**PO 10: Environment and sustainability** – Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

**PO 11: Life-Long Learning** – Recognize the need for and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## **Academic Regulations for Bachelor of Pharmacy (AR-21)**

### **1. Short Title and Commencement**

These regulations shall be called as “Academic Regulations for the Bachelor of Pharmacy (AR-21) Degree Program - Choice Based Credit System (CBCS) of the Raghavendra Institute of Pharmaceutical Education & Research (RIPER)-Autonomous, Anantapur”. They shall come into effect from the Academic Year 2021-22. The regulations framed are subject to modifications from time to time by Board of studies & Academic Council of RIPER-Autonomous.

### **2. Minimum qualification for admission**

**2.1 First year B. Pharm:** Admission to this programme shall be made subject to the eligibility and qualifications prescribed by the awarding university (JNTUA), State government of Andhra Pradesh/Govt. of India and as per regulatory bodies like All India Council for Technical Education (AICTE) and Pharmacy Council of India (PCI), New Delhi, from time to time.

- i. 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the two subjects: Mathematics or Biology.
- ii. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.
- iii. Provided that a student should complete the age of 17 years on or before 31<sup>st</sup> December of the year of admission to the course.
- iv. Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

**2.2. B. Pharm lateral entry (to third semester):** A pass in D. Pharm. course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

### **3. Duration of the program**

The course of study for B. Pharm shall extend over a period of eight semesters (four academic years) and six semesters (three academic years) for lateral entry students. The curricula and syllabi for the program shall be prescribed from time to time by Board of studies & Academic Council of RIPER-Autonomous.

**4. Medium of instruction and examinations:** Medium of instruction and examination shall be in English.

## **5. Working days in each semester**

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

## **6. Attendance and progress**

- A student shall be eligible to appear for the semester end examinations, if the student acquires a minimum of 75% of attendance in aggregate of all the subjects and not less than 50% in any of the subject.
- Shortage of attendance in aggregate up to 10% (65% and above, and below 75%) in each semester may be condoned by the college academic committee on genuine and valid grounds, based on the student's representation with supporting evidence.
- A stipulated fee shall be payable for condoning of shortage of attendance. Shortage of attendance below 65% in aggregate shall in no case be condoned.
- Students whose shortage of attendance is not condoned in any semester are not eligible to take their end examinations of that semester.

## **7. Program/Course credit structure**

As per the philosophy of Choice Based Credit System (CBCS), certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

### **7.1. Credit assignment**

#### **7.1.1. Theory and Laboratory courses**

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and/or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

## 7.2. Minimum credit requirements

The minimum credit points required for award of a B. Pharm. degree is 221<sup>\$</sup>/222<sup>#</sup> (<sup>#</sup>Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at Intermediate/HSC and appearing for Remedial Biology (RB)course. <sup>\$</sup>Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at Intermediate/HSC and appearing for Remedial Mathematics (RM)course). These credits are divided into Theory courses, Tutorials, Practical, Practice School and Project, extra/co-curricular activities over the duration of eight semesters. The credits are distributed semester-wise as shown in Table IX. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

The lateral entry students shall get 52 credit points transferred from their D. Pharm program. Such students shall take up additional remedial courses of ‘Communication Skills’ (Theory and Practical) and ‘Computer Applications in Pharmacy’ (Theory and Practical) equivalent to 3 and 4 credit points respectively, a total of 7 credit points to attain 59 credit points, the maximum of I and II semesters.

## 7.3. Audit Courses

All the students of II & IV Semester shall choose any one out of five audit courses. A candidate is required to submit report at the end of the semester to the examining authority of the RIPER-Autonomous. Satisfactory report from the concerned faculty is required to declare him/her as pass. However, Universal Human Values audit course is introduced by JNTUA in III semester. The student has to get a minimum of 50% in internal examination to declare him/her as pass. The maximum marks for this audit course (Universal Human Values) is 50.

## 8. Academic work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses. A faculty advisor/mentor shall be assigned to advise students on the programme, its Course Structure and Curriculum, Choice of Courses, based on his competence, progress, pre-requisites and interest.

**9. Course structure:** The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII.

**Table-I: Course of study for semester I**

<b>Course code</b>	<b>Name of the course</b>	<b>No. of hours</b>	<b>Tutorial</b>	<b>Credit points</b>
BP101T	Human Anatomy and Physiology I– Theory (CC)	3	1	4
BP102T	Pharmaceutical Analysis I – Theory (CC)	3	1	4
BP103T	Pharmaceutics I – Theory (CC)	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory (CC)	3	1	4
BP105T	Communication skills – Theory (SEC)	2	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory (AECC)	2	-	2
BP107P	Human Anatomy and Physiology – Practical (CC)	4	-	2
BP108P	Pharmaceutical Analysis I – Practical (CC)	4	-	2
BP109P	Pharmaceutics I – Practical (CC)	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical (CC)	4	-	2
BP111P	Communication skills – Practical (SEC)	2	-	1
BP112RBP	Remedial Biology – Practical (AECC)	2	-	1
BP113CE	Comprehensive online examination (AECC)	-	-	-
<b>Total</b>		<b>34<sup>\$</sup>/36<sup>#</sup></b>	<b>4</b>	<b>29<sup>\$</sup>/30<sup>#</sup></b>

<sup>#</sup>Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at Intermediate/HSC and appearing for Remedial Biology (RB) course.

<sup>\$</sup>Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at Intermediate/HSC and appearing for Remedial Mathematics (RM) course.

**CC: Core Course**

**AECC: Ability Enhancement Compulsory Course**

**SEC: Skill Enhancement Course**

**DSE: Discipline Specific Elective**

**GE: General Elective**

**Table-II: Course of study for semester II**

<b>Course Code</b>	<b>Name of the course</b>	<b>No. of Hours</b>	<b>Tutorial</b>	<b>Credit points</b>
BP201T	Human Anatomy and Physiology II – Theory (CC)	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory (CC)	3	1	4
BP203T	Biochemistry – Theory (CC)	3	1	4
BP204T	Pathophysiology – Theory (CC)	3	1	4
BP205T	Computer Applications in Pharmacy – Theory (AECC)	3	-	3
BP206T	Environmental sciences – Theory (SEC)	3	-	3
BP207P	Human Anatomy and Physiology II –Practical (CC)	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical (CC)	4	-	2
BP209P	Biochemistry – Practical (CC)	4	-	2
BP210P	Computer Applications in Pharmacy – Practical (SEC)	2	-	1
BP211A1	Yoga & Stress Management#	2	-	-
BP211A2	Human Rights & Responsibilities#			
BP211A3	Constitution of India#			
BP211A4	Pedagogy studies#			
BP211A5	Soil and Water Conservation#			
BP212CE	Comprehensive online examination (AECC)	-	-	-
<b>Total</b>		<b>34</b>	<b>4</b>	<b>29</b>

# Audit Course

**CC: Core Course**

**AECC: Ability Enhancement Compulsory Course**

**SEC: Skill Enhancement Course**

**DSE: Discipline Specific Elective**

**GE: General Elective**

**Table-III: Course of study for semester III**

<b>Course code</b>	<b>Name of the course</b>	<b>No. of Hours</b>	<b>Tutorial</b>	<b>Credit points</b>
BP301T	Pharmaceutical Organic Chemistry II – Theory (CC)	3	1	4
BP302T	Physical Pharmaceutics I – Theory (CC)	3	1	4
BP303T	Pharmaceutical Microbiology – Theory (CC)	3	1	4
BP304T	Pharmaceutical Engineering – Theory (CC)	3	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical (CC)	4	-	2
BP306P	Physical Pharmaceutics I – Practical (CC)	4	-	2
BP307P	Pharmaceutical Microbiology – Practical (CC)	4	-	2
BP 308P	Pharmaceutical Engineering –Practical (CC)	4	-	2
BP309CE	Comprehensive online examination (AECC)	-	-	-
BP310UHV	Universal Human Values#	2	-	-
<b>Total</b>		<b>30</b>	<b>4</b>	<b>24</b>

# Audit Course

**CC: Core Course**

**AECC: Ability Enhancement Compulsory Course**

**SEC: Skill Enhancement Course**

**DSE: Discipline Specific Elective**

**GE: General Elective**



**Table-IV: Course of study for semester IV**

<b>Course Code</b>	<b>Name of the course</b>	<b>No. of Hours</b>	<b>Tutorial</b>	<b>Credit points</b>
BP401T	Pharmaceutical Organic Chemistry III– Theory (CC)	3	1	4
BP402T	Medicinal Chemistry I – Theory (CC)	3	1	4
BP403T	Physical Pharmaceutics II – Theory (CC)	3	1	4
BP404T	Pharmacology I – Theory (CC)	3	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory (CC)	3	1	4
BP406P	Medicinal Chemistry I – Practical (CC)	4	-	2
BP407P	Physical Pharmaceutics II – Practical (CC)	4		2
BP408P	Pharmacology I – Practical (CC)	4	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical (CC)	4	-	2
BP410A1	Disaster Management#	2	-	-
BP410A2	Personality development through life enlightenment skills#			
BP410A3	Drug abuse: Problem, prevention & management#			
BP410A4	Industrial Waste Management#			
BP410A5	English for Research Paper Writing#			
BP411CE	Comprehensive online examination (AECC)	-	-	-
<b>Total</b>		<b>33</b>	<b>5</b>	<b>28</b>

# Audit Course

**CC: Core Course****AECC: Ability Enhancement Compulsory Course****SEC: Skill Enhancement Course****DSE: Discipline Specific Elective****GE: General Elective**

**Table-V: Course of study for semester V**

<b>Course code</b>	<b>Name of the course</b>	<b>No. of Hours</b>	<b>Tutorial</b>	<b>Credit points</b>
BP501T	Medicinal Chemistry II – Theory (CC)	3	1	4
BP502T	Industrial Pharmacy I – Theory (CC)	3	1	4
BP503T	Pharmacology II – Theory (CC)	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory (CC)	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory (AECC)	3	1	4
BP506P	Industrial Pharmacy I – Practical (CC)	4	-	2
BP507P	Pharmacology II – Practical (CC)	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical (CC)	4	-	2
BP509ET	Pharma Marketing Management (GE)	3	1	4
BP510ET	Health care dietary supplements (GE)			
BP511ET	Entrepreneurship Development (GE)			
BP512CE	Comprehensive online examination (AECC)	-	-	-
<b>Total</b>		<b>30</b>	<b>6</b>	<b>30</b>

**CC: Core Course****AECC: Ability Enhancement Compulsory Course****SEC: Skill Enhancement Course****DSE: Discipline Specific Elective****GE: General Elective**

**Table-VI: Course of study for semester VI**

<b>Course code</b>	<b>Name of the course</b>	<b>No. of hours</b>	<b>Tutorial</b>	<b>Credit points</b>
BP601T	Medicinal Chemistry III – Theory (CC)	3	1	4
BP602T	Pharmacology III – Theory (CC)	3	1	4
BP603T	Herbal Drug Technology – Theory (CC)	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory (CC)	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory (CC)	3	1	4
BP606T	Biostatistics and Research Methodology (CC)	3	1	4
BP607P	Medicinal chemistry III – Practical (CC)	4	-	2
BP608P	Pharmacology III – Practical (CC)	4	-	2
BP609P	Herbal Drug Technology – Practical (CC)	4	-	2
BP610CE	Comprehensive online examination (AECC)	-	-	-
<b>Total</b>		<b>30</b>	<b>6</b>	<b>30</b>

**CC: Core Course**

**AECC: Ability Enhancement Compulsory Course**

**SEC: Skill Enhancement Course**

**DSE: Discipline Specific Elective**

**GE: General Elective**

**Table-VII: Course of study for semester VII**

<b>Course code</b>	<b>Name of the course</b>	<b>No. of hours</b>	<b>Tutorial</b>	<b>Credit points</b>
BP701T	Instrumental Methods of Analysis – Theory (CC)	3	1	4
BP702T	Industrial Pharmacy II – Theory (CC)	3	1	4
BP703T	Pharmaceutical Quality Assurance –Theory (CC)	3	1	4
BP704T	Novel Drug Delivery System – Theory (CC)	3	1	4
BP705P	Instrumental Methods of Analysis –Practical (CC)	4	-	2
BP706PS	Practice School (SEC)	12	-	6
BP707CE	Comprehensive online examination (AECC)	-	-	-
<b>Total</b>		<b>28</b>	<b>4</b>	<b>24</b>

**CC: Core Course**

**AECC: Ability Enhancement Compulsory Course**

**SEC: Skill Enhancement Course**

**DSE: Discipline Specific Elective**

**GE: General Elective**

**Table-VIII: Course of study for semester VIII**

<b>Course code</b>	<b>Name of the course</b>	<b>No. of hours</b>	<b>Tutorial</b>	<b>Credit points</b>
BP801T	Pharmacy Practice – Theory (CC)	3	1	4
BP802T	Social and Preventive Pharmacy (CC)	3	1	4
BP803ET	Pharmaceutical Regulatory Science (DSE)	3 + 3 = 6	1 + 1 = 2	4 + 4 = 8
BP804ET	Computer Aided Drug Design (DSE)			
BP805ET	Cell and Molecular Biology (DSE)			
BP806ET	Cosmetic Science (DSE)			
BP807ET	Experimental Pharmacology (DSE)			
BP808ET	Advanced Instrumentation Techniques (DSE)			
BP809ET	Quality Control and Standardization of Herbals (DSE)			
BP810PW	Project Work	12	-	6
BP811CE	Comprehensive online examination (AECC)	-	-	-
<b>Total</b>		<b>24</b>	<b>4</b>	<b>22</b>

**CC: Core Course****AECC: Ability Enhancement Compulsory Course****SEC: Skill Enhancement Course****DSE: Discipline Specific Elective****GE: General Elective****Extracurricular/ Co-curricular activities**

<b>S. No.</b>	<b>Name of the Category</b>
1.	Add-on Courses-compulsory credit-1
2.	NSS, NCC and other social service activities- Compulsory credit-1
3.	Achievements- Compulsory credits- 2
4.	<b>5<sup>th</sup> Credit can be any one of the above</b>

**Table-IX: Semester wise credits distribution**

<b>Semester</b>	<b>Credit Points</b>
I	29 <sup>\$</sup> /30 <sup>#</sup>
II	29
III	24
IV	28
V	30
VI	30
VII	24
VIII	22
Extracurricular/ Co-curricular activities	05*
<b>Total credit points for the program</b>	<b>221<sup>\$</sup>/222<sup>#</sup></b>

<sup>\$</sup>Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at Intermediate/HSC and appearing for Remedial Mathematics course.

<sup>#</sup>Applicable ONLY for the students studied Mathematics / Physics / Chemistry at Intermediate/HSC and appearing for Remedial Biology course.

**Extracurricular/ Co-curricular activities -5 Credits**

**Rules and Regulations:**

**Categories**

1. Add on courses (**1 credit**)
2. NSS, NCC and other social service activities (**1 credit**)
3. Achievements (**2 credits**)
4. **5<sup>th</sup> credit can be any one of the above three categories.**

### **Award of Credits**

#### **1. Add on courses (1 credit Compulsory) (In campus/Off campus) (Offline/online)**

One credit -Each short-term course certificate as per UGC norms for add on courses.

(30hrs Duration/8 weeks).

Two credits- Diploma course certificate as per UGC norms for add on courses

(60hrs Duration/16 weeks).

Others discretion of Director of Academics/CE/Principal.

#### **2. NSS, NCC and other social activities (1 Credit Compulsory)**

(30 hours for One credit. 60 hours for Two credits)

### **Calculation of Hours**

A. Three Commemoration day celebrations/Any other day celebration participation=1 hr. (i.e.- Independence Day, Republic day, Gandhi Jayanti, etc.)

B. One Participation in Rally = 2 hrs.

C. For one day camp participation= 3 hrs.

D. One day Yoga/training involving learn and practice participation =2 hrs.

E. One session of Plantation day- 2 hrs.

F. Donating blood donation at Blood donation camp at college or hospital- 5 hrs. (Maximum one per year allowed. Certificate is required in case in outside of the college)

G. One day participation in Clean India like activities at outside -5 hrs.

H. Three Awareness program participation-1hrs

I. One Street play performance/flash mob performance -3 hrs.

J. Four audience participation in programs (Discretion of NSS Officer/CE/Principal)- 1 hr.

K. Any performance in any of the events which are not listed here (Discretion of NSS officer/CE/Principal)-2 hrs.

L. One Social service merit certificate (Lion's club/Rotary club/Traffic police/Police volunteers/Other Govt. Organizations)-1 credit

M. Others discretion of NSS officer/CE/Principal.

#### **3. Achievements (Compulsory Credits 2)**

**Note:** (One credit is compulsory from listed research Scholar Initiative activities Only one credit can be obtained from own institute for any of the clause of the "Achievement" Category).

### **Research Scholarly Activities**

- A. One publication – 1 credit
- B. One indexed Publication- 2 credits
- C. One IPC Participation-1 credit
- D. One IPC presentation (Oral/Poster)-2 Credits
- E. Local chapters like IPA/ISPOR/RSC publications or presentations-1 credit
- F. One Presentations at seminars/conferences at india-1 credit
- G. One Presentations at seminars/conferences at outside India-2 credits
- H. Four Conferences/seminars/workshops Participation national level -1 credit
- I. Three International level Conferences/seminars/workshops Participation at India - 1 credit
- J. Two International Conferences/seminars/workshops Participation at outside India -2 credit
- K. Others discretion of R&D Director/CE/Principal.

### **Certificates for Achievements (Sports/cultural/others)**

- A. One National/State/District/University level certificate-2 credits (winner/runner)
- B. One National/State/District/University level certificate-1 credit (only when Participation certificate received).
- C. One Non-government/affiliated institution Merits/own institute level certificate-1 credit (winner/runner).
- D. Others discretion of NSS officer/CE/Principal.

### **Evaluation of Extracurricular/Co-curricular activities**

A detailed report has to be prepared by the student, consisting of Extracurricular/Co-curricular activities (Proofs/Certificates of Add on courses, Research scholarly activities, Participation in social service activities like NSS & NCC). All these certificates shall be duly verified, signed and forwarded by the project guide to the internal & external evaluator along with their project work at the time of Project Viva Voce. Final award of credits shall be done by the internal & external evaluator.



## **10. Program Committee**

1. The B. Pharm. program shall have a Program Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Program Committee shall be as follows: A senior teacher/Principal shall be the Chairperson; One Teacher from each department handling B. Pharm courses/HODs of the departments; senior faculty.
3. Duties of the Program Committee:
  - i. Periodically reviewing the progress of the classes.
  - ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
  - iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
  - iv. Communicating its recommendation to the Head of the institution on academic matters.
  - v. The Program Committee shall meet at least twice in a semester preferably at the end of each Sessional exam.

## **11. Examinations/Assessments**

The scheme for internal assessment and end semester examinations is given in Table – X.

**Tables-X: Schemes for internal assessments and end semester examinations semester wise**

**Semester I**

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (Hrs.)	
			Marks	Duration (Hrs.)				
BP101T	Human Anatomy and Physiology I– Theory	10	15	1	25	75	3	100
BP102T	Pharmaceutical Analysis I – Theory	10	15	1	25	75	3	100
BP103T	Pharmaceutics I – Theory	10	15	1	25	75	3	100
BP104T	Pharmaceutical Inorganic Chemistry – Theory	10	15	1	25	75	3	100
BP105T	Communication skills – Theory	5	10	1	15	35	1.5	50
BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory	5	10	1	15	35	1.5	50
BP107P	Human Anatomy and Physiology – Practical	5	10	4	15	35	4	50
BP108P	Pharmaceutical Analysis I – Practical	5	10	4	15	35	4	50
BP109P	Pharmaceutics I – Practical	5	10	4	15	35	4	50
BP110P	Pharmaceutical Inorganic Chemistry – Practical	5	10	4	15	35	4	50
BP111P	Communication skills – Practical	5	5	2	10	15	2	25
BP112RBP	Remedial Biology – Practical	5	5	2	10	15	2	25
BP113CE	Comprehensive online examination	-	-	-	-	50	1	50
Total		75\$/80#	125\$/130#	24\$/26#	200\$/210#	575\$/590#	34\$/ 36#	775\$/800#

<sup>#</sup>Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

<sup>\$</sup>Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

## Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (Hrs.)	
			Marks	Duration (Hrs.)				
BP201T	Human Anatomy and Physiology II – Theory	10	15	1	25	75	3	100
BP202T	Pharmaceutical Organic Chemistry I – Theory	10	15	1	25	75	3	100
BP203T	Biochemistry – Theory	10	15	1	25	75	3	100
BP204T	Pathophysiology – Theory	10	15	1	25	75	3	100
BP205T	Computer Applications in Pharmacy – Theory	10	15	1	25	50	2	75
BP206T	Environmental sciences – Theory	10	15	1	25	50	2	75
BP207P	Human Anatomy and Physiology II –Practical	5	10	4	15	35	4	50
BP208P	Pharmaceutical Organic Chemistry I– Practical	5	10	4	15	35	4	50
BP209P	Biochemistry – Practical	5	10	4	15	35	4	50
BP210P	Computer Applications in Pharmacy – Practical	5	5	2	10	15	2	25
BP212CE	Comprehensive online examination	-	-	-	-	50	1	50
Total		80	125	20	205	570	31	775

### Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (Hrs.)	
			Marks	Duration (Hrs.)				
BP301T	Pharmaceutical Organic Chemistry II – Theory	10	15	1	25	75	3	100
BP302T	Physical Pharmaceutics I –Theory	10	15	1	25	75	3	100
BP303T	Pharmaceutical Microbiology – Theory	10	15	1	25	75	3	100
BP304T	Pharmaceutical Engineering – Theory	10	15	1	25	75	3	100
BP305P	Pharmaceutical Organic Chemistry II – Practical	5	10	4	15	35	4	50
BP306P	Physical Pharmaceutics I – Practical	5	10	4	15	35	4	50
BP307P	Pharmaceutical Microbiology – Practical	5	10	4	15	35	4	50
BP308P	Pharmaceutical Engineering – Practical	5	10	4	15	35	4	50
BP309CE	Comprehensive online examination (AECC)	-	-	-	-	50	1	50
BP310UHV	Universal Human Values#	20	30	2	50	-	-	50
Total		80	130	22	210	490	29	700

# Audit Course

## Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (Hrs.)	
			Marks	Duration (Hrs.)				
BP401T	Pharmaceutical Organic Chemistry III– Theory	10	15	1	25	75	3	100
BP402T	Medicinal Chemistry I – Theory	10	15	1	25	75	3	100
BP403T	Physical Pharmaceutics II – Theory	10	15	1	25	75	3	100
BP404T	Pharmacology I – Theory	10	15	1	25	75	3	100
BP405T	Pharmacognosy I – Theory	10	15	1	25	75	3	100
BP406P	Medicinal Chemistry I – Practical	5	10	4	15	35	4	50
BP407P	Physical Pharmaceutics II – Practical	5	10	4	15	35	4	50
BP408P	Pharmacology I – Practical	5	10	4	15	35	4	50
BP409P	Pharmacognosy I – Practical	5	10	4	15	35	4	50
BP411CE	Comprehensive online examination	-	-	-	-	50	1	50
Total		70	115	21	185	565	32	750

## Semester V

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (Hrs.)	
			Marks	Duration (Hrs.)				
BP501T	Medicinal Chemistry II – Theory	10	15	1	25	75	3	100
BP502T	Industrial Pharmacy I– Theory	10	15	1	25	75	3	100
BP503T	Pharmacology II – Theory	10	15	1	25	75	3	100
BP504T	Pharmacognosy II – Theory	10	15	1	25	75	3	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1	25	75	3	100
BP506P	Industrial Pharmacy I– Practical	5	10	4	15	35	4	50
BP507P	Pharmacology II – Practical	5	10	4	15	35	4	50
BP508P	Pharmacognosy II – Practical	5	10	4	15	35	4	50
BP509ET	Pharma Marketing Management	10	15	1	25	75	3	100
BP510ET	Health Care Dietary Supplements							
BP511ET	Entrepreneurship Development							
BP512CE	Comprehensive online examination (AECC)	-	-	-	-	50	1	50
Total		75	120	18	195	605	31	800

## Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (Hrs.)	
			Marks	Duration (Hrs.)				
BP601T	Medicinal Chemistry III – Theory	10	15	1	25	75	3	100
BP602T	Pharmacology III – Theory	10	15	1	25	75	3	100
BP603T	Herbal Drug Technology – Theory	10	15	1	25	75	3	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1	25	75	3	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1	25	75	3	100
BP606T	Biostatistics and Research Methodology – Theory	10	15	1	25	75	3	100
BP607P	Medicinal chemistry III – Practical	5	10	4	15	35	4	50
BP608P	Pharmacology III – Practical	5	10	4	15	35	4	50
BP609P	Herbal Drug Technology – Practical	5	10	4	15	35	4	50
BP610CE	Comprehensive online examination	-	-	-	-	50	1	50
Total		75	120	18	195	605	31	800

## Semester VII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (Hrs.)	
			Marks	Duration (Hrs.)				
BP701T	Instrumental Methods of Analysis – Theory	10	15	1	25	75	3	100
BP702T	Industrial Pharmacy – Theory	10	15	1	25	75	3	100
BP703T	Pharmaceutical Quality Assurance – Theory	10	15	1	25	75	3	100
BP704T	Novel Drug Delivery System – Theory	10	15	1	25	75	3	100
BP705 P	Instrumental Methods of Analysis – Practical	5	10	4	15	35	4	50
BP706 PS	Practice School*	25	-	-	25	125	5	150
BP707CE	Comprehensive online examination	-	-	-	-	50	1	50
Total		70	70	8Hrs	140	510	22	650

\* The subject experts at college level shall conduct examinations



# Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration (Hrs.)	
			Marks	Duration (Hrs.)				
BP801T	Pharmacy Practice – Theory	10	15	1	25	75	3	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1	25	75	3	100
BP803ET	Pharmaceutical Regulatory Science – Theory	10+10=20	15+15=30	1+1=2	25+25=50	75+75=150	3+3=6	100+100=200
BP804ET	Computer Aided Drug Design – Theory							
BP805ET	Cell and Molecular Biology – Theory							
BP806ET	Cosmetic Science – Theory							
BP807ET	Experimental Pharmacology – Theory							
BP808ET	Advanced Instrumentation Techniques – Theory							
BP808ET	Quality Control and Standardization of Herbals							
BP810PW	Project Work	-	-	-	-	150	4	150
BP811CE	Comprehensive online examination	-	-	-	-	50	1	50
Total		40	60	4	100	500	17	600

### 11.1. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

**Table-XI: Scheme for awarding internal assessment: Continuous mode**

<b>Theory</b>		
<b>Criteria</b>	<b>Maximum Marks</b>	
Assignment	5	2.5
Student – Teacher interaction		
i. Seminar	3	1.5
ii. Group Discussion	2	1
<b>Total</b>	<b>10</b>	<b>5</b>
<b>Practical</b>		
Regular viva voce	<b>5</b>	

#### 11.2.1. Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the Academic calendar schedule. The scheme of question paper for theory and practical Sessional examinations is given below. Final sessional marks shall be arrived at by considering the marks secured by the student in both the mid examinations with 80% weightage to the better mid examination and 20% to the other. **The final sessional examinations shall be computed for internal assessment as per the requirements given in tables – X.**

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. **However, for the courses such as, Communication skills theory, Remedial biology theory shall be conducted for 30 marks and shall be computed for 10 marks.** Similarly, Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks. **However, for the courses such as, Communication skills practical, Remedial biology practical, Computer applications in pharmacy practical shall be conducted for 20 marks and shall be computed for 5 marks.**

**Question paper pattern for theory sessional examinations**

I.	MCQs	: 10×1=10
II.	Long answer (Answer 1 out of 2)	: 1×10=10
III.	Short answers (Answer 2 out of 3)	: 2×5=10
<b>Total</b>		<b>: 30 Marks</b>

**Question paper pattern for practical sessional examinations**

I.	Synopsis	: 10
II.	Experiment	: 25
III.	Viva	: 05
<b>Total</b>		<b>: 40 Marks</b>

**Question paper pattern for practical sessional examinations** (Communication skills practical, Remedial biology practical, Computer applications in pharmacy practical).

I.	Synopsis	: 05
II.	Experiment	: 10
III.	Viva	: 05
<b>Total</b>		<b>: 20 Marks</b>

**The End examinations shall be conducted as per the requirements given in tables – X.**

**Question paper pattern for end semester theory examinations**

**For 75 marks paper**

I. Objective Type Questions (10 x 2)	=	10 x 2 = 20
(Answer all the questions)		
II. Long Answers (Answer 2 out of 3)	=	2 x 10 = 20
III. Short Answers (Answer 7 out of 9)	=	7 x 5 = 35
<hr/>		
Total	=	75 marks
<hr/>		

**For 50 marks paper**

I. Long Answers (Answer 2 out of 3)	=	2 x 10 = 20
II. Short Answers (Answer 6 out of 8)	=	6 x 5 = 30
<hr/>		
Total=		50 marks
<hr/>		

**For 35 marks paper**

I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 5 out of 7)	=	5 x 5 = 25
<hr/>		
Total=		35 marks
<hr/>		

**Question paper pattern for end semester practical examinations**

**For 35 Marks paper**

I. Synopsis	=	5
II. Experiments	=	25
III. Viva voce	=	5
<hr/>		
Total	=	35 marks
<hr/>		

**Question paper pattern for end semester practical examinations**

**For 15 marks paper**

I. Synopsis	=	3
II. Experiments	=	10
III. Viva voce	=	2
<hr/>		
Total	=	15 marks
<hr/>		

## **12. Promotion and award of grades**

A student shall be declared PASS and eligible for getting grade in a course of B. Pharm program if he/she secures at least 50% marks in that particular course including internal assessment. For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination.

## **13. Carry forward of marks**

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However, his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

## **14. Improvement of internal assessment**

- A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and has failed in the end examination
- The candidate should have passed all the subjects for which the Internal Evaluation marks secured are more than 50%. Out of the subjects, if the candidate has failed in the examination due to Internal Evaluation marks secured being less than 50%, the candidate shall be given one chance for each Theory subject and for a maximum of three Theory subjects for Improvement of Internal evaluation marks.
- The candidate has to re-register for the chosen subjects and fulfill the academic requirements.
- For reregistration the candidates must apply to the college by paying the requisite fees and get approval before the start of the semester in which re-registration is required
- In the event of availing the Improvement of Internal evaluation marks, the internal evaluation marks as well as the End Examinations marks secured in the previous attempt(s) for the reregistered subjects stand cancelled.

## **15. Advanced supplementary examination**

Advanced supplementary examination shall be conducted immediately after the declaration of results. The exact dates of examinations shall be notified from time to time.

## 16. Academic Progression:

No student shall be admitted to any examination unless he/she fulfills the norms given in

6. Academic progression rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of V semester until all the courses of I and II semesters are successfully completed.

A student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of I, II, III and IV semesters are successfully completed.

A student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of I, II, III, IV, V and VI semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to VIII semesters within the stipulated time period as per the norms specified in 26.

A lateral entry student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of III and IV semesters are successfully completed.

A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of III, IV, V and VI semesters are successfully completed. A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms specified in 26.

Any student who has given more than 4 chances for successful completion of I / III semester courses and more than 3 chances for successful completion of II / IV semester courses shall be permitted to attend V / VII semester classes ONLY during the subsequent academic year as the case may be. In simpler terms there shall NOT be any ODD BATCH for any semester.

**Note:** Grade AB should be considered as failed and treated as one head for deciding academic progression. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

## 17. Grading of performances

### 17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – XII.

**Table – XII: Letter grades and grade points equivalent to Percentage of marks and performances**

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

## 18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called ‘Semester Grade Point Average’ (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C<sub>1</sub>, C<sub>2</sub>, C<sub>3</sub>, C<sub>4</sub> and C<sub>5</sub> and the student’s grade points in these courses are G<sub>1</sub>, G<sub>2</sub>, G<sub>3</sub>, G<sub>4</sub> and G<sub>5</sub>, respectively, and then students’ SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example, if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$C_1G_1 + C_2G_2 + C_3G_3 + C_4* \text{ZERO} + C_5G_5$$

$$\text{SGPA} = \frac{\quad}{C_1 + C_2 + C_3 + C_4 + C_5}$$

## 19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all VIII semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8}{C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + C_8}$$

where  $C_1, C_2, C_3, \dots$  is the total number of credits for semester I, II, III .... and  $S_1, S_2, S_3, \dots$  is the SGPA of semester I, II, III....

## 20. Declaration of class

The class shall be awarded on the basis of CGPA as follows: First Class with Distinction = CGPA of 7.50 and above  
First Class = CGPA of 6.00 to 7.49  
Second Class = CGPA of 5.00 to 5.99



## 21. Project work

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subjects opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below.

### ***Evaluation of Dissertation Book:***

Objective(s) of the work done	15 Marks
Methodology adopted	20 Marks
Results and Discussions	20 Marks
Conclusions and Outcomes	20 Marks

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<b>Total</b>	<b>75 Marks</b>
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### **Evaluation of Presentation:**

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Presentation of work	25 Marks
Communication skills	20 Marks
Question and answer skills	30 Marks

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<b>Total</b>	<b>75 Marks</b>
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*Explanation:* The 75 marks assigned to the dissertation book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

## **22. Industrial training (Desirable)**

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

## **23. Practice School**

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level, and grade point shall be awarded.

## **24. Award of Ranks**

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the B. Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

**25. Withholding of results:** If the candidate has any dues not paid institute or if any case of indiscipline or malpractice is pending against him/her, the result of the candidate shall be withheld and he will not be allowed / promoted into the next higher semester. The issue of awarding a degree is liable to be withheld in such cases.

**26. Award of degree:** Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

## **27. Duration for completion of the program of study**

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh registration.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Human anatomy and Physiology-I (Theory)</b>
<b>Course Code</b>	<b>BP101T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides basic knowledge required to understand the various disciplines of pharmacy.

**Course outcomes:** Upon completion of this course the student should be able to

CO1: Use anatomical knowledge to predict physiological consequences, and use knowledge of function to predict the features of anatomical structures.

CO2: Synthesize ideas to make a connection between knowledge of anatomy and physiology and real-world situations, including healthy lifestyle decisions and homeostatic imbalances.

CO3: Describe the structure and functions of various organs of the human body

#### **Theory course contents**

<b>Unit</b>	<b>Topics</b>	<b>No. of hours</b>
<b>I</b>	<p><b>Introduction to human body</b></p> <p>Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.</p> <p><b>Cellular level of organization</b></p> <p>Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b)</p>	<b>12</b>

	<p>Paracrine c) Synaptic d) Endocrine</p> <p><b>Tissue level of organization</b></p> <p>Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.</p>	
<b>II</b>	<p><b>Integumentary system</b></p> <p>Structure and functions of skin</p> <p><b>Skeletal system</b></p> <p>Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system.</p> <p>Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction.</p> <p><b>Joints</b></p> <p>Structural and functional classification, types of joints movements and its articulation.</p>	<b>12</b>
<b>III</b>	<p><b>Body fluids and blood</b></p> <p>Body fluids, composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.</p> <p><b>Lymphatic system</b></p> <p>Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system.</p>	<b>12</b>
<b>IV</b>	<p><b>Peripheral nervous system</b></p> <p>Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.</p> <p>Origin and functions of spinal and cranial nerves.</p> <p><b>Special senses:</b> Structure and functions of eye, ear, nose and tongue and their disorders.</p>	<b>12</b>
<b>V</b>	<p><b>Cardiovascular system</b></p> <p>Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction</p>	

	system of heart and heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.	<b>12</b>
	<b>Total</b>	<b>60</b>

#### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Tortora Gerard J, Derrickson Bryan. Principles of anatomy and physiology. 11<sup>th</sup> ed. Wiley: 2006.
2. Wilson K JW. Ross and Wilson's foundations of anatomy and physiology. 5<sup>th</sup> ed. Churchill Livingstone: Edinburg; 1981.
3. Guyton arthur C. Physiology of human body. 6<sup>th</sup> ed. Brooks coole Publisher: 1983.
4. Chatterjee C C. Human physiology. Volume I & II. Medical allied agency: Calcutta; 2004.
5. Anne Waugh and Alon Grant. Ross and Wilson Anatomy & Physiology. 11<sup>th</sup> ed. Churchill Livingstone: 2010.
6. Guyton Arthur C. Text book of Medical Physiology. 10<sup>th</sup> ed. Harcot Publishers: Singapore; 2000.
7. Inderbir Singh. Textbook of Human Histology. Jaypee Brother's Medical Publishers: New Delhi.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Pharmaceutical Analysis I – Theory</b>
<b>Course Code</b>	<b>BP 102T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs.

**Course Description:**

The pharmaceutical analysis I course provides the knowledge of sources of errors, impurities and titrimetric analysis in quantitative pharmaceutical analysis and aid opportunity to develop awareness of drug quality and its control. It also covers different analytical techniques like Potentiometry, Conductometry, and Polarography techniques.

**Course Outcomes:** Upon successful completion of this course, the student should be able to

**CO 1:** Know the different types of errors, its minimization and sources of impurities in pharmaceuticals.

**CO 2:** Understand the principles of volumetric and electro chemical analysis methods.

**CO 3:** Develop analytical skills in the determination of percentage purity of the various pharmaceuticals.

**Course Content**

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I (4 Weeks)</b>	(a) <b>Pharmaceutical analysis</b> - Definition and scope Different techniques of analysis Methods of expressing concentration Primary and secondary standards. Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide,	<b>16</b>
	Hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate.	

	<p><b>(b) Errors:</b> Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures</p> <p><b>(c) Pharmacopoeia,</b> Sources of impurities in medicinal agents, limit tests.</p>	
<p><b>II</b> <b>(2 Weeks)</b></p>	<p><b>Acid base titration:</b> Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves</p> <p><b>Non-aqueous titration:</b> Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl</p>	<p><b>8</b></p>
<p><b>III</b> <b>(3 Weeks)</b></p>	<p><b>Precipitation titrations:</b> Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.</p> <p><b>Complexometric titration:</b> Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.</p> <p><b>Gravimetry:</b> Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.</p> <p>Basic Principles, methods and application of diazotisation titration.</p>	<p><b>12</b></p>
<p><b>IV</b> <b>(3 Weeks)</b></p>	<p><b>Redox titrations</b></p> <p>Concepts of oxidation and reduction</p> <p>Types of redox titrations (Principles and applications)</p> <p>Cerimetry, Iodimetry, Iodometry, Bromatometry,</p> <p>Dichrometry, Titration with potassium iodate</p>	<p><b>12</b></p>
<p><b>V</b> <b>(3 Weeks)</b></p>	<p><b>Electrochemical methods of analysis</b></p> <p><b>Conductometry-</b> Introduction, Conductivity cell, Conductometric titrations, applications.</p> <p><b>Potentiometry -</b> Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.</p>	<p><b>12</b></p>

	<b>Polarography</b> - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications.	
<b>TOTAL</b>		<b>60</b>

#### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Vogel AI. Textbook of quantitative chemical analysis. Fifth ed. Newyork: Longman Scientific & Technical; 1989. ISBN 0582446937
2. Indian pharmacopeia. (2014). Government of India, Ministry of health and family welfare. Vol 1, 2, 3. Ghaziabad: Published by Indian Pharmacopeial commission.
3. The British Pharmacopoeia. (2014). The commission of human medicines pursuant to the medicines act 1968, Vol 1 to 5, London: Published by stationery office on behalf of the medicines and health care products regulatory agency (MHRA).
4. The United states pharmacopoeia-National formulary. (USP 37-NF 32). Rockville: Published by the United States Pharmacopeial convention.
5. The European pharmacopoeia. (2008). sixth ed., Strasbourg: Published by the council of Europe.
6. The Japanese Pharmacopoeia. (2006). 13th ed., Japan: Published by the society of Japanese Pharmacopoeia, under the supervision of the R & D division, Pharmaceutical affairs bureau, Ministry of health & welfare.
7. Skoog DA, James HF, Crouch SR. Principles of Instrumental Analysis. Sixth ed. India: Cengage Learning; 2007. ISBN-13: 978-0495012016, ISBN-10: 0495012017.
8. Connors KA. A textbook of Pharmaceutical Analysis. Third ed. India: Wiley India Pvt. Ltd; 1982. ISBN: 8LGYW9TY5P8.



<b>Program</b>	<b>B. PHARMACY</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Pharmaceutics-1</b>
<b>Course Code</b>	<b>BP103T</b>
<b>Credits</b>	<b>4</b>
<b>Hours/week</b>	<b>3hours(lectures) and 1 hour (Tutorial)</b>
<b>Pre/ co-requisite/s</b>	<b>Nil</b>

### Course Description

This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

### Course outcome

At the end of the theory course, the student will be able to

CO 1: Define various medical and pharmaceutical terms

CO 2: Explain various principles and procedures involved in formulation of different types of dosage forms

CO 3: Demonstrate professional way of handling the prescription and pharmaceutical incompatibilities

CO 4: Calculate different pharmaceutical calculations involved in formulation

### Course content

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I</b> <b>(4 Weeks)</b>	<b>Historical background and development of profession of pharmacy:</b> History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career,	<b>16</b>
	<b>Pharmacopoeias:</b> Introduction to IP, BP, USP and Extra Pharmacopoeia.	
	<b>Pharmaceutical calculations:</b> Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, allegation, proof spirit and isotonic solutions based on freezing point and molecular weight	
	<b>Posology:</b> Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.	
<b>II</b> <b>(3 weeks)</b>	<b>Dosage forms:</b> Introduction to dosage forms, classification and definitions., Prescription: Definition, Parts of prescription, handling of Prescription and Errors in prescription	<b>12</b>

	<p><b>Solid Dosage forms:</b></p> <p><b>Powders:</b> Definition, classification, advantages and disadvantages, Simple &amp; compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.</p> <p><b>Liquid dosage forms:</b> Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques.</p>	
<b>III</b> <b>(3 weeks)</b>	<p><b>Monophasic liquids:</b> Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.</p> <p><b>Biphasic liquids:</b></p> <p><b>Suspensions:</b> Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension &amp; stability problems and methods to overcome.</p> <p><b>Emulsions:</b> Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation &amp; stability problems and methods to overcome.</p>	<b>12</b>
<b>IV</b> <b>(2 Weeks)</b>	<p><b>Suppositories:</b> Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value &amp; its calculations, evaluation of suppositories.</p> <p><b>Pharmaceutical incompatibilities:</b> Definition, classification, physical, chemical and therapeutic incompatibilities with examples.</p>	<b>10</b>
<b>V</b> <b>(2 Weeks)</b>	<p>Semisolid dosage forms: Definitions, classification, mechanisms and factors influencing dermal penetration of drugs.</p> <p>Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms</p>	<b>10</b>
<b>TOTAL</b>		<b>60</b>

### **Recommended reference Books**

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, the Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Pharmaceutical Inorganic Chemistry – Theory</b>
<b>Course Code</b>	<b>BP 104T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** This subject deals with the monographs of inorganic compounds and pharmaceuticals.

**Course description:** Pharmaceutical Inorganic chemistry course mainly deals with fundamentals of chemical composition, preparation methods, properties, identification tests, storage, assay & medicinal uses of various inorganic pharmaceuticals according to their monographs mentioned in the various pharmacopoeias. This course provides knowledge on sources of impurities, methods to determine the impurities in inorganic drugs and gives the importance of radiopharmaceuticals in the various fields.

**Course Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: State the concept & content of specifications mentioned in monograph for various categories of inorganic pharmaceuticals along with their medicinal uses.

CO 2: Demonstrate the knowledge of various types of errors and various sources of impurities in the pharmaceuticals.

CO 3: Apply the suitable principles in determination of purity by limit tests and percentage purity by assay methods as per the pharmacopoeias (Indian Pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia)

#### **Course Content**

Unit	Topics	Hours
I (3 Weeks)	<b>Impurities in pharmaceutical substances:</b> History of Pharmacopoeia, Sources and types of impurities,	12
	Principle involved in the limit test for Chloride, Sulphate, Iron, Lead	
	Principle involved in the limit test for Arsenic, Heavy metals and modified limit test for Chloride and Sulphate.	
<i>General methods of preparation, assay for the compounds superscripted with <b>asterisk (*)</b>,</i>		

*properties and medicinal uses of inorganic compounds belonging to the following classes*

<b>II</b> <b>(4 Weeks)</b>	<b>Acids, Bases and Buffers:</b> Concepts of acid and bases – Arrhenius, Bronsted-Lowry and Lewis. Concept of pH and buffer, types of buffers with examples	<b>16</b>
	<b>Major extra and intracellular electrolytes:</b> Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride,	
	Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.	
	<b>Dental products:</b> Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.	
<b>III</b> <b>(3 Weeks)</b>	<b>Gastrointestinal agents</b> <b>Acidifiers:</b> Ammonium chloride* and Dil. HCl <b>Antacid:</b> Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture	<b>12</b>
	<b>Cathartics:</b> Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite	
	<b>Antimicrobials:</b> Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations	
<b>IV</b> <b>(3 Weeks)</b>	<b>Miscellaneous compounds</b> <b>Expectorants:</b> Potassium iodide, Ammonium chloride*. <b>Emetics:</b> Copper sulphate*, Sodium potassium tartarate	<b>10</b>
	<b>Haematinics:</b> Ferrous sulphate*, Ferrous gluconate	
	<b>Poison and Antidote:</b> Sodium thiosulphate*, Activated charcoal, Sodium nitrite	
	<b>Astringents:</b> Zinc Sulphate, Potash Alum	
<b>V</b>	<b>Radiopharmaceuticals:</b> Radio activity, Measurement of	<b>10</b>

<b>(3 Weeks)</b>	radioactivity, Properties of $\alpha$ , $\beta$ , $\gamma$ radiations, Half-life,	
	Radioisotopes and study of radioisotopes - Sodium iodide $I^{131}$ , Storage conditions, precautions & pharmaceutical application of radioactive substances.	
	<b>Revision</b>	
<b>TOTAL</b>		<b>60</b>

#### **Learning Resources/Recommended Texts/Reference books/web resources**

##### **Text Books:**

1. A.H.Beckett and J.B.Stenlake. Practical pharmaceutical chemistry. Part-I. The Athtome press: University of London; 1968.
2. J.H Block, E.Roche, T.O Soine and C.O. Wilson. Inorganic Medical and Pharmaceutical Chemistry. Lea & Febiger Philadelphia PA; 1974.
3. G.R. Chatwal. Pharmaceutical Chemistry – Inorganic. Fifth edition. Himalaya Publishing House: Mumbai, India; 2014.
4. A.A. Napoleon. Pharmaceutical Titrimetric Analysis Theory and Practical. Second ed. Kalaimani Publishers & Distributers: Kanchipuram; 2013.
5. J. Mendham, R.C. Denney, J. D. Barnes and M.J.K. Thomas. Vogel's Quantitative Chemical Analysis. Sixth edition. Pearson education Delhi; 2000.

##### **References:**

1. Gary L. Miessler, Paul J. Fischer and Donald A. Tarr. Inorganic chemistry. Fifth edition. Pearson education New Delhi; 2014.
2. P. Gundu Rao. Pharmaceutical and Medicinal Inorganic Chemistry. First edition. Vallabh Prakashan Delhi; 2008.
3. G.D. Tuli, R.D. Madan, S.K. Basu and Satya Prakash. Advanced Inorganic Chemistry. Volume 1. Published by S. Chand & Company Ltd; 2014.
4. William L. Jolly. Modern Inorganic Chemistry. Second edition. Mc Graw-Hill: New York; 1984.
5. A.H.Beckett and J.B.Stenlake. Textbook of Pharm. Analysis. CBS Publishers, Delhi.
6. Indian Pharmacopoeia.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Communication Skills</b>
<b>Course Code</b>	<b>BP105T</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>2</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

**Course Learning Outcomes:** Upon completion of this course, the student shall be able to:

CO1: Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation.

CO2: Communicate effectively (Verbal and Non-Verbal)

CO3: Effectively manage the team as a team player.

CO4: Develop interview skills, Leadership qualities and essentials.

#### **Theory Course: Contents**

<b>UNIT</b>	<b>Topic</b>	<b>Hours</b>
<b>I</b>	<b>Communication Skills:</b> Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context. <b>Barriers to Communication:</b> Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional Barriers. <b>Perspectives in Communication:</b> Introduction, Visual Perception, Language, Other factors affecting our Perspective – Past Experiences, Prejudices, Feelings, Environment.	07
<b>II</b>	<b>Elements of Communication:</b> Introduction, Face to Face Communication – Tone of Voice, Body Language (Non – Verbal communication), Verbal Communication, Physical Communication.	07

	<b>Communication Styles:</b> Introduction, The Communication Styles Matrix with example for each – Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style.	
<b>III</b>	<b>Basic Listening Skills:</b> Introduction, Self – Awareness, Active Listening, Becoming an Active Listening in Difficult Situations. <b>Effective Written Communication:</b> Introduction, When and When Not to Use Written Communication – Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication. <b>Writing Effectively:</b> Subject Line, Put the Main Point First, Know Your Audience, Organization of the Message.	07
<b>IV</b>	<b>Interview Skills:</b> Purpose of an interview, Do's and Don't's of an interview. <b>Giving Presentations:</b> Dealing with Fears, planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery.	05
<b>V</b>	<b>Group Discussion:</b> Introduction, Communication skills in group discussion, Do's and Don't's of group discussion.	04
<b>Total</b>		30

**Recommended Books: (Latest Editions)**

1. Basic communication skills for Technology, Andreha.J. Ruther Ford, 2<sup>nd</sup> Edition, Pearson Education, 2011.
2. Communication skills, Sanjay Kumar, Pushpalata, 1<sup>st</sup> Edition, Oxford Press, 2011.
3. Organizational Behaviorur, Stephen . P . Robbins, 1<sup>st</sup> Edition, Pearson, 2013
4. Brilliant – Communication skills, Gill Hasson, 1<sup>st</sup> Edition, Pearson Life, 2011
5. The Ace of soft skills : Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5<sup>th</sup> Edition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1<sup>st</sup> Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2<sup>nd</sup> Edition, New arrivals – PHI, 2011.



8. Soft skill for everyone, Butter Field, 1<sup>st</sup> Edition, Cengage Learning India Pvt.Ltd, 2011
9. Soft skills and professional communication, Francis Peters SJ, 1<sup>st</sup> Edition, Mc Graw Hill Education, 2011
10. Effective communication, John Adair, 4<sup>th</sup> Edition, Pan Mac Millan, 2009.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Remedial Biology (Theory)</b>
<b>Course Code</b>	<b>BP 106RBT</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>2 Hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

**Course Learning Outcomes:**

Upon completion of the course, the student shall be able to

CO1: Know the classification and salient features of five kingdoms of life

CO2: Understand the basic components of anatomy & physiology of plant

CO3: Know understand the basic components of anatomy & physiology animal with special reference to human

**Theory Course: Contents**

<b>UNIT</b>	<b>Topic</b>	<b>Hours</b>
<b>I</b>	<b>Living world:</b> Definition and characters of living organisms Diversity in the living world Binomial nomenclature Five kingdoms of life and basis of classification. Salient features of Monera, Protista, Fungi, Animalia and Plantae, Virus, <b>Morphology of Flowering plants:</b> Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed. General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledons.	07

<b>II</b>	<p><b>Body fluids and circulation</b></p> <p>Composition of blood, blood groups, coagulation of blood</p> <p>Composition and functions of lymph</p> <p>Human circulatory system</p> <p>Structure of human heart and blood vessels</p> <p>Cardiac cycle, cardiac output and ECG</p> <p><b>Digestion and Absorption</b></p> <p>Human alimentary canal and digestive glands</p> <p>Role of digestive enzymes</p> <p>Digestion, absorption and assimilation of digested food</p> <p><b>Breathing and respiration</b></p> <p>Human respiratory system</p> <p>Mechanism of breathing and its regulation</p> <p>Exchange of gases, transport of gases and regulation of respiration</p> <p>Respiratory volumes</p>	07
<b>III</b>	<p><b>Excretory products and their elimination</b></p> <p>Modes of excretion</p> <p>Human excretory system- structure and function</p> <p>Urine formation</p> <p>Rennin angiotensin system</p> <p><b>Neural control and coordination</b></p> <p>Definition and classification of nervous system</p> <p>Structure of a neuron</p> <p>Generation and conduction of nerve impulse</p> <p>Structure of brain and spinal cord</p> <p>Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata</p> <p><b>Chemical coordination and regulation</b></p> <p>Endocrine glands and their secretions</p> <p>Functions of hormones secreted by endocrine glands</p> <p><b>Human reproduction</b></p>	07

	Parts of female reproductive system Parts of male reproductive system Spermatogenesis and Oogenesis Menstrual cycle	
<b>IV</b>	<b>Plants and mineral nutrition:</b> Essential mineral, macro and micronutrients Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation <b>Photosynthesis</b> Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.	05
<b>V</b>	<b>Plant respiration:</b> Respiration, glycolysis, fermentation (anaerobic). <b>Plant growth and development</b> Phases and rate of plant growth, Condition of growth, Introduction to plant growth regulators <b>Cell - The unit of life</b> Structure and functions of cell and cell organelles. Cell division <b>Tissues</b> Definition, types of tissues, location and functions.	04
<b>Total</b>		30

### Text Books

1. Text book of Biology by S. B. Gokhale
2. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

### Reference Books

1. A Text book of Biology by B.V. Sreenivasa Naidu
2. A Text book of Biology by Naidu and Murthy
3. Botany for Degree students By A.C.Dutta.
4. D.Outlines of Zoology by M. Ekambaranathaayyer and T. N. Ananthakrishnan.
5. E. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Remedial Mathematics</b>
<b>Course Code</b>	<b>BP106RMT</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>2 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This is an introductory course in mathematics. This subject deals with the Introduction to Algebra, Trigonometry, Co-Ordinate geometry, Differential Calculus, Integral Calculus, Differential Equations, Laplace Transforms.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Define Algebra, Trigonometry, Co-Ordinate geometry, Differential Calculus, Integral Calculus, Differential Equations, Laplace Transforms and their applications.

CO 2: Solve the problems of different types by applying theory.

CO 3: Appreciate the important applications of Mathematics in Pharmacy.

#### **Theory Course: Contents**

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I</b>	<b>Algebra:</b> Arithmetic Progression –Geometric Progression, Logarithms: Logarithm of a real number to an arbitrary base, theorems on Logarithms, application of logarithms in Pharmaceutical computations and Partial fractions.	<b>5</b>
<b>II</b>	<b>Trigonometry:</b> Trigonometric ratios and the relations between them, Sin (A+B), Cos (A+B), Tan (A+B) formulae only, Trigonometric ratios of multiple and submultiple angles.	<b>5</b>
<b>III</b>	<b>Co-Ordinate Geometry</b> Distance between points, Area of a Triangle, Co-Ordinates of a point dividing a given line segment in a given ratio, equation to a straight line in different forms.	<b>5</b>

<b>IV</b>	<b>Differential calculus:</b> Limit of a function differentiation, derivatives of trigonometric functions, logarithmic and partial differentiation, Maxima and minima (elementary).	<b>4</b>
<b>V</b>	<b>Integration:</b> Definition of integration, indefinite of integrals, standard integrals, fundamental rules of Integration, Integration by substitution, integration by parts and definite Integrals, properties of definite Integrals	<b>5</b>
<b>VI</b>	<b>Differential Equations:</b> Order and degree, formation of the differential equation, solutions of the first order and first-degree differential equations (variable separable). Applications of first order and first-degree differential equation: law of natural growth and decay, Newton's law of cooling.	<b>6</b>
<b>VII</b>	<b>Laplace transforms:</b> Definition, elementary functions, Properties of linearity and shifting, transforms of multiplication by $tn$	<b>2</b>
<b>Total</b>		<b>30</b>

#### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Intermediate first and second year mathematics text books printed and published by Telugu Academy.
2. P. Seshagiri Rao. A Text book of Remedial Mathematics. Pharma med press; 2008.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Human Anatomy &amp; Physiology – I Practical</b>
<b>Course Code</b>	<b>BP107P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course outcomes**

CO 1: Identify the various tissues and organs of different systems of human body.

CO 2: Perform the various experiments related to special senses and nervous system.

CO 3: Appreciate coordinated working pattern of different organs of each system.

### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Introduction to laboratory safety techniques and Study of compound microscope
2	Microscopic study of epithelial tissue and connective tissue
3	Microscopic study of muscular tissue and nervous tissue
4	Identification of axial bones
5	Identification of appendicular bones
6	Introduction of hemocytometry and Enumeration of white blood cell (WBC) count
7	Enumeration of total red blood corpuscles (RBC) count
8	Determination of bleeding time
9	Determination of clotting time
10	Estimation of hemoglobin content
11	Determination of blood group
12	Determination of erythrocyte sedimentation rate (ESR)
13	Determination of heart rate and pulse rate

14	Recording of Blood pressure.
15	<b>Revision</b>

### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Tortora Gerard J, Derrickson Bryan. Principles of anatomy and physiology. 11<sup>th</sup> ed. Wiley: 2006.
2. Wilson K JW. Ross and Wilson's foundations of anatomy and physiology. 5<sup>th</sup> ed. Churchill Livingstone: Edinburg; 1981.
3. Guyton arthur C. Physiology of human body.6<sup>th</sup> ed. Brooks coole Publisher: 1983.
4. Chatterjee C C. Human physiology. Volume I & II. Medical allied agency: Calcutta; 2004.
5. Anne Waugh and Alon Grant. Ross and Wilson Anatomy & Physiology. 11<sup>th</sup> ed. Churchill Livingstone: 2010.
6. Guyton Arthur C. Text book of Medical Physiology. 10<sup>th</sup>ed. Harcot Publishers: Singapore; 2000.
7. Kale S R,Kale R R.practical human anatomy and physiology.19<sup>th</sup> ed. Pune. Nirali prakashan;2009.
8. Goyal R K, Natvar M P, Shah S A. Practical anatomy, Physiology and biochemistry,1<sup>st</sup> ed. Publisher: B S Shah Publisher: Ahmadabad; 1988.
9. C.L. Ghai. Textbook of Practical Physiology. Jaypee brother's medical publishers.
10. K. Srinageswari Rajeev Sharma. Practical workbook of Human Physiology. Jaypee brother's medical publisher



<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Pharmaceutical Analysis I – Practical</b>
<b>Course Code</b>	<b>BP 108P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 Hours</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Pharmaceutical Analysis – I practical course describes the fundamental skills of limit tests, standardization and assay methods for the various pharmaceutical products. It also provides the awareness of determinate and indeterminate errors while performing the analysis like Potentiometry, Conductometry.

**Course Outcomes:** Upon successful completion of this course, the student should be able to

**CO 1:** Illustrate the limits of chloride, sulphate & heavy metals content in various pharmaceuticals.

**CO 2:** Understand the quantitative standardization and assay methods by volumetric analysis.

**CO 3:** Adapt various electrochemical techniques to quantify the acids & bases.

<b>Week</b>	<b>Topic</b>
<b>I. Limit test of the following</b>	
<b>1</b>	Chloride
<b>2</b>	Sulphate
<b>3</b>	Iron
<b>4</b>	Arsenic
<b>II. Preparation and standardization of</b>	
<b>5</b>	Sodium hydroxide
<b>6</b>	Sulphuric acid
<b>7</b>	Sodium thiosulfate
<b>8</b>	Potassium permanganate
<b>9</b>	Ceric ammonium sulphate
<b>III Assay of the following compounds along with Standardization of Titrant</b>	
<b>10</b>	Ammonium chloride by acid base titration

<b>11</b>	Ferrous sulphate by Cerimetry
<b>12</b>	Copper sulphate by Iodometry
<b>13</b>	Calcium gluconate by Complexometry
<b>14</b>	Hydrogen peroxide by Permanganometry
<b>15</b>	Sodium benzoate by non-aqueous titration
<b>16</b>	Sodium Chloride by precipitation titration
<b>IV. Determination of Normality by electro-analytical methods</b>	
<b>17</b>	Conductometric titration of strong acid against strong base
<b>18</b>	Conductometric titration of strong acid and weak acid against strong base
<b>19</b>	Potentiometric titration of strong acid against strong base

#### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Vogel AI. Textbook of quantitative chemical analysis. Fifth ed. New York: Longman Scientific & Technical; 1989. ISBN 0582446937
2. Indian pharmacopeia. (2014). Government of India, Ministry of health and family welfare. Vol 1, 2, 3. Ghaziabad: Published by Indian Pharmacopeial commission.
3. The British Pharmacopoeia. (2014). The commission of human medicines pursuant to the medicines act 1968, Vol 1 to 5, London: Published by stationery office on behalf of the medicines and health care products regulatory agency (MHRA).
4. The United states pharmacopoeia-National formulary. (USP 37-NF 32). Rockville: Published by the United States Pharmacopeial convention.
5. Skoog DA, James HF, Crouch SR. Principles of Instrumental Analysis. Sixth ed. India: Cengage Learning; 2007. ISBN-13: 978-0495012016, ISBN-10: 0495012017.
6. Connors KA. A textbook of Pharmaceutical Analysis. Third ed. India: Wiley India Pvt. Ltd; 1982. ISBN: 8LGYW9TY5P8.
7. Napoleon AA. Pharmaceutical titrimetric analysis, India: Kalaimani publishers and distributors; 2013.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Pharmaceutics I – Practical</b>
<b>Course Code</b>	<b>BP109P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours</b>

**Course Description:** The General Pharmacy and Dosage forms practical course is aimed to train the students on formulation of different types of dosage forms. This course also deals with pharmaceutical calculations which are essential in compounding and utilization of dosage forms. This course also provides the skills to identify various incompatibilities in handling of prescriptions.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Identify various incompatibilities in handling of Prescriptions

CO 2: Calculate different pharmaceutical calculations involved in formulation.

CO 3: Formulate different types of dosage forms.

**Practical Course Contents:**

<b>S. No</b>	<b>Experiments</b>
1	<b>Syrups</b> Syrup IP'66 Orange Syrup
2	<b>Elixirs</b> Piperazine citrate elixir Paracetamol pediatric elixir
3	<b>Linctus</b> Terpin Hydrate Linctus IP'66 Iodine Throat Paint (Mandles Paint)
4	<b>Solutions</b> Strong solution of ammonium acetate Cresol with soap solution

	Lugol's solution
5	<b>Suspensions</b> Calamine lotion Magnesium Hydroxide mixture Aluminium Hydroxide gel
6	<b>Emulsions</b> Turpentine Liniment Liquid paraffin emulsion
7	<b>Powders and Granules</b> ORS powder (WHO) Effervescent granules Dusting powder Divided powders
8	<b>Suppositories</b> Glycero gelatin suppository Cocoa butter suppository Zinc Oxide suppository
9	<b>Semisolids:</b> Sulphur ointment, Non staining-iodine ointment with methyl salicylate
10	<b>Gargles and Mouthwashes:</b> Iodine gargle, Chlorhexidine mouthwash Phenol Gargle

**Recommended Books: (Latest Editions)**

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science & Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The University of Michigan.

7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Pharmaceutical Inorganic Chemistry – Practical</b>
<b>Course Code</b>	<b>BP 110P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** Pharmaceutical inorganic chemistry laboratory course aimed to train the students on experimental techniques for the determination of impurities and their limits as per the pharmacopoeias. This course also deals with identification of various cations & anions of inorganic compounds by their chemical tests. This course also provides laboratory skills related to calibration and percentage purity analysis by volumetric titrations as per monographs specified in various pharmacopoeias.

**Course Outcomes:** Upon successful completion of this course, the student should be able to

**CO 1:** Perform the limit tests, assay methods to know the impurities limit, and percentage purity of the pharmaceuticals.

**CO 2:** Differentiate various cations and anions by chemical tests.

**CO 3:** Identify the purity of the various pharmaceuticals by suitable methods

<b>Week</b>	<b>TOPICS</b>
<b>Limit tests for the following ions</b>	
1	Limit test for Chlorides
2	Limit test for Sulphates
3	Modified limit test for Chlorides and Sulphates
4	Limit test for Iron
5	Limit test for Lead
6	Limit test for Arsenic
<b>Identification tests for the following</b>	
7	Identification tests for Ferrous sulphate
8	Identification tests for Sodium bicarbonate
9	Identification tests for Potassium chloride

<b>Test for purity</b>	
10	Swelling power of Bentonite
11	Neutralizing capacity of aluminum hydroxide gel
12	Estimation of Sodium carbonate and sodium hydroxide in mixture
13	Estimation of borax and boric acid mixture
<b>Preparation of inorganic pharmaceuticals</b>	
14	Boric acid
15	Potash alum

#### **Recommended Books (Latest Editions)**

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4<sup>th</sup> edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3<sup>rd</sup> Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia
8. Pharmacopoeia.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>I</b>
<b>Name of the course</b>	<b>Communication Skills -Practical</b>
<b>Course Code</b>	<b>BP111P</b>
<b>Credits</b>	<b>1</b>
<b>Hours /week</b>	<b>2 hours</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

**Course Learning Outcomes:** Upon completion of this course, the student shall be able to:

CO1: Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation.

CO2: Communicate effectively (Verbal and Non-Verbal).

#### **Practical Course: Contents**

<b>S. No.</b>	<b>Topic</b>
1.	<b>Basic communication covering the following topics:</b> Meeting People, Asking Questions, Making Friends, what did you do? Do's and Don'ts.
2.	<b>Pronunciations covering the following topics:</b> Pronunciation (Consonant Sounds), Pronunciation and Nouns, Pronunciation (Vowel Sounds).
3.	<b>Advanced Learning:</b> Listening Comprehension/Direct and Indirect Speech, Figures of Speech, Effective Communication, Writing Skills, Effective Writing, Interview Handling Skills, E – Mail etiquette, Presentation Skills.

#### **Recommended Books: (Latest Editions)**

1. Basic communication skills for Technology, Andreha.J. Ruther Ford, 2<sup>nd</sup> Edition, Pearson Education, 2011.
2. Communication skills, Sanjay Kumar, Pushpalata, 1<sup>st</sup> Edition, Oxford Press, 2011.
3. Organizational Behaviour, Stephen. P. Robbins, 1<sup>st</sup> Edition, Pearson, 2013.
4. Brilliant – Communication skills, Gill Hasson, 1<sup>st</sup> Edition, Pearson Life, 2011.



5. The Ace of soft skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5<sup>th</sup> Edition, Pearson, 2013.
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1<sup>st</sup> Edition Universe of Learning LTD, 2010.
7. Communication skills for professionals, Konar nira, 2<sup>nd</sup> Edition, New arrivals – PHI, 2011.
8. Soft skill for everyone, Butter Field, 1<sup>st</sup> Edition, Cengage Learning India Pvt.Ltd, 2011.
9. Soft skills and professional communication, Francis Peters SJ, 1<sup>st</sup> Edition, Mc Graw Hill Education, 2011.
10. Effective communication, John Adair, 4<sup>th</sup> Edition, Pan Mac Millan, 2009.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>II</b>
<b>Name of the course</b>	<b>Human Anatomy &amp; Physiology – II</b>
<b>Course Code</b>	<b>BP201T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 (Lectures) + 1 (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** This course aimed to provide fundamental knowledge on the structure and functions of the human body. This course deals with the role of hormones and its regulation. This course describes the structure and functions of various organ systems of the human body like nervous, digestive, respiratory, urinary, endocrine, reproductive systems. This course describes about basics of genetics.

**Course outcomes:** Upon completion of this course the student should be able to

CO1. Describe the structure and functions of various organs of the human body.

CO2. Explain the various hormones and their imbalances.

CO3. Synthesize ideas to make a connection between knowledge of anatomy and physiology and real-world situations, including healthy lifestyle decisions and homeostatic imbalances.

<b>Unit</b>	<b>Topics</b>	<b>No. of hours</b>
<b>I</b>	<b>Nervous system</b> Organization of nervous system, neuron, neuroglia, classification and properties of nerve fiber, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters. Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. Structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)	<b>12</b>
<b>II</b>	<b>Digestive system:</b> Anatomy of GI Tract with special reference to anatomy	

	and functions of stomach, ( Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.	<b>12</b>
<b>III</b>	<b>Respiratory system</b> Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration. Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods. <b>Urinary system</b> Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.	<b>12</b>
<b>IV</b>	<b>Endocrine system</b> Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.	<b>12</b>
<b>V</b>	<b>Reproductive system</b> Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition.	<b>12</b>
	<b>Total</b>	<b>60</b>

#### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Tortora Gerard J, Derrickson Bryan. Principles of anatomy and physiology. 11<sup>th</sup> ed. Wiley: 2006.
2. Wilson K JW. Ross and Wilson's foundations of anatomy and physiology. 5<sup>th</sup> ed. Churchill Livingstone: Edinburg; 1981.
3. Guyton arthur C. Physiology of human body. 6<sup>th</sup> ed. Brooks coole Publisher: 1983.

4. Chatterjee C C. Human physiology. Volume I & II. Medical allied agency: Calcutta; 2004.
5. Anne Waugh and Alon Grant. Ross and Wilson Anatomy & Physiology. 11<sup>th</sup> ed. Churchill Livingstone: 2010.
6. Guyton Arthur C. Text book of Medical Physiology. 10<sup>th</sup>ed. Harcot Publishers: Singapore; 2000.
7. Inderbir Singh. Textbook of Human Histology. Jaypee Brother's Medical Publishers: New Delhi.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>II</b>
<b>Name of the course</b>	<b>Pharmaceutical Organic Chemistry-I</b>
<b>Course Code</b>	<b>BP202T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 (Lectures) + 1 (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Pharmaceutical Organic Chemistry-I course is aimed to present fundamental in chemistry of organic compounds. It emphasizes on basic nomenclature, physical and chemical properties of various organic compounds. The course will describe the pharmaceutical importance of these functional groups, isomerism and their molecular structures and properties in chemistry of drug substances. This also deals with various mechanisms involved in synthesis and reaction of chemical compounds.

**Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

**CO1:** Define the nomenclature, physical and chemical properties of a molecule in relation to the structure of organic compounds.

**CO2:** Write the structure, name and the type of isomerism of the organic compound

**CO3:** Explain the possible mechanism and the intermediate product involved in a chemical reaction

**CO4:** Identify and confirm the unknown organic compound

**Course Content:**

General methods of preparation and reactions of compounds superscripted with asterisk (\*) to be explained. To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I (3 weeks)</b>	Classification, nomenclature and isomerism Classification of Organic Compounds Common and IUPAC systems of nomenclature of organic compounds. (up to 10 Carbons open chain and carbocyclic compounds) Structural	<b>8</b>

	isomerisms in organic compounds	
<b>II</b> <b>(4 Weeks)</b>	Alkanes*, Alkenes* and Conjugated dienes* SP <sup>3</sup> hybridization in alkanes, Halogenation of alkanes, uses of paraffins.	<b>15</b>
	Stabilities of alkenes, SP <sup>2</sup> hybridization in alkenes E1 and E2 reactions–kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences.	
	E1 verses E2 reactions, Factors affecting E1 and E2 reactions. Ozonolysis, electrophilic addition reactions of alkenes	
	Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.	
	Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement	
<b>III</b> <b>(3 Weeks)</b>	Alkyl halides* SN <sup>1</sup> and SN <sup>2</sup> reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.	<b>15</b>
	SN <sup>1</sup> versus SN <sup>2</sup> reactions, Factors affecting SN <sup>1</sup> and SN <sup>2</sup> reactions. Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.	
	Alcohols*- Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol.	
<b>IV</b> <b>(3 Weeks)</b>	Carbonyl compounds* (Aldehydes and ketones) Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation,.	<b>12</b>
	Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin	

	condensation, Perkin condensation, qualitative tests,	
	Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde	
<b>V</b> <b>(3 Weeks)</b>	<b>Carboxylic acids</b> Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids. Chemistry, reactivity and qualitative tests of esters and amides.	<b>10</b>
	<b>Aliphatic amines-</b> Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of ethanolamine, Ethylenediamine, Amphetamine	
	<b>Structure and Uses of</b> Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid	
<b>Total</b>		<b>60</b>

## References

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar, Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Organic Chemistry by Vogel
6. Organic Chemistry by McGraw Hill
7. Organic reactions and mechanism by Jerry March
8. Organic chemistry by Solomons and Graham

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>II</b>
<b>Name of the course</b>	<b>Biochemistry</b>
<b>Course Code</b>	<b>BP203T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 (Lectures) + 1 (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course Description

Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

**CO 1:** Define enzymes, enzyme inhibitors, carbohydrates, proteins, lipids and nucleic acids, electron transport chain and oxidative phosphorylation.

**CO 2:** Explain the chemistry, classification, uses and metabolism of carbohydrates, proteins, lipids and nucleic acids.

**CO 3:** Discuss the metabolic disorders of carbohydrates, proteins, lipids and nucleic acids. Synthesize DNA and RNA

**CO 4:** Analyze the constituents present in urine.

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I (3 Weeks)</b>	<b>Biomolecules</b> Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.	<b>12</b>
	<b>Bioenergetics:</b> Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy.	



	Redox potential. Energy rich compounds; classification; biological significances of ATP and cyclic AMP	
<b>II</b> <b>(3Weeks)</b>	<p><b>Carbohydrate metabolism</b> Glycolysis – Pathway, energetics and significance, Citric acid cycle- Pathway, energetics and significance, HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency.</p> <p>Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its significance Hormonal regulation of blood glucose level and Diabetes mellitus</p> <p><b>Biological oxidation</b> Electron transport chain (ETC) and its mechanism. Oxidative phosphorylation &amp; its mechanism and substrate level phosphorylation, Inhibitors ETC and oxidative phosphorylation/Uncouplers</p>	<b>12</b>
<b>III</b> <b>(4 Weeks)</b>	<p><b>Lipid metabolism:</b> <math>\beta</math>-Oxidation of saturated fatty acid (Palmitic acid) Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fattyacids (Palmitic acid) ,</p> <p>Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D, Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.</p> <p><b>Amino acid metabolism</b> General reactions of amino acid metabolism: Transamination, deamination &amp; decarboxylation, urea cycle and its disorders. Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alpeptonuria, tyrosinemia)</p> <p>Significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline. Catabolism of heme; hyperbilirubinemia and jaundice</p>	<b>16</b>
	Nucleic acid metabolism and genetic information transfer. Biosynthesis of purine and pyrimidine nucleotides.	<b>10</b>

<b>IV</b> <b>(3 Weeks)</b>	Catabolism of purine nucleotides and Hyperuricemia and Gout disease. Organization of mammalian genome, Structure of DNA and RNA and their functions DNA replication (semi conservative model)	
	Transcription or RNA synthesis Genetic code, Translation or Protein synthesis and inhibitors	
<b>V</b> <b>(3 Weeks)</b>	Enzymes: Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot) Enzyme inhibitors with examples Regulation of enzymes:	<b>10</b>
	enzyme induction and repression, allosteric enzymes regulation Therapeutic and diagnostic applications of enzymes and isoenzymes	
	Coenzymes –Structure and biochemical functions	
<b>Total</b>		<b>60</b>

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>II</b>
<b>Name of the course</b>	<b>Pathophysiology</b>
<b>Course Code</b>	<b>BP204T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 (Lectures) + 1 (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** The Pathophysiology course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions and understanding of basic pathophysiological mechanisms. The course covers the basics of cell biology, inflammation, mechanism of body defense, abnormal cell growth and focuses on the pathophysiology of common disease processes of human body system.

**Course Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Define the basic terminology related to pathophysiology.

CO 2: Describe the etiology and pathogenesis of the selected disease states.

CO 3: Name the signs, symptoms and complications of the diseases.

CO 4: Define the basic approach to diagnosis and diagnostic procedures of human diseases.

CO 5: Correlate the Pathophysiology with prognosis, medical treatment of the diseases.

#### **Theory Course: Contents**

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I</b>	<p><b>Basic principles of Cell injury and Adaptation:</b> Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis &amp; Alkalosis, Electrolyte imbalance.</p> <p><b>Basic mechanism involved in the process of inflammation and repair:</b> Introduction, Clinical signs of inflammation, Different types</p>	

	of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis	<b>12</b>
<b>II</b>	<b>Cardiovascular System:</b> Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis). <b>Respiratory system:</b> Asthma, Chronic obstructive airways diseases. <b>Renal system:</b> Acute and chronic renal failure	<b>12</b>
<b>III</b>	<b>Hematological Diseases:</b> Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalassemia, hereditary acquired anemia, hemophilia. <b>Endocrine system:</b> Diabetes, thyroid diseases, disorders of sex hormones. <b>Nervous system:</b> Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease. <b>Gastrointestinal system:</b> Peptic Ulcer	<b>12</b>
<b>IV</b>	Inflammatory bowel diseases, jaundice, hepatitis (A, B, C, D, E, F) alcoholic liver disease. <b>Disease of bones and joints:</b> Rheumatoid arthritis, osteoporosis and gout. <b>Diseases of bones and joints:</b> Rheumatoid Arthritis, Osteoporosis, Gout. <b>Principles of cancer:</b> Classification, etiology and pathogenesis of cancer. <b>Principles of Cancer:</b> Classification, etiology and pathogenesis of Cancer.	<b>12</b>
<b>V</b>	<b>Infectious Diseases:</b> Meningitis, Typhoid, Leprosy, Tuberculosis, Urinary Tract Infections. <b>Sexually transmitted diseases:</b> AIDS, Syphilis, Gonorrhea	<b>12</b>
	<b>Total</b>	<b>60</b>

### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6<sup>th</sup> edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K.; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12<sup>th</sup> edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12<sup>th</sup> ed; united states
5. William and Wilkins, Baltimore;1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21<sup>st</sup> edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12<sup>th</sup> edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9<sup>th</sup> edition; London; McGraw-Hill Medical; 2014.
9. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6<sup>th</sup> edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3<sup>rd</sup> edition; London; Churchill Livingstone publication; 2003.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>II</b>
<b>Name of the course</b>	<b>Computer Applications in Pharmacy</b>
<b>Course Code</b>	<b>BP205T</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>3</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Computer Applications In Pharmacy course is aimed at to learn the fundamentals of computers like scope, classification of computers, their number system, software, data base, application of computer in pharmacy and role of management information system used in the organizations.

Computer is mandatory in this advanced era and pharmacy and related subjects are not exception to it. This review mainly focuses on the various applications, software's and use of computers in pharmacy. Computer science and technology is deeply utilized in pharmacy field everywhere like in pharmacy colleges, pharmaceutical industries, research centers, hospital pharmacy and many more. Computer significantly reduces the time, expenditure, and manpower required for any kind of work. Development of various software's makes it trouble-free to handle huge data. In short, computers are playing critical role in pharmacy field, without computers pharmacy research will be long-lasting and expensive.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO1: Demonstrates the introduction of computers.

CO2: State importance of computers, processing the data in MS-Office.

CO3: Navigate a Windows operating system environment as well as install and operate basic software utilities

CO4: Identifies the development life cycle of system.

CO5: Demonstrates the maintenance of pharmacy drug database.

CO6: Recognize basic technologies related to an office environment

### Theory Course: Contents

UNIT	Topic	Hours
I	<b>Introduction to Computers:</b> <b>Number system:</b> Binary number system, Decimal number system, Octal number system, Hexadecimal number systems. Conversion decimal to binary, binary to decimal, octal to binary etc., Binary addition, subtraction, multiplication, division One's complement, Two's complement method. <b>Concept of Information Systems and Software:</b> Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project.	12
II	<b>Web technologies:</b> Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products. Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database.	10
III	<b>Application of computers in Pharmacy:</b> Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring. Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System.	10
IV	<b>Bioinformatics:</b> Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery.	8

<b>V</b>	<b>Computers as data analysis in Preclinical development:</b> Chromatographic data analysis (CDS), Laboratory Information management System (LIMS) and Text Information Management System (TIMS).	5
<b>Total</b>		45

#### **Recommended Books: (Latest Editions)**

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA.
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA).
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002



<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>II</b>
<b>Name of the course</b>	<b>Environmental Sciences – Theory</b>
<b>Course Code</b>	<b>BP 206T</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>3 Hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course description:** Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

**Course Outcomes:** Upon completion of the course, the student shall be able to

**CO 1:** Create the awareness about environmental problems among learners.

**CO 2:** Impart basic knowledge about the environment, its allied problems and develop an attitude of concern for the environment.

**CO 3:** Motivate learner to participate in environment protection and environment improvement.

**CO 4:** Acquire skills to help the concerned individuals in identifying and solving environmental problems.

### Course Content

<b>Unit</b>	<b>Topic</b>	<b>Hours</b>
<b>I (6 Weeks)</b>	<p>The Multidisciplinary nature of environmental studies Natural Resources</p> <p>Renewable and non-renewable resources: Natural resources and associated problems of the following-In context to INDIA.</p> <p>a) Forest resources: Types, distribution, Uses and deforestation and its consequences. Conservation of Forests.</p> <p>b) Water resources: Types, distribution and conservation of water sources</p> <p>c) Mineral resources: Distribution and conservation</p> <p>d) Food resources: Sources of food, supply and security context</p> <p>e) Energy resources: overview on types.</p>	18

	f) Land resources: overview on types, Distribution and conservation	
<b>II</b> <b>(5 Weeks)</b>	<p>Ecosystems</p> <p>Concept of an ecosystem.</p> <p>Structure and function of an ecosystem.</p> <p><i>Introduction, types, characteristic features, structure and function of the ecosystems</i></p> <p>Forest ecosystem</p> <p>Grassland ecosystem; Desert ecosystem, Desertification causes and consequence. Aquatic Ecosystem: Fresh water and marine ecosystem. Biodiversity: Levels of biodiversity and its conservation methods, Role of International organization like UNFCCC, IUCCD, IUCBD and etc. in Ecosystem.</p>	15
<b>III</b> <b>(4 Weeks)</b>	<p>Environmental Pollution: Causes, consequences and overview on preventive measures in India for the following</p> <p>Air pollution, Water pollution, Soil pollution</p>	12
<b>TOTAL</b>		45

**Recommended Books (Latest edition):**

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India.
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd. Down of Earth, Centre for Science and Environment
8. Shankar IAS, Environment.2021, Shankar IAS Academy, Chennai.
9. Goh Cheng Leong, Certificate Physical and Human Geography, Oxford University Press YMCA Library, New Delhi.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>II</b>
<b>Name of the course</b>	<b>Human Anatomy &amp; Physiology – II Practical</b>
<b>Course Code</b>	<b>BP207P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** This course is aimed to train the students on experimental techniques and allows the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This course also aimed to expertise the students on identification of various types of tissues & organ systems of the human body.

**Course Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Understand the coordinated working pattern of different organs of each system

CO 2: Explain different family planning methods.

CO 3: Estimate tidal volumes, vital capacity, temperature and basal mass index

CO 4: Demonstrate laboratory procedures used to examine anatomical structures and evaluate physiological functions of each organ system.

#### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Study the integumentary and special senses using specimen, models, etc.,
2	Study of the nervous system using specimen, models, etc.,
3	Study of the endocrine system using specimen, models, etc
4	Demonstrate the general neurological examination
5	Demonstrate the function of olfactory nerve
6	Examine the different types of taste.
7	Demonstrate the visual acuity and reflex activity
8	Recording of body temperature and basal mass index
9	Demonstrate positive and negative feedback mechanism.
10	Determination of tidal volume and vital capacity.
11	Study of digestive, respiratory, cardiovascular systems, urinary and

	reproductive systems with the help of models, charts and specimens.
12	Study of family planning devices and pregnancy diagnosis test.
13	Demonstration of total blood count by cell analyser
14	Permanent slides of vital organs and gonads.
	<b>Revision</b>

### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Tortora Gerard J, Derrickson Bryan. Principles of anatomy and physiology. 11<sup>th</sup> ed. Wiley: 2006.
2. Wilson K JW. Ross and Wilson's foundations of anatomy and physiology. 5<sup>th</sup> ed. Churchill Livingstone: Edinburg; 1981.
3. Guyton arthur C. Physiology of human body. 6<sup>th</sup> ed. Brooks coole Publisher: 1983.
4. Chatterjee C C. Human physiology. Volume I & II. Medical allied agency: Calcutta; 2004.
5. Anne Waugh and Alon Grant. Ross and Wilson Anatomy & Physiology. 11<sup>th</sup> ed. Churchill Livingstone: 2010.
6. Guyton Arthur C. Text book of Medical Physiology. 10<sup>th</sup> ed. Harcot Publishers: Singapore; 2000.
7. Kale S R, Kale R R. practical human anatomy and physiology. 19<sup>th</sup> ed. Pune. Nirali prakashan; 2009.
8. Goyal R K, Natvar M P, Shah S A. Practical anatomy, Physiology and biochemistry, 1<sup>st</sup> ed. Publisher: B S Shah Publisher: Ahmadabad; 1988.
9. C.L. Ghai. Textbook of Practical Physiology. Jaypee brother's medical publishers.
10. K. Srinageswari Rajeev Sharma. Practical workbook of Human Physiology. Jaypee brother's medical publishers.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>II</b>
<b>Name of the course</b>	<b>Pharmaceutical Organic Chemistry-I Practical</b>
<b>Course Code</b>	<b>BP208P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The pharmaceutical organic chemistry I laboratory course is aimed to train the students on experimental techniques for the determination of physical constants of organic compounds. This course also deals with wet laboratory-based experiments on identification of various chemical classes of organic compounds using basic principle of organic chemistry. This course also provides the laboratory skills related to reaction design, chemical synthesis and purification process for few organic medicinal compounds.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

**CO1:** Demonstrate the skills on determination of various physical properties of organic molecules.

**CO2:** Differentiate various classes of organic compounds by experimental techniques.

**CO3:** Perform chemical reaction and purification of organic compounds of pharmaceutical interest.

**CO4:** Analyze the identification of the organic compounds with different functional groups.

<b>S. No</b>	<b>Name of the experiment</b>
I	1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc. 2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test 3. Solubility test 4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides. 5. Melting point/Boiling point of organic compounds 6. Identification of the unknown compound from the literature using meltingpoint/boiling point.

	7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point. 8. Minimum 5 unknown organic compounds to be analyzed systematically.
II	Preparation of suitable solid derivatives from organic compounds
III	Construction of molecular models

### **Recommended Books (Latest Editions)**

1. Practical Organic Chemistry by Mann and Saunders.
2. Vogel's text book of Practical Organic Chemistry
3. Advanced Practical organic chemistry by N.K. Vishnoi.
4. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
5. Reaction and reaction mechanism by Ahluwaliah/Chatwal
6. Systematic Experiments

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>II</b>
<b>Name of the course</b>	<b>Biochemistry Practical</b>
<b>Course Code</b>	<b>BP209P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The pharmaceutical Biochemistry laboratory course is aimed to train the students on experimental techniques for the identification of carbohydrates, proteins, amino acids and lipids. This course also deals with experiments on estimation of constituents in urine and blood and their significance in diagnosis of various diseases.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

**CO 1:** Identify the carbohydrates proteins and lipids based upon chemical tests.

**CO 2:** Quantify the sugars, proteins and lipids in blood and serum.

**CO 3.** Demonstrate the skills on determination of various constituents present in urine.

Course content

<b>Week</b>	<b>Name of the experiment</b>
<b>1</b>	Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch
<b>2</b>	Identification tests for Proteins (albumin and Casein)
<b>3</b>	Determination of Glucose in sample by benedict's reagent method
<b>4</b>	Quantitative analysis of Proteins (Biuret method)
<b>5</b>	Qualitative analysis of urine for abnormal constituents
<b>6</b>	Qualitative analysis of urine for normal constituents
<b>7</b>	Determination of blood creatinine
<b>8</b>	Determination of blood sugar
<b>9</b>	Preparation of buffer solution and measurement of pH
<b>10</b>	Determination of chlorides in urine
<b>11</b>	Determination of urea in blood

<b>12</b>	Study the effect of Temperature on Salivary amylase activity.
<b>13</b>	Study the effect of Energy on Salivary amylase activity
<b>14</b>	Estimation of Na <sup>+</sup> /K <sup>+</sup> levels in serum

**Recommended Books (Latest Editions)**

- 1 Practical Biochemistry by R.C. Gupta and S. Bhargavan
- 2 Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
- 3 Practical Biochemistry for Medical students by Rajagopal and Ramakrishna
- 4 Practical Biochemistry by Harold Varley.



<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>II</b>
<b>Name of the course</b>	<b>Computer Applications in Pharmacy (Practical)</b>
<b>Course Code</b>	<b>BP210P</b>
<b>Credits</b>	<b>1</b>
<b>Hours /week</b>	<b>2 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Pharmacognosy and Phytochemistry I laboratory course is aimed to train the students regarding practical skills of different computer technologies, programming languages and development of web pages. This course also deals with laboratory-based experiments on maintenance of database in MS-Access, formation of queries, exporting queries, tables, forms and reports to web page.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Demonstrates the introduction of MS-Access, CRUD operations on data base.

CO2: State importance of tables, queries, forms and reports.

CO 2: Demonstrate knowledge on creation of web pages, working with tables and queries.

#### **Practical Course: Contents**

<b>S. No.</b>	<b>Topic</b>
4.	Design a questionnaire using a word processing package to gather information about a particular disease.
5.	Create a HTML web page to show personal information.
6.	Retrieve the information of a drug and its adverse effects using online tools.
7.	Creating mailing labels Using Label Wizard, generating label in MS WORD.
8.	Create a database in MS Access to store the patient information with the required fields Using access.
9.	Design a form in MS Access to view, add, delete and modify the patient record in the database.
10.	Generating report and printing the report from patient database.
11.	Creating invoice table using – MS Access.

12.	Drug information storage and retrieval using MS Access.
13.	Creating and working with queries in MS Access.
14.	Exporting Tables, Queries, Forms and Reports to web pages.
15.	Exporting Tables, Queries, Forms and Reports to XML pages.

**Recommended Books: (Latest Editions)**

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA.
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA).
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi – 110002.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>III</b>
<b>Name of the course</b>	<b>Pharmaceutical Organic Chemistry II – Theory</b>
<b>Course Code</b>	<b>BP 301T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course description:** This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of benzene, polynuclear compounds and cycloalkane compounds also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. This course also deals with the chemistry of fats and oils.

**Course Outcomes:** Upon completion of the course, the student shall be able to

1. Read the evidences in the derivation of structure of benzene, its reactivity, orientation towards the reactions and polynuclear compounds.
2. Interpret the effect of substituents on acidity or basicity, reactivity and uses of different phenols, aromatic amines and carboxylic acids.
3. Judge the reactivity/stability of organic compounds like fats, oils and cycloalkanes.

#### Course Content

Unit	Topics	Hours
<i>General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained. To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences</i>		
<b>I</b> <b>(4 Weeks)</b>	<b>Benzene and its derivatives</b> Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule.	<b>16</b>
	Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedel crafts alkylation- reactivity, limitations, Friedel crafts acylation.	
	Substituents, effect of substituents on reactivity and orientation of mono	

	substituted benzene compounds towards electrophilic substitution reaction.	
	Structure and uses of DDT, Saccharin, BHC and Chloramine	
<b>II</b> <b>(3 Weeks)</b>	<b>Phenols*</b> - Acidity of phenols, effect of substituents on acidity, qualitative tests, structure and uses of phenol, cresols, resorcinol, naphthols.	<b>12</b>
	<b>Aromatic Amines*</b> - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts.	
	<b>Aromatic Acids*</b> –Acidity, effect of substituents on acidity and important reactions of benzoic acid.	
<b>III</b> <b>(2 Weeks)</b>	<b>Polynuclear hydrocarbons:</b> Synthesis, reactions	<b>8</b>
	Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives.	
<b>IV</b> <b>(3 Weeks)</b>	<b>Cyclo alkanes*</b> Stabilities – Baeyer’s strain theory, limitation of Baeyer’s strain theory, Coulson and Moffitt’s modification,	<b>12</b>
	Sachse Mohr’s theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only.	
<b>V</b> <b>(3 Weeks)</b>	<b>Fats and Oils</b> a. Fatty acids – reactions.	<b>12</b>
	b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.	
	c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.	
<b>TOTAL</b>		<b>60</b>

**Learning Resources/Recommended Texts/Reference books/web resources**

1. Allyn, Bacon. Morrison and Boyd: Organic Chemistry. 7thEd. Pearson education; New Delhi: 2011.
2. T.W. Solomons. Organic Chemistry. 8thEd. University of South Florida, John Wiley & Sons, Inc; New York: 2004.
3. Arun Bahl, B.S. Bahl. Advanced Organic Chemistry. S.Chand and limited; New Delhi: 2010.
4. I.L. Finar. Organic Chemistry. Longman, Scientific & Technical. 5thEd. Co published in USA with John Wiley & Sons, Inc; New York: 2004.
5. Zimmerman and Zimmerman. Elements of Organic Chemistry. 2ndEd. Collier Macmillan Publishers; London: 1983.
6. O. P Agarwal. Organic chemistry Reaction and Reagents. 26<sup>th</sup> Ed. Goel Publishing House. New Delhi: 1996.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>III</b>
<b>Name of the course</b>	<b>Physical pharmaceutics-1 Theory</b>
<b>Course Code</b>	<b>BP 302TP</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3+1</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description**

The course deals with the various physical and physicochemical properties, and principals involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

### **Course outcome**

At the end of the theory course, the student will be able to

CO1 Understand various physicochemical properties of drug molecules in the designing the dosage forms

CO2 Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulation

CO3 Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

### **Course Content:**

<b>Unit</b>	<b>Contents</b>	<b>Hours</b>
<b>1</b>	<p><b>States of Matter and properties of matter:</b></p> <p>State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols – inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid crystalline, amorphous &amp; polymorphism.</p> <p><b>Physicochemical properties of drug molecules:</b> Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations, and applications.</p>	<b>12</b>

<b>2</b>	<b>Solubility of drugs:</b> Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions, Phase Rule. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications.	12
<b>3</b>	<b>pH, buffers and Isotonic solutions:</b> Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.	12
<b>4</b>	<b>Surface and interfacial phenomenon:</b> Liquid interface, surface & interfacial tensions, surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilization, detergency, adsorption at solid interface.	12
<b>5</b>	<b>Complexation and protein binding:</b> Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.	12
<b>Total</b>		<b>60</b>

#### **Recommended reference Books**

1. Sinko P.J. Martin's Physical Pharmacy and Pharmaceutical Sciences. 5th ed. New Delhi: Wolters Kluwer Health Pvt. Ltd.; 2007.
2. Subramanyam C.V.S. Essentials of Physical Pharmacy. 1st ed. Delhi: VallabhPrakashan; 2008.
3. Manavalan. R, Ramaswamy. C. Physical pharmaceutics. 2nded. Tamilnadu: Vigneshpublisher; 2008.
4. Experimental Pharmaceutics by Eugene, Parott.
5. Tutorial Pharmacy by Cooper and Gunn.

6. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
7. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
8. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
9. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
10. Test book of Physical Phramacy, by Gaurav Jain &Roop K. Khar. <http://www.e-booksdirectory.com> 12.<http://www.jblearning.com>



<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>III</b>
<b>Name of the course</b>	<b>Pharmaceutical Microbiology Theory</b>
<b>Course Code</b>	<b>BP 303 T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3+1 hours</b>

**Course Description:** The course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It also discusses with sterilization of pharmaceutical products, equipment, media etc.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO01: Understand methods of identification, cultivation and preservation of various microorganisms.

CO2: To understand the importance and implementation of sterilization in pharmaceutical processing and industry

CO3: Learn sterility testing of pharmaceutical products.

CO 4: Carried out microbiological standardization of Pharmaceuticals.

CO5: Understand the cell culture technology and its applications in pharmaceutical industries.

#### **Theory course contents**

<b>Unit</b>	<b>Topic</b>	<b>Hours</b>
I	Introduction, history of microbiology, its branches, scope and its importance. Introduction to Prokaryotes and Eukaryotes. Study of different type of microscopes: Types of Light and electron microscopy and their techniques. Study of ultra-structure and morphological classification of bacteria, nutritional requirements and classification of bacteria based on nutrient requirement, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of aerobic and anaerobic microbes, quantitative measurement of bacterial growth (total & viable count).	<b>15</b>

II	<p>Identification of bacteria using staining techniques (simple, Grams' &amp; Acid-fast staining) and biochemical tests (Extra and intra cellular enzyme tests).</p> <p>Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization.</p> <p>Industrial sterilization methods and equipments/setup employed for the same.</p> <p>Sterility validation.</p>	15
III	<p>Study of morphology, classification, reproduction/replication and Cultivation of Fungi and Viruses.</p> <p>Classification and mode of action of disinfectants.</p> <p>Factors influencing disinfection and antiseptics</p> <p>Evaluation of Disinfectants, antiseptics, bactericidal &amp; Bacteriostatic agents.</p> <p>Sterility testing of products (solids, liquids, ophthalmic and other sterile Products) according to IP, BP and USP.</p>	10
IV	<p>Designing of aseptic area, laminar air flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, Clean area classification.</p> <p>Principles and methods of microbiological assay for Standardization of antibiotics, vitamins and amino acids.</p> <p>Assessment of antimicrobial activity and MIC.</p>	10
V	<p>Sources and types of microbial contaminants in pharmaceuticals. Assessment of microbial contamination and spoilage.</p> <p>Preservation of pharmaceutical products using antimicrobial agents,</p> <p>Evaluation of microbial stability of formulations.</p> <p>Growth of animal cells in culture, general procedure for cell culture.</p> <p>Types of animal cell cultures/</p> <p>Application of cell cultures in pharmaceutical industry and research.</p>	10
<b>Total</b>		<b>60</b>

**Recommended Books (Latest edition)**

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn. Industrial Microbiology, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology. Rose: Industrial Microbiology.
5. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
6. Peppler: Microbial Technology.
7. I.P., B.P., U.S.P. - latest editions.
8. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergey's manual of systematic bacteriology, Williams and Wilkins- a Waverly Company

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>III</b>
<b>Name of the course</b>	<b>Pharmaceutical Engineering – Theory</b>
<b>Course Code</b>	<b>BP304T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3+1 hours</b>

#### **Course Description:**

This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry. This course emphasizes pharmaceutical importance of different equipment's, their construction, working applications, merits and demerits.

**Course Learning Outcomes:** Upon completion of this course the student should be able to:

CO 1: Define various unit operations and material handling techniques used in Pharmaceutical industries.

CO 2: Recognize significance of plant lay out design for optimum use of resources.

CO 3: Demonstrate various processes involved in pharmaceutical manufacturing process.

CO 4: Appraise the various preventive methods used for corrosion control in Pharmaceutical industries.

#### **Theory Course Contents:**

<b>Unit</b>	<b>Topic</b>	<b>Hours</b>
I	<p><b>Size Reduction:</b> Objectives, Mechanisms &amp; Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill &amp; end runner mill.</p> <p><b>Size Separation:</b> Objectives, applications &amp; mechanism of size separation, Official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter &amp; elutriation tank.</p> <p><b>Flow of fluids:</b> Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturi meter, Pitot tube and Roto meter.</p>	14

II	<p><b>Heat Transfer:</b> Objectives, applications &amp; Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection &amp; radiation. Heat interchangers &amp; heat exchangers.</p> <p><b>Evaporation:</b> Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator&amp; Economy of multiple effect evaporator.</p> <p><b>Distillation:</b> Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation &amp; molecular distillation</p>	14
III	<p><b>Drying:</b> Objectives, applications &amp; mechanism of drying process, measurements&amp; applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.</p> <p><b>Mixing:</b> Objectives, applications &amp; factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles &amp; Silverson Emulsifier,</p>	12
IV	<p><b>Filtration:</b> Objectives, applications, Theories &amp; Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate &amp; frame filter, filter leaf, rotary drum filter, Meta filter &amp; Cartridge filter, membrane filters and Seidtz filter.</p> <p><b>Centrifugation:</b> Objectives, principle &amp; applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge &amp; super centrifuge.</p>	10
V	<p><b>Materials of pharmaceutical plant construction, Corrosion and its prevention:</b> Factors affecting during materials selected for Pharmaceutical</p>	10

	plant construction, Theories of corrosion, types of corrosion and their prevention. Ferrous and nonferrous metals, inorganic and organic nonmetals, basic of material handling systems.	
<b>Total</b>		60

**Recommended Books: (Latest Editions)**

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceuticals- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>III</b>
<b>Name of the course</b>	<b>Pharmaceutical Organic Chemistry II – Practical</b>
<b>Course Code</b>	<b>BP 305P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Pharmaceutical Organic Chemistry II laboratory course aimed to train the students on laboratory techniques for purification of organic compounds. This course also deals with experiments on identification of purity and standard of the oils by their analytical constants. This course also provides the laboratory skills related to reaction design, chemical synthesis and purification process for few organic medicinal compounds.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

**CO 1:** Demonstrate the skills on separation & purification of various organic molecules.

**CO 2:** Analyze the analytical constants (values) by different tests to find the purity of oils.

**CO 3:** Identify the preparation mechanism and purification process of the various organic compounds.

<b>Week</b>	<b>TOPICS</b>
<b>Experiments involving laboratory techniques</b>	
1	Recrystallization
2	Steam distillation
<b>Determination of following oil values (including standardization of reagents)</b>	
3	Acid value
4	Saponification value
5	Iodine value
<b>Preparation of compounds</b>	
6	<b>Benzanilide/Phenyl benzoate from Aniline/ Phenol by acylation reaction.</b>
7	2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/ Acetanilide by halogenation (Bromination) reaction.

8	5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
9	Benzoic acid from Benzyl chloride by oxidation reaction.
10	Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
11	1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
12	Benzil from Benzoin by oxidation reaction.
13	Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction

#### **Recommended Books (Latest Editions)**

1. Vogel, A.I, Tatchell A.R, Furnis B.S, Hannaford A.J, Smith P.W.G. Practical Organic Chemistry. 5<sup>th</sup> Ed. Pearson Publishers Prentice Hall; New Delhi: 1996.
2. R.K. Bansal, Laboratory Manual of Organic Chemistry, 5th Ed. New Age International; New Delhi 2007.
3. O.P. Agarwal, Advanced Practical Organic Chemistry, 3rd Ed. Goel Publication; Meerut: 2011.
4. F.G.Mann & B.C. Saunders, Practical Organic Chemistry, 4th Ed. Chaman enterprises; New 5. Delhi: 2004.



<b>Program</b>	<b>B. Pharmacy</b>
<b>Year &amp; Semester</b>	<b>III</b>
<b>Name of the course</b>	<b>Physical pharmaceutics-1 (Practical)</b>
<b>Course Code</b>	<b>BP 306P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description**

The Physical Pharmacy – I laboratory course is aimed to train the students on experimental techniques for the determination of Physico - chemical properties. This course also deals with wet laboratory-based experiments on identification critical solution temperatures of binary phase systems. This course also provides the laboratory skills related to determination of pH, physical & colligative properties.

### **Course Outcomes**

At the end of the practical course of experiments, the student will be able to

CO 1: Demonstrate the skills on determination of various physical properties of drug molecules.

Co 2: Operate equipment's like pH meter, Refractometer etc.

CO 3: Calculate the buffer capacities of pharmaceutical buffers by experimental techniques.

S. No.	Description of Activity /Experiments	Hours
1	Determination the solubility of drug at room temperature	3
2	Determination of pKa value by Half Neutralization/ Henderson Hassel Balch equation.	3
3	Determination of Partition co- efficient of benzoic acid in benzene and water	3
4	Determination of Partition co- efficient of Iodine in CCl <sub>4</sub> and water	3
5	Determination of % composition of NaCl in a solution using phenol-water system by CST method	3

6	Determination of surface tension of given liquids by drop count and drop weight method	3
7	Determination of HLB number of a surfactant by saponification method	3
8	Determination of Freundlich and Langmuir constants using activated char coal	3
9	Determination of critical micellar concentration of surfactants	3
10	Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method	3
11	Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method	3

**Recommended Books: (Latest Editions)**

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. LaboratoryManual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

<b>Program</b>	<b>B. Pharm</b>
<b>Year</b>	<b>III</b>
<b>Name of the course</b>	<b>Pharmaceutical Microbiology (Lab)</b>
<b>Course Code</b>	<b>BP 307P</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>4 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The course is designed to focus on identification, nutritional requirements of microorganisms. Since microbiology is an upcoming and fascinating branch of biological sciences, medical and pharmaceutical sciences, the approach of performing experiments will lead to success of learning the subject.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Learn about microbial techniques related to Sterilization, Aseptic handling as well as microbial utilization in the Pharma industry

CO2: Learn procedure to cultivate and identification of the microorganisms in the laboratory

CO3: Learn about the utilization of microbes in assay of various pharmaceuticals.

#### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Introduction and study of different equipments, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2	Sterilization and preparation of Nutrient Broth
3	Sterilization and Preparation of Nutrient slant, Deep tube and petri plate
4	Aseptic transfer of organism into Nutrient Broth
5	Aseptic transfer of Organism into Slant.
6	Isolation of pure culture of micro-organisms by Different streak plate techniques
7	Isolation of pure culture of micro-organisms Spread and Pour plate technique
8	Simple and Negative staining

9	Grams' staining
10	Acid Fast Staining
11	Microbiological assay of antibiotics by cup plate/Disc plate method.
12	Sterility testing of pharmaceuticals
13	Bacteriological analysis of water
14	Biochemical tests (IMViC Tests/Intra and Extracellular enzyme tests)
15	Revision/Assessment

**Recommended Books (Latest edition)**

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn. Industrial Microbiology, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology. Rose: Industrial Microbiology.
5. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
6. Peppler: Microbial Technology.
7. I.P., B.P., U.S.P. - latest editions.
8. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergey's manual of systematic bacteriology, Williams and Wilkins- a Waverly Company.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>III</b>
<b>Name of the course</b>	<b>Pharmaceutical Engineering – Practical</b>
<b>Course Code</b>	<b>BP308P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours</b>

**Course Description:** The Pharmaceutical Engineering Practical course is aimed to train the students on handling of equipments related to size reduction, size separation and mixing. This course also deals with determination of humidity using thermometers, rate of drying, rate of filtration, rate of evaporation and extraction by distillation.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Operate major equipments used in pharmaceutical industry

CO 2: Experiment to determine various parameters and factors effecting of unit processes.

CO3: Construct plots related to various unit operations.

**Practical Course Contents:**

<b>S. No</b>	<b>Experiments</b>
1.	Calculation of efficiency of steam distillation.
2.	Determination of overall heat transfer coefficient by heat exchanger.
3.	Construction of drying curves (for calcium carbonate and starch).
4.	Determination of moisture content and loss on drying.
5.	Determination of humidity of air by a) Wet and dry bulb temperatures b) Dew point method.
6.	Description of Construction working and application of rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
7.	Evaluation of size distribution of tablet granulations by sieving – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
8.	Verification of the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.

9.	Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer
10	Study of factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity)
11	Study of effect of time on the Rate of Crystallization.
12	Calculation of uniformity Index for given sample by using Double Cone Blender.

### **Recommended reference Books**

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>IV</b>
<b>Name of the course</b>	<b>Pharmaceutical Organic Chemistry III – Theory</b>
<b>Course Code</b>	<b>BP 401T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course description:** This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important heterocyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

**Course Outcomes:** At the end of the course, the student shall be able to

**CO 1:** Understand the methods of preparation and properties of organic compounds

**CO 2:** Explain the stereo chemical aspects of organic compounds and stereo chemical reactions

**CO 3:** know the medicinal uses and other applications of organic compounds

#### Course Content

Unit	Topics	Hours
<b>Note:</b> To emphasize on definition, types, mechanisms, examples, uses/applications		
<b>I</b> <b>(3 Weeks)</b>	<b>Stereo isomerism:</b> Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds Elements of symmetry, chiral and achiral molecules,	<b>12</b>
	DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers, Reactions of chiral molecules,	
	Racemic modification and resolution of racemic mixture. Asymmetric synthesis: partial and absolute.	
<b>II</b> <b>(3 Weeks)</b>	<b>Geometrical isomerism</b> Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems), Methods of determination of configuration of geometrical isomers.	<b>12</b>
	Conformational isomerism in Ethane, n-Butane and Cyclohexane.	

	Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity. Stereospecific and stereoselective reactions	
<b>III</b> <b>(3 Weeks)</b>	<b>Heterocyclic compounds:</b> Nomenclature and classification	<b>12</b>
	Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene.	
	Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene	
<b>IV</b> <b>(3 Weeks)</b>	Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrazole, Imidazole, Oxazole and Thiazole.	<b>12</b>
	Pyridine, Quinoline, Isoquinoline, Acridine and Indole.	
	Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives	
<b>V</b> <b>(3 Weeks)</b>	Reactions of synthetic importance, Metal hydride reduction ( $\text{NaBH}_4$ and $\text{LiAlH}_4$ ), Clemmensen reduction, Birch reduction, Wolff Kishner reduction,	<b>12</b>
	Oppenauer-oxidation and Dakin reaction, Beckmann rearrangement and Schmidt rearrangement, Claisen-Schmidt condensation.	
	<b>Revision</b>	
<b>TOTAL</b>		<b>60</b>

#### Learning Resources/Recommended Texts/Reference books/web resources

1. Allyn, Bacon. Morrison and Boyd: Organic Chemistry. 7thEd. Pearson education; New Delhi: 2011.
2. T.W. Solomons. Organic Chemistry. 8thEd. University of South Florida, John Wiley & Sons, Inc; New York: 2004.
3. Arun Bahl, B.S. Bahl. Advanced Organic Chemistry. S.Chand and limited; New Delhi: 2010.
4. I.L. Finar. Organic Chemistry. Longman, Scientific & Technical. 5thEd. Co published in USA with John Wiley & Sons, Inc; New York: 2004.
5. Zimmerman and Zimmerman. Elements of Organic Chemistry. 2ndEd. Collier Macmillan Publishers; London: 1983.
6. O. P Agarwal. Organic chemistry Reaction and Reagents. 26<sup>th</sup> Ed. Goel Publishing House. New Delhi: 1996.



<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>IV</b>
<b>Name of the course</b>	<b>Medicinal Chemistry I – Theory</b>
<b>Course Code</b>	<b>BP 402T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course description:** This course designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

**Course Outcomes:** Upon completion of the course, the student shall be able to

**CO 1:** Understand the chemistry of drugs with respect to their pharmacological activity

**CO 2:** Identify the drug metabolic pathways, adverse effect and therapeutic value of drugs

**CO 3:** Know the Structural Activity Relationship (SAR) of different class of drugs

**CO 4:** Write the chemical synthesis of some drugs

#### **Course Content**

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<i>Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)</i>		
<b>I (3 Weeks)</b>	<b>Introduction to Medicinal Chemistry</b> History and development of medicinal chemistry Physicochemical properties in relation to biological action	<b>12</b>
	Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.	
	<b>Drug metabolism</b> Drug metabolism principles- Phase I and Phase II. Factors affecting drug metabolism including stereo chemical aspects.	

<b>II</b> <b>(3 Weeks)</b>	<p><b>Drugs acting on Autonomic Nervous System</b></p> <p><b>Adrenergic Neurotransmitters:</b></p> <p>Biosynthesis and catabolism of catecholamine.</p> <p>Adrenergic receptors (Alpha &amp; Beta) and their distribution.</p> <hr/> <p><b>Sympathomimetic agents: SAR of Sympathomimetic agents</b></p> <p><b>Direct acting:</b> Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.</p> <p><b>Indirect acting agents:</b> Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.</p> <p><b>Agents with mixed mechanism:</b> Ephedrine, Metaraminol.</p> <hr/> <p><b>Adrenergic Antagonists:</b></p> <p><b>Alpha adrenergic blockers:</b> Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.</p> <p><b>Beta adrenergic blockers:</b> SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.</p>	<b>12</b>
<b>III</b> <b>(3 Weeks)</b>	<p><b>Cholinergic neurotransmitters:</b></p> <p>Biosynthesis and catabolism of acetylcholine.</p> <p>Cholinergic receptors (Muscarinic &amp; Nicotinic) and their distribution.</p> <p><b>Parasympathomimetic agents: SAR of Parasympathomimetic agents</b></p> <p><b>Direct acting agents:</b> Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.</p> <p><b>Indirect acting/ Cholinesterase inhibitors (Reversible &amp; Irreversible):</b></p> <p>Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorophate, Echothiophate iodide, Parathione, Malathion.</p> <p><b>Cholinesterase reactivator:</b> Pralidoxime chloride.</p>	<b>12</b>

	<p><b>Cholinergic Blocking agents:</b> SAR of cholinolytic agents</p> <p><b>Solanaceous alkaloids and analogues:</b> Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.</p>	
	<p><b>Synthetic cholinergic blocking agents:</b> Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.</p>	
<p><b>IV</b> <b>(3 Weeks)</b></p>	<p><b>Drugs acting on Central Nervous System</b></p> <p><b>A. Sedatives and Hypnotics:</b></p> <p><b>Benzodiazepines:</b> SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem</p> <p><b>Barbiturtes:</b> SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital</p> <p><b>Miscellaneous:</b></p> <p>Amides &amp; imides: Glutethimide.</p> <p>Alcohol &amp; their carbamate derivatives: Meprobumate, Ethchlorvynol.</p> <p>Aldehyde &amp; their derivatives: Triclofos sodium, Paraldehyde.</p> <p><b>B. Antipsychotics</b></p> <p><b>Phenothiazines:</b> SAR of Phenothiazines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.</p> <p><b>Ring Analogues of Phenothiazines:</b> Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.</p> <p><b>Fluoro buterophenones:</b> Haloperidol, Droperidol, Risperidone.</p>	<p><b>12</b></p>

	<b>Beta amino ketones:</b> Molindone hydrochloride. <b>Benzamides:</b> Sulpieride.	
	<b>C. Anticonvulsants:</b> SAR of Anticonvulsants, mechanism of anticonvulsant action <b>Barbiturates:</b> Phenobarbitone, Methabarbital. <b>Hydantoins:</b> Phenytoin*, Mephentyoin, Ethotoin <b>Oxazolidine diones:</b> Trimethadione, Paramethadione <b>Succinimides:</b> Phensuximide, Methsuximide, Ethosuximide* <b>Urea and monoacyl ureas:</b> Phenacemide, Carbamazepine* <b>Benzodiazepines:</b> Clonazepam <b>Miscellaneous:</b> Primidone, Valproic acid, Gabapentin, Felbamate	
<b>V</b> <b>(3 Weeks)</b>	<b>Drugs acting on Central Nervous System</b> <b>General anesthetics:</b> <b>Inhalation anesthetics:</b> Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane. <b>Ultra-short acting barbiturates:</b> Methohexital sodium*, Thiamylal sodium, Thiopental sodium. <b>Dissociative anesthetics:</b> Ketamine hydrochloride. *	<b>12</b>
	<b>Narcotic and non-narcotic analgesics</b> <b>Morphine and related drugs:</b> SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate. <b>Narcotic antagonists:</b> Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.	
	<b>Anti-inflammatory agents:</b> Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepiac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.	
<b>TOTAL</b>		<b>60</b>

**Learning Resources/Recommended Texts/Reference books/web resources**

1. William O. Foye, Textbook of Medicinal Chemistry, Lea Febiger, Philadelphia.
2. Graham. L. Patrick, an Introduction to Medicinal Chemistry, Oxford University publishers.
3. JH Block & JM Beale (Eds), Wilson & Griswold's textbook of organic Medicinal Chemistry and pharmaceutical chemistry, 11th Ed, Lipcolt, Raven, Philadelphia, 2004
4. Rama Rao Nadendla, Medicinal Chemistry, Mc Millan Publishers.
5. Hansch, Comprehensive medicinal chemistry, Vol 1 – 6 Elsevier pergmon press, Oxford.
6. D. Abraham (Ed), Burger Medicinal chemistry and Drug discovery, Vol. 1 & 2, 6<sup>th</sup> Ed, John Wiley & Sons, New York 2003.
7. M. Atherden, Bentley and Driver's Textbook of Pharmaceutical Chemistry Ed: 1. Oxford University Press, Delhi.
8. Daniel lednicer, Strategies for Organic Drug Synthesis and Design, John Wiley, N. Y. 1998.
9. D. Lednicer, Organic drug synthesis, Vol, 1 – 6, J. Wiley N.Y.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>IV</b>
<b>Name of the course</b>	<b>Physical pharmaceutics-II Theory</b>
<b>Course Code</b>	<b>BP403T</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. The theoretical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

#### **Course outcome**

At the end of the theory course, the student will be able to

CO 1: Define the fundamental aspects of solubility, distribution, flow of liquids & solids.

CO 2: Recognize the importance of micromeritics, rheology & interfacial phenomenon in manufacturing of dosage form

CO 3: Apply the principles of diffusion and complexation in formulations

CO 4: Test the drug decomposition kinetics & stability of dispersed systems

#### **Course Content**

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I (3 Weeks)</b>	<b>Colloidal dispersions:</b> Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles,	<b>12</b>
	Classification of colloids & comparative account of their general properties.	
	Optical, kinetic & electrical properties. Stability of colloids. Effect of electrolytes, coacervation, peptization & protective action.	
<b>II (3 Weeks)</b>	<b>Rheology:</b> Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic,	<b>12</b>
	thixotropy, thixotropy in formulation, determination of viscosity by capillary, falling Sphere, rotational viscometers	
	<b>Deformation of solids:</b> Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus	
<b>III</b>	<b>Coarse dispersion:</b> Suspension, interfacial properties of suspended	<b>12</b>

(3 Weeks)	particles, settling in suspensions, formulation of flocculated and deflocculated suspensions.	
	Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions	
	Rheological properties of emulsions and emulsion formulation by HLB method.	
IV (3 Weeks)	<b>Micromeritics:</b> Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods,	12
	particle shape, specific surface, methods for determining surface area,	
	Permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.	
V (3 Weeks)	<b>Drug stability:</b> Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order.	12
	Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems.	
	Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention.	
<b>TOTAL</b>		<b>60</b>

### Learning Resources/Recommended Texts/Reference books/web resources

1. Sinko P.J. Martin's Physical Pharmacy and Pharmaceutical Sciences. 5th ed. New Delhi:Wolters Kluwer Health Pvt.Ltd.,; 2007.
2. Subramanyam C.V.S. Essentials of Physical Pharmacy. 1st ed. Delhi: Vallabh Prakashan; 2008.
3. Manavalan. R, Ramaswamy. C. Physical pharmaceutics. 2nded. Tamilnadu: Vignesh publisher; 2008.
4. Experimental Pharmaceutics by Eugene, Parott.
5. Tutorial Pharmacy by Cooper and Gunn.
6. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.

<b>Program /Year/Sem</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>IV</b>
<b>Name of the course</b>	<b>Pharmacology- I (Theory)</b>
<b>Course Code</b>	<b>BP 404 T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** This course aimed to provide basic knowledge on principles of general pharmacology such as sources of drug, drug development phases, routes of drug administration, mechanism of drug action and pharmacokinetic aspects like drug absorption, distribution, metabolism and excretion. Subsequently, this course also covers about the drugs acting on central and peripheral nervous system.

**Course Outcomes:** Upon successful completion of this course, the student should be able to:

CO.1. Appraise the different stages of drug discovery and development

CO.2. Recall the pharmacological actions of different categories of drugs

CO.3. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.

CO.4. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.

#### **Theory Course: Contents**

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I</b>	General Pharmacology Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists (competitive and noncompetitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs. Enzyme induction, enzyme inhibition,	<b>12</b>
<b>II</b>	<b>General Pharmacology</b> Pharmacodynamics- Principles and mechanisms of drug action. Receptor	<b>12</b>



	<p>theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.</p> <p>Adverse drug reactions.</p> <p>Drug interactions (pharmacokinetic and pharmacodynamic)</p> <p>Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.</p>	
III	<p><b>2. Pharmacology of drugs acting on peripheral nervous system</b></p> <p>a. Organization and function of ANS.</p> <p>b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.</p> <p>Para sympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.</p> <p>Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).</p> <p>Local anesthetic agents.</p> <p>Drugs used in myasthenia gravis and glaucoma</p>	12
IV	<p><b>3. Pharmacology of drugs acting on central nervous system</b></p> <p>Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.</p> <p>General anesthetics and pre-anesthetics.</p> <p>Sedatives, hypnotics and centrally acting muscle relaxants.</p> <p>Anti-epileptics</p> <p>Alcohols and disulfiram</p>	12
V	<p><b>3. Pharmacology of drugs acting on central nervous system</b></p>	12

Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-maniacs and hallucinogens. Drugs used in Parkinson's disease and Alzheimer's disease. CNS stimulants and nootropics. Opioid analgesics and antagonists	
<b>Total</b>	<b>60</b>

### **Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>IV</b>
<b>Name of the course</b>	<b>Pharmacognosy and Phytochemistry I</b>
<b>Course Code</b>	<b>BP405T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3+1</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Pharmacognosy and Phytochemistry I course is aimed at the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties. The subject deals with cultivation and plant tissue culture aspects of medicinal plants.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO1: Demonstrates the introduction to pharmacognosy.

CO2: State importance of Natural sources of drugs, scientific names, active constituents, uses of drugs

CO3: Identifies the cultivation and plant tissue culture aspects of medicinal plants.

CO4: Recognize the importance of crude drugs belong to Fibers, Carbohydrates, Proteins, Lipids and marine drugs.

#### **Theory Course: Contents**

<b>UNIT</b>	<b>Topic</b>	<b>Hours</b>
<b>I</b>	<b>Introduction to Pharmacognosy:</b> Definition, history, scope and development of Pharmacognosy Sources of Drugs – Plants, Animals, Marine & Mineral source. Organized drugs, unorganized drugs. <b>Classification of drugs:</b> Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo taxonomical classification of drugs. <b>Quality control of Drugs of Natural Origin:</b> Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and	15

	properties. Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, Camera Lucida and diagrams of microscopic objects to scale with Camera Lucida.	
<b>II</b>	<b>Cultivation, Collection, Processing and storage of drugs of natural origin:</b> Cultivation and Collection of drugs of natural origin. Factors influencing cultivation of medicinal plants. Plant hormones and their applications. Polyploidy, mutation and hybridization with reference to medicinal plants.	15
<b>III</b>	<b>Plant tissue culture:</b> Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacognosy.	12
<b>IV</b>	<b>Pharmacognosy in various systems of medicine:</b> Role of Pharmacognosy in Allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine. <b>Introduction to secondary metabolites:</b> Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins	10
<b>V</b>	<b>Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs</b> <b>Plant Products:</b> Fibers - Cotton, Jute, Hemp <b>Primary metabolites:</b> General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, therapeutic uses and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites: <b>Carbohydrates:</b> Acacia, Agar, Tragacanth, Honey <b>Proteins and Enzymes:</b> Gelatin, casein, proteolytic enzymes (Papain, bromelain, serrati peptidase, urokinase, streptokinase, pepsin). <b>Lipids (Waxes, fats, fixed oils):</b> Castor oil, Chaulmoogra oil, Wool	08

	Fat, Bees Wax	
	<b>Marine Drugs:</b> Novel medicinal agents from marine sources.	
	<b>Total</b>	60

#### **Recommended Books: (Latest Editions)**

- 1.W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
- 2.Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
- 3.Text Book of Pharmacognosy by T.E. Wallis
- 4.Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 5.Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
- 6.Herbal drug industry by R.D. Choudhary (1996), IstEdn, Eastern Publisher, New Delhi.
- 7.Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 8.Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
- 9.Anatomy of Crude Drugs by M.A. Iyengar

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>IV</b>
<b>Name of the course</b>	<b>Medicinal Chemistry I – Practical</b>
<b>Course Code</b>	<b>BP 406P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Medicinal chemistry I laboratory course is aimed to train the students on experimental techniques for the determination and Synthesis of different biologically active compound libraries and evaluation of their biological activity using cytotoxicity assays. Analysis of structure activity relationships using the data generated. This course also provides the laboratory skills related to reaction design, chemical synthesis and purification process for few medicinal compounds.

**Course Outcomes:** Upon successful completion of this course, the student should be able to:

**CO 1:** Perform chemical reaction and purification of medicinal compounds of pharmaceutical interest.

**CO 2:** Analyze the percentage purity of various classes of drugs as per the monographs in pharmacopoeias.

<b>Week</b>	<b>TOPICS</b>
<b>I. Preparation of drugs / intermediates</b>	
1	<b>Antipyrine</b>
2	1,3-oxazole
3	Benzimidazole
4	Benztriazole
5	2,3- diphenyl quinoxaline
6	Benzocaine
7	Phenytoin
8	Phenothiazine
9	Barbiturate
<b>II. Assay of drugs</b>	

10	Chlorpromazine
11	Phenobarbitone
12	Ibuprofen
13	Aspirin
14	Furosemide
15	<b>III. Determination of Partition coefficient for any two drugs</b>

**Learning Resources/Recommended Texts/Reference books/web resources**

1. A.I. Vogel, Text Book of Practical Organic Chemistry, 5th Edition. Pearson Prentice Hall.
2. F.G. Mann & B.C. Saunders, Practical Organic Chemistry, 4<sup>th</sup> Edition. Pearson Publishers.
3. Indian Pharmacopoeia
4. British Pharmacopoeia

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>IV</b>
<b>Name of the course</b>	<b>Physical pharmaceutics II – Practical</b>
<b>Course Code</b>	<b>BP 407P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Physical Pharmacy- II laboratory course aimed to train the students on experimental techniques for the determination of Physico–chemical properties of substances. This course also deals with wet laboratory that determines order of kinetics, flow of solids & liquids. This course also provides the laboratory skills related to solubility, partition & evaluation of dispersed systems.

**Course Outcomes:** Upon successful completion of this course, the student should be able to

**CO 1:** Demonstrate the skills on determination of Physico – chemical properties.

**CO2:** Analyze the stability of dispersed systems by experimental techniques.

**CO 3:** Interpret the scientific data from graphical presentations.

#### **Course Content**

<b>Week</b>	<b>Topic</b>
<b>1</b>	Determination of particle size, particle size distribution using Microscopic method
<b>2</b>	Determination of bulk density, true density and porosity
<b>3</b>	Determine the angle of repose and influence of lubricant on angle of repose
<b>4</b>	Determination of viscosity of liquid using Ostwald's viscometer
<b>5</b>	Determination sedimentation volume with effect of different suspending agent
<b>6</b>	Determination sedimentation volume with effect of different concentration of single suspending agent
<b>7</b>	Identification and evaluation of Physical stability of an emulsion.
<b>8</b>	Determination of viscosity of semisolid by using Brookfield viscometer
<b>9</b>	Determination of reaction rate constant first order.



<b>10</b>	Determination of reaction rate constant second order
<b>11</b>	Accelerated stability studies

### **Recommended reference Books**

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

<b>Program /Year/Sem</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>IV</b>
<b>Name of the course</b>	<b>Pharmacology – I (Practical)</b>
<b>Course Code</b>	<b>BP 408 P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This course aimed to expertise the students on Basic needs of Pharmacology like handling of animals, Routes of drug administration, Collection of blood samples by various techniques. This course also describes about different preclinical screening models employed in drug discovery and development.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate the Basic needs and skills required for pharmacology laboratory.

CO2: Perform the experiments on isolated tissue and experimental animals

CO 3: Handle & maintain the laboratory animals as per CPCSEA guidelines

#### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Introduction to Experimental Pharmacology
2	Commonly used instruments in experimental pharmacology.
3	Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
4	Maintenance of laboratory animals as per CPCSEA guidelines.
5	Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6	Study of different routes of drugs administration in mice/rats
7	Effect of Psychotropic drugs on condition avoidance response
8	To study the antidepressant activity of drugs using forced swim test
9	Effect of drugs on rabbit eye.

10	Effects of skeletal muscle relaxants using Rota-rod apparatus.
11	Effect of drugs on locomotor activity using actophotometer.
12	Anticonvulsant effect of drugs by MES and PTZ method.
13	Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14	Study of anxiolytic activity of drugs using rats/mice.
15	To study anti-amnesic effect by using Y- Maze
16	<b>Revision</b>

*Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by software's and videos*

### **Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>IV</b>
<b>Name of the course</b>	<b>Pharmacognosy and Phytochemistry I (Practical)</b>
<b>Course Code</b>	<b>BP409P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Pharmacognosy and Phytochemistry I laboratory course is aimed to train the students regarding laboratory skills of various chemical test of the drugs mentioned in theory under lipids, carbohydrates. This course also deals with laboratory-based experiments on identification of crude drugs by physical and microscopic evaluation.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Evaluate crude drugs by chemical test.

CO 2: Demonstrate knowledge on evaluation of crude drugs.

#### **Practical Course: Contents**

<b>S. No.</b>	<b>Topic</b>
5.	Analysis of crude drugs by chemical tests: (i) Tragacanth (ii) Acacia (iii) Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
6.	Determination of stomatal number and index
7.	Determination of vein islet number, vein islet termination and palisade ratio
8.	Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
9.	Determination of Fiber length and width
10.	Determination of number of starch grains by Lycopodium spore method
11.	Determination of Ash value
12.	Determination of Extractive values of crude drugs
13.	Determination of moisture content of crude drugs
14.	Determination of swelling index and foaming

**Recommended Books: (Latest Editions)**

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), IstEdn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs by M.A. Iyengar.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>V</b>
<b>Name of the course</b>	<b>Medicinal Chemistry II– Theory</b>
<b>Course Code</b>	<b>BP 501T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course description:** This subject designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

**Course Outcomes:** Upon completion of the course, the student shall be able to

**CO 1:** Understand the chemistry of drugs with respect to their pharmacological activity

**CO 2:** Identify the drug metabolic pathways, adverse effect and therapeutic value of drugs

**CO 3:** Know the Structural Activity Relationship of different class of drugs

**CO 4:** Report the chemical synthesis of selected drugs

#### Course Content

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<i>Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)</i>		
<b>I (3 Weeks)</b>	<p><b>Antihistaminic agents:</b> Histamine, receptors and their distribution in the human body.</p> <p><b>H<sub>1</sub>-antagonists:</b> Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartrate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine Cromolyn</p>	<b>12</b>

	sodium	
	<b>H<sub>2</sub>-antagonists:</b> Cimetidine*, Famotidine, Ranitidine. <b>Gastric Proton pump inhibitors:</b> Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole	
II (3 Weeks)	<b>Anti-neoplastic agents:</b> <b>Alkylating agents:</b> Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa <b>Antimetabolites:</b> Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine <b>Antibiotics:</b> Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin <b>Plant products:</b> Etoposide, Vinblastin sulphate, Vincristin sulphate <b>Miscellaneous:</b> Cisplatin, Mitotane.	12
	<b>Anti-anginal:</b> <b>Vasodilators:</b> Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbidedinitrite*, Dipyridamole. <b>Calcium channel blockers:</b> Verapamil, Bepridil hydrochloride, Diltiazemhydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.	
	<b>Diuretics:</b> <b>Carbonic anhydrase inhibitors:</b> Acetazolamide*, Methazolamide, Dichlorphenamide. <b>Thiazides:</b> Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, <b>Loop diuretics:</b> Furosemide*, Bumetanide, Ethacrynic acid. <b>Potassium sparing Diuretics:</b> Spironolactone, Triamterene, Amiloride. <b>Osmotic Diuretics:</b> Mannitol	
	<b>Anti-hypertensive Agents:</b> Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopatehydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide,	

	Minoxidil, Reserpine, Hydralazine hydrochloride.	
<b>III</b> <b>(3 Weeks)</b>	<b>Anti-arrhythmic Drugs:</b> Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcaïnide hydrochloride, Amiodarone, Sotalol.	<b>12</b>
	<b>Anti-hyperlipidemic agents:</b> Clofibrate, Lovastatin, Cholesteramine and Cholestipol	
	<b>Coagulant &amp; Anticoagulants:</b> Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel	
	<b>Drugs used in Congestive Heart Failure:</b> Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.	
<b>IV</b> <b>(3 Weeks)</b>	<b>Drugs acting on Endocrine system</b> Nomenclature, Stereochemistry and metabolism of steroids <b>Sex hormones:</b> Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrone, Diethyl stilbestrol.	<b>12</b>
	<b>Drugs for erectile dysfunction:</b> Sildenafil, Tadalafil.	
	<b>Oral contraceptives:</b> Mifepristone, Norgestrel, Levonorgestrel	
	<b>Corticosteroids:</b> Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone <b>Thyroid and antithyroid drugs:</b> L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.	
<b>V</b> <b>(3 Weeks)</b>	<b>Antidiabetic agents:</b> Insulin and its preparations <b>Sulfonyl ureas:</b> Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. <b>Biguanides:</b> Metformin.	<b>12</b>
	<b>Thiazolidinediones:</b> Pioglitazone, Rosiglitazone. <b>Meglitinides:</b> Repaglinide, Nateglinide. <b>Glucosidase inhibitors:</b> Acarbose, Voglibose. <b>Local Anesthetics:</b> SAR of Local anesthetics <b>Benzoic Acid derivatives:</b> Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.	



	<b>Amino Benzoic acid derivatives:</b> Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate. <b>Lidocaine/Anilide derivatives:</b> Lignocaine, Mepivacaine, Prilocaine, Etidocaine. <b>Miscellaneous:</b> Phenacaine, Dipiperidon, Dibucaine.*	
<b>TOTAL</b>		<b>60</b>

#### **Learning Resources/Recommended Texts/Reference books/web resources**

1. William O. Foye. Principle of medicinal chemistry, 5th Ed. New Delhi: Wolter's Kluwer health (India) Pvt Ltd.; 2008.
2. Block JH & Beale JM. Wilson & Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, 12th ed. Philadelphia: Wolter's Kluwer health (India) PvtLtd.; 2011.
3. Abraham D. Burger, Medicinal Chemistry and Drug Discovery, 6th Ed. New York:John Wiley & Sons. 2007.
4. Graham L. Patrick. An Introduction to Medicinal Chemistry, 1st ed. U K: OxfordUniversity Publishers; 2002.
5. Rama Rao Nadendla. Medicinal Chemistry: Mc Millan Publishers; 2007.
6. Hansch. Comprehensive Medicinal Chemistry, Vol 1-6 ed. Oxford: Elsevier pergmon press.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>V</b>
<b>Name of the course</b>	<b>Industrial Pharmacy I Theory</b>
<b>Course Code</b>	<b>BP 502T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Industrial Pharmacy I course is aimed to present fundamentals and importance of pre-formulation studies and the effect of physic-chemical properties of drug on formulations. It emphasizes various techniques in the development and evaluation of tablets, capsules, Parenteral, ophthalmics and Aerosols. The course also deals with the formulation, equipments for manufacture of pellets and the cosmetic preparations for skin, hair. It also describes about the packaging components and their specifications.

**Course Learning Outcomes:**

**Upon successful completion of this course, the student should be able to:**

C502.1: Define the different types of tablets.

C502.2: Demonstrate the various techniques used in tablet coating.

C502.3: Analyze the fundamentals in designing of Parenteral formulations.

C502.4: Propose the appropriate packaging system for the drug products.

**Course Content**

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I</b>	<p><b>Pre-formulation Studies:</b> Introduction to pre-formulation, goals and objectives, study of physicochemical characteristics of drug substances.</p> <p><b>Physical properties:</b> Physical form (crystal &amp; amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism.</p> <p><b>Chemical Properties:</b> Hydrolysis, oxidation, reduction, racemization, polymerization. BCS classification of drugs &amp; its significant application.</p>	12

II	<p><b>Tablets:</b></p> <p>Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Pre-formulation considerations and Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.</p> <p><b>Tablet coating:</b> Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. Quality control tests: In process and finished product tests</p> <p><b>Liquid orals:</b> Pre-formulation, Formulation and manufacturing consideration of Syrups, elixirs, suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia</p>	14
III	<p><b>Capsules:</b></p> <p><b>Hard gelatin capsules:</b></p> <p>Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.</p> <p><b>Soft gelatin capsules:</b> Introduction, Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.</p> <p><b>Pellets:</b> Introduction, formulation requirements, pelletization process, equipment for manufacture of pellets</p>	12
	<p><b>Parenteral Products:</b></p> <p>Definition, types, advantages and limitations. Pre-formulation factors and essential requirements, vehicles, additives, Formulation requirements, importance of Iso-tonicity, Production procedure, production facilities and controls, aseptic processing,</p>	12

<b>IV</b>	Formulation of injections, sterile powders, large volume parenteral and lyophilized products. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products. <b>Ophthalmic Preparations:</b> Introduction, formulation and pre-formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers, evaluation of ophthalmic preparations	
<b>V</b>	<b>Pharmaceutical Aerosols:</b> Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies. <b>Packaging Materials Science:</b> Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, Stability aspects of packaging materials, quality control tests. <b>Cosmetics:</b> Introduction to cosmetics, Formulation and preparation of: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.	10
<b>Total</b>		<b>60</b>

#### **Learning Resources/Recommended Texts/Reference books/web resources**

##### **Text books**

1. Lachman L, Lieberman HA, Kanig JL. Theory & Practice of Industrial pharmacy. 3<sup>rd</sup> ed. Philadelphia: Lea & Febieger; 1990.
2. Allen LV, Popovich NG, Ansel HC. Pharmaceutical dosage forms and drug delivery systems. 8<sup>th</sup>ed. Lippincott Williams & Wilkins; 2005.
3. Aulton Pharmaceutics ME. The science of dosage form design. 2<sup>nd</sup> ed. Churchill Livingstone; 2002.
4. Mithal B.M. A text book of pharmaceutical formulations. 6<sup>th</sup>ed. Delhi: vallabh prakashan; 2010.
5. Mithal BM , Saha RN. A hand book of cosmetics. 1<sup>st</sup>ed. Delhi: vallabhprakashan; 2004.
6. Lippincott Williams, Wilkin Remington. The science and practice of pharmacy. 21<sup>st</sup> ed. New Delhi: Wolterskluwer Health Pvt ltd; 2006.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>V</b>
<b>Name of the course</b>	<b>Pharmacology- II (Theory)</b>
<b>Course Code</b>	<b>BP503T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** This course aimed to provide knowledge on mechanism of action, adverse effects, drug interactions, contraindications and therapeutic uses of drugs acting on cardiovascular system, hematopoietic system, renal system, Endocrine system. This course also describes about pharmacological actions of autacoids and their antagonists.

**Course Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Recall the mechanism of drug action and its relevance in the treatment of different diseases

CO2: Explain the pharmacology of drugs used in hormonal disorders

CO3: Describe the various bioassay methods used to estimate the potency of drugs

**Course Content:**

<b>Unit</b>	<b>Contents</b>	<b>Hours</b>
<b>I</b>	<b>Pharmacology of drugs acting on cardio vascular system</b> Drugs used in congestive heart failure Anti-hypertensive drugs. Anti-anginal drugs. Anti-arrhythmic drugs. Anti-hyperlipidemic drugs	<b>12</b>
<b>II</b>	<b>Pharmacology of drugs acting on cardio vascular system</b> Drug used in the therapy of shock. Hematinics, coagulants and anticoagulants. Fibrinolytics and anti-platelet drugs Plasma volume expanders <b>Pharmacology of drugs acting on urinary system</b> Diuretics	<b>12</b>

	Anti-diuretics.	
III	<b>Autocoids and related drugs</b> Introduction to autocoids and classification Histamine, 5-HT and their antagonists. Prostaglandins, Thromboxanes and Leukotrienes. Angiotensin, Bradykinin and Substance P. Non-steroidal anti-inflammatory agents Anti-gout drugs Antirheumatic drugs	12
IV	<b>Pharmacology of drugs acting on endocrine system</b> Basic concepts in endocrine pharmacology. Anterior Pituitary hormones- analogues and their inhibitors. Thyroid hormones- analogues and their inhibitors. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D. Insulin, Oral Hypoglycemic agents and glucagon. ACTH and corticosteroids.	12
V	<b>Pharmacology of drugs acting on endocrine system</b> Androgens and Anabolic steroids. Estrogens, progesterone and oral contraceptives. Drugs acting on the uterus. <b>Bioassay</b> a. Principles and applications of bioassay. b. Types of bioassay c. Bioassay of insulin, ACTH, d-tubocurarine, digitalis	12
<b>Total</b>		<b>60</b>

### **Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
6. K.D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>V</b>
<b>Name of the course</b>	<b>Pharmacognosy and Phytochemistry II</b>
<b>Course Code</b>	<b>BP504T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Pharmacognosy and Phytochemistry II course is aimed to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. This subject involves the study of pharmacognosy of alkaloids, glycosides, Iridoids, Other terpenoids & Naphthoquinones and industrial production, identification and analysis of important phytoconstituents. The subject involves in imparting knowledge on basic phytochemical aspects.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO1: Underline the importance of biogenesis

CO2: Translates pharmacognosy of alkaloids, glycosides, Iridoids, Other terpenoids & Naphthoquinones.

CO3: Illustrate industrial production, identification and analysis of important phytoconstituents.

CO4: Locate knowledge on basic phytochemical aspects.

#### **Course Contents**

<b>UNIT</b>	<b>Contents</b>	<b>Hours</b>
<b>I</b>	<b>Metabolic pathways in higher plants and their determination:</b> Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways. Study of utilization of radioactive isotopes in the investigation of Biogenetic studies. Biosynthesis of alkaloids, biosynthesis of glycosides.	10
<b>II</b>	General introduction, classification, chemistry, chemical tests, of following categories of chemical constituents. <b>Biological source, chemical constituents, therapeutic uses of</b>	20



	<p><b>crude drugs under following categories.</b></p> <p><b>Alkaloids:</b> Vinca, Rauwolfia, Belladonna, Opium.</p> <p><b>Glycosides:</b> Senna, Aloes, Bitter Almond.</p> <p><b>Volatile oils:</b> Mentha, Clove, Cinnamon, Fennel, Coriander,</p> <p><b>Tannins:</b> Catechu, Pterocarpus0.</p> <p><b>Resins:</b> Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony.</p> <p><b>Phenylpropanoids and Flavonoids:</b> Lignans, Tea, Ruta.</p> <p><b>Steroids, Cardiac Glycosides &amp; Triterpenoids:</b> Liquorice, Dioscorea, Digitalis.</p> <p><b>Iridoids, Other terpenoids &amp; Naphthaquinones:</b> Gentian, Artemisia, taxus, carotenoids</p>	
<b>III</b>	<p>Isolation, Identification and Analysis of Phytoconstituents</p> <p>a) Terpenoids: Menthol, Citral,</p> <p>b) Glycosides: Glycyrrhetic acid &amp; Rutin</p> <p>c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine</p> <p>d) Resins: Podophyllotoxin, Curcumin</p>	10
<b>IV</b>	<p>Biological source, chemistry, uses and estimation of the following phytoconstituents:</p> <p>Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine.</p>	10
<b>V</b>	<p><b>Basics of Phytochemistry:</b></p> <p>Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.</p>	10
<b>Total</b>		<b>60</b>

**Recommended Books: (Latest Editions)**

- 1.W.C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
- 2.Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
- 3.Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, NiraliPrakashan, New Delhi.
- 4.Herbal drug industry by R.D. Choudhary (1996), Ist Ed., Eastern Publisher, New Delhi.
- 5.Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
- 6.Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc., New Delhi.
- 7.A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
- 8.R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
- 9.Pharmacognosy & Pharmaco biotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>V</b>
<b>Subject</b>	<b>Pharmaceutical Jurisprudence (Theory)</b>
<b>Course Code</b>	<b>BP 505 T</b>
<b>Credits</b>	<b>04</b>
<b>Hours /week</b>	<b>3 Hours (Lectures) &amp; 1 Hour (Tutorial)</b>
<b>Pre /co-requisite(s)</b>	<b>No</b>

**Course Description** This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, Narcotic Drugs and Psychotropic substances Act, Medicinal and Toilet preparation Act etc. Besides this the new drug policy, DPCO, professional ethics, Patent and design Act etc., will be discussed.

**Course Outcomes** Upon completion of the subject student shall be able to–

CO1: Know the significance of pharmaceutical legislations in India and role of ethics in pharmacy profession.

CO2: Understand the import, export, manufacture, and sale regulations and pertaining schedules to the acts and rules.

CO2: Know and understand the administrative bodies, authorities, and officer's roles and responsibilities.

CO3: Know the constitution, functions of central, state councils, registration procedure and importance of education regulations.

CO4: Know the new drugs pricing policies, procedures and other legislations.

CO6: Know the amendments, other laws as prescribed by the central and state Councils from time to time including international laws.

## Course Content

UNIT	Contents	Hours
<b>I</b>	<p><b>Code of Pharmaceutical ethics:</b> Definition, principles and significance of ethics, Code of Pharmaceutical ethics as adopted by Pharmacy Council of India. Pharmacist's oath.</p> <p><b>The Drugs and Cosmetics Act, 1940 and Rules 1945:</b> Objectives, Definitions to the Act and Rules.</p> <p>Administration of the Act and Rules – Drugs Technical Advisory Board (DTAB), Central drugs Laboratory (CDL), Drugs Consultative Committee (DCC), Government drug analysts, licensing authorities, Controlling authorities, Drugs Inspectors.</p>	<b>10</b>
<b>II</b>	<p><b>The Drugs and Cosmetics Act, 1940 and Rules 1945:</b> General Study of Schedules to the Act and Rules and detailed study of Part XII B of Schedule F, Schedules G, H, H1, K, M, M-I, M-II, M-III, N, P, Q, T, U, V, X, Y. Import of drugs and cosmetics – Types of import license, procedure and conditions for grant of import license or permit and conditions of import license. Manufacture and sale of drugs –Types of manufacturing license, procedure and conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug. Sale of drugs – Types of sale license, procedure and conditions for sale license and conditions of sale license. Classes of drugs and cosmetics prohibited from import, manufacture and sale or distribution or exhibit for sale. Offences and penalties. Labeling and packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, Offences and penalties.</p>	<b>14</b>
<b>III</b>	<p><b>The Pharmacy Act, 1948:</b> Objectives, Definitions, Pharmacy Council of India (PCI)– constitution and functions, Education Regulations, State and Joint state pharmacy councils – constitution and functions, Registration of Pharmacists, Offences and penalties.</p> <p><b>Medicinal and Toilet Preparation Act (Excise Duties), 1955:</b></p>	<b>12</b>

	<p>Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent &amp; Proprietary Preparations. Levy and collection of duties. Offences and Penalties.</p> <p><b>Narcotic Drugs and Psychotropic substances Act, 1985 and Rules:</b> Objectives, Definitions, Authorities and Officers, Constitution and Functions of Narcotic and Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse. Prohibition, Control and Regulation of cultivation of Opium poppy, Cannabis plant, Coca plant and production of poppy straw, manufacture, sale and export of any narcotic drug and psychotropic substance. Offences and Penalties.</p>	
<b>IV</b>	<p><b>Study of Salient Features of Drugs and Magic Remedies Act, 1954 and Rules:</b> Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Schedule to the Act. Offences and Penalties.</p> <p><b>Prevention of Cruelty to animals Act-1960:</b> Objectives, Definitions, Institutional Animal Ethics Committee (IAEC), The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, offences and Penalties.</p> <p><b>National Pharmaceutical Pricing Authority (NPPA):</b> Introduction, National Pharmaceutical Pricing Policy (NPPP) -2012.</p>	<b>12</b>
<b>V</b>	<p><b>Drugs Price Control Order (DPCO)-2013:</b> Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations. Schedules to DPCO, Schedule-I: National List of Essential Medicines (NLEM).</p> <p><b>Study of Salient Features of Medical Termination of Pregnancy Act, 1971</b></p> <p><b>Right to Information Act, 2005:</b> Objectives, Definitions, right to</p>	<b>12</b>

	<p>information and obligations of public authorities, procedure in filing RTI application and supply of information, information exempted from disclosure.</p> <p><b>Intellectual Property Rights (IPR):</b> Introduction to intellectual property rights – Patents and designs, Copyright, Trademarks, Trade Secrets, Geographical indications, Plant variety rights etc.</p> <p><b>Medical Device and Diagnostics:</b> Medical Device Rules, 2017.</p>	
<b>Total</b>		<b>60</b>

#### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Mithal B.M. Text Book of Forensic Pharmacy. New Delhi: Vallabh Prakashan.
2. Kokate C.K, Gokhale S.B. Text Book of Forensic Pharmacy. Hyderabad:Pharma Book Syndicate.
3. Jain N.K. Text Book of Forensic Pharmacy. New Delhi: Vallabh Prakashan.
4. Agarwal S.P, Rajesh Khanna. Pharmaceutical Jurisprudence and Ethics. NewDelhi: Birla Publications.
5. Hand book of drug law-by M.L. Mehra.
6. Drugs and Cosmetics Act/Rules by Govt. of India publications.
7. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
8. Narcotic drugs and psychotropic substances act by Govt. of India publications.
9. Drugs and Magic Remedies act by Govt. of India publication.
10. B. S. Kuchekar. Forensic Pharmacy. Pune: Nirali Prakashan.
11. <https://www.indiacode.nic.in/> (It is a database of all Central enactments which are in force and their subordinate legislations made from time to time. It also contains Legislations enacted by the States and Union Territory Administrations along with their relevant subordinate legislations)

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>V</b>
<b>Name of the course</b>	<b>Industrial Pharmacy I (Practical)</b>
<b>Course Code</b>	<b>BP 506P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Industrial Pharmacy I laboratory course is aimed to train the students on experimental techniques for the preparation of pharmaceutical dosage forms like tablets, injections and ophthalmics. This course also deals with various quality control tests to be performed on tablets and capsules. This course also provides the laboratory skills related to formulation of cosmetic preparations like creams.

**Course Learning Outcomes:**

**Upon successful completion of this course, the student should be able to:**

CO1 Demonstrate the skills in handling of different Equipments.

CO2 Formulate different types of tablets, injections and ophthalmics.

CO3 Evaluate the tests on tablets and capsules.

<b>Week</b>	<b>Topics</b>
1	Pre-formulation studies on Paracetamol/Aspirin/or any other drug
2	Preparation and evaluation of Paracetamol tablets
3	Preparation and evaluation of Aspirin tablets
4	Coating of tablets- film coating of tablets/granules
5	Preparation and evaluation of Tetracycline capsules
6	Preparation of Calcium Gluconate injection
7	Preparation of Ascorbic Acid injection
8	Quality control test of (as per IP) marketed tablets and capsules
9	Preparation of Eye drops/ and Eye ointments
10	Preparation of Creams (cold / vanishing cream)
11	Evaluation of Glass containers (as per IP)

## **Learning Resources/Recommended Texts/Reference books/web resources**

### **Text books**

1. Lachman L, Lieberman HA, Kanig JL. Theory & Practice of industrial pharmacy. 3rded. Philadelphia: Lea & Febieger; 1990.
2. Allen LV, Popovich NG, Ansel HC. Pharmaceutical dosage forms and drug delivery systems. 8<sup>th</sup> ed. Lippincott Williams & Wilkins; 2005.
3. Aulton Pharmaceutics ME. The science of dosage form design. 2<sup>nd</sup>ed. Churchill Livingstone; 2002.
4. Mithal B.M. A text book of pharmaceutical formulations. 6thed. Delhi: vallabh prakashan; 2010.
5. MithalBM , Saha RN. A hand book of cosmetics. Isted. Delhi: vallabh prakashan; 2004.
6. Lippincott Williams, Wilkin Remington. The science and practice of pharmacy. 21<sup>st</sup> ed. New delhi: Wolterskluwer Health pvt ltd; 2006.



<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>V</b>
<b>Name of the course</b>	<b>Pharmacology – II (Practical)</b>
<b>Course Code</b>	<b>BP 507 P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4hrs (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** This course aimed to provide skill for the students on various aspects of bioassay experiments. This course also provides an idea about the calculations of pA<sub>2</sub> value for antagonists. This course also expertises the students on drug screening methods by using intact animals.

#### **Course Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate Bioassays of drugs on isolation isolated organ or tissue preparation by simulated experiments

CO2: Calculate the pA<sub>2</sub> value of Different antagonists by using suitable organ or tissue preparation.

CO 3: Perform the Experiments on intact animals related to screening of analgesic and anti-inflammatory agents

#### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Introduction to <i>in-vitro</i> pharmacology and physiological salt solutions.
2	Effect of drugs on isolated frog heart
3	Effect of drugs on blood pressure and heart rate of dog.
4	Study of diuretic activity of drugs using rats/mice.
5	DRC of acetylcholine using frog rectus abdominis muscle.
6	Effect of physostigmine and atropine on DRC of acetylcholine using frog
7	rectus abdominis muscle and rat ileum respectively.
8	Bioassay of histamine using guinea pig ileum by matching method.
9	Bioassay of oxytocin using rat uterine horn by interpolation method.
10	Bioassay of serotonin using rat fundus strip by three-point bioassay.

11	Bioassay of acetylcholine using rat ileum/colon by four-point bioassay.
12	Determination of PA <sub>2</sub> value of prazosin using rat anococcygeus muscle (by Schilds plot method).
13	
14	Determination of PD <sub>2</sub> value using guinea pig ileum/rat ileum/chick ileum. Effect of seasons and spasmolytics using rabbit jejunum/ rat ileum/chick ileum.
15	Anti-inflammatory activity of drugs using carrageenan induced paw-edema model. Analgesic activity of drug using central and peripheral methods

*Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by software's and videos*

### **Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>V</b>
<b>Name of the course</b>	<b>Pharmacognosy and Phytochemistry II (Practical)</b>
<b>Course Code</b>	<b>BP508P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Pharmacognosy and Phytochemistry II laboratory course is aimed to train the students on Morphological, histology and powder characteristics, extraction & detection of crude drugs. The subject refers to isolation & detection of active principles. This course also emphasis on analysis of crude drugs by chemical tests and chromatographic methods.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate the skills on Morphology, histology and powder characteristics & extraction & detection of crude drugs

CO 2: Illustrate isolation & detection of active principles.

CO 3. Analysis of crude drugs by chemical tests and chromatographic methods.

#### **Practical Course: Contents**

<b>S. No.</b>	<b>Topic</b>
1.	Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2.	Exercise involving isolation & detection of active principles Caffeine - from tea dust.
3.	Diosgenin from Dioscorea
4.	Atropine from Belladonna
5.	Sennosides from Senna
6.	Separation of sugars by Paper chromatography
7.	TLC of herbal extract
8.	Distillation of volatile oils and detection of phytoconstituents by TLC
9.	Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii)

**Recommended Books: (Latest Editions)**

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Ed., Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc., New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

<b>Program</b>	<b>B. Pharm</b>
<b>Year /Semester</b>	<b>V</b>
<b>Name of the course</b>	<b>Pharma Marketing Management</b>
<b>Course Code</b>	<b>BP509ET</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 hours (Lectures) &amp; 1 hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO1: Understand marketing concepts and techniques.

CO2: Apply marketing management concepts in the pharmaceutical industry.

CO3: Apply pricing techniques over any proposed product.

CO4: Analyse business scenarios in an integrative way

CO5: Craft alternative strategies to address complex business-related situations as well as evaluate the pros and cons of those alternatives.

#### **Theory Course: Contents**

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I (3 Weeks)</b>	<b>Marketing:</b> Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior. <b>Pharmaceutical market:</b> Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation&	<b>12</b>

	targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.	
<b>II</b> <b>(3 Weeks)</b>	<b>Product decision:</b> Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.	<b>12</b>
<b>III</b> <b>(3 Weeks)</b>	<b>Promotion:</b> Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.	<b>12</b>
<b>IV</b> <b>(3 Weeks)</b>	<b>Pharmaceutical marketing channels:</b> Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management. <b>Professional sales representative (PSR):</b> Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.	<b>12</b>
<b>V</b> <b>(3 Weeks)</b>	<b>Pricing:</b> Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority). <b>Emerging concepts in marketing:</b> Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.	<b>12</b>
	<b>Total</b>	<b>60</b>

### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi.
2. Walker, Boyd and Larreche: Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill.
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India.
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition).
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt: Global Perspective, IndianContext, Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi.
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.
9. Smarta RB. Strategic Pharma Marketing. India: A.H. Wheeler Publishing Co Ltd; 1996. ISBN-10: 8185814996, ISBN-13: 9788185814995
10. Vidyasagar G. Pharmaceutical Industrial Management. India: Pharma book syndicate; 2005. ISBN-10: 8188449121, ISBN-13: 978-8188449125
11. Subbarao C. Pharmaceutal Marketing in India – Concepts and Strategy Cases. Hyderabad: Pharma Book Syndicate; 2007. ISBN 10: 8188449253 ISBN 13: 9788188449255.
12. Khanna OP. Industrial engineering and management. New Delhi: Dhanpat Rai Publishing Company; 2010. ISBN-10: 818992835X, ISBN-13: 9788189928353.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>V</b>
<b>Name of the course</b>	<b>Health Care and Dietary Supplements</b>
<b>Course Code</b>	<b>BP510ET</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 hours (Lectures) &amp; 1 hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

**Course Learning Outcomes:**

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

CO1: Understand the need of supplements by the different group of people to maintain Healthy life.

CO2: Understand the outcome of deficiencies in dietary supplements.

CO3: Appreciate the components in dietary supplements and the application.

CO4: Appreciate the regulatory and commercial aspects of dietary supplements Including health claims.

**Theory Course: Contents**

<b>UNIT</b>	<b>Topic</b>	<b>Hours</b>
<b>I</b>	<b>Definitions of Functional foods,</b> Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as Spirulina,	15



	<p>foods; Nutraceuticals /functional</p> <p>Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds.</p>	
<b>II</b>	<p><b>Phytochemicals as nutraceuticals:</b> Occurrence and characteristic features (chemical nature medicinal benefits) of following</p> <p>Carotenoids- <math>\alpha</math> and <math>\beta</math>-Carotene, Lycopene, Xanthophylls, leutin , Sulfides: Diallyl sulfides, Allyltrisulfide.</p> <p>Polyphenolics: Resveratrol</p> <p>Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones.</p> <p>Prebiotics/ Probiotics: Fructo oligosaccharides, Lacto bacillum</p> <p>Phyto estrogens : Isoflavones, daidzein, Geobustan, lignans</p> <p>Tocopherols, Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.</p>	15
<b>III</b>	<p><b>Introduction to free radicals:</b> Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.</p> <p>Dietary fibres and complex carbohydrates as functional food ingredients</p>	10
<b>IV</b>	<p>Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.</p> <p>Antioxidants: Endogenous antioxidants – enzymatic and non-enzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, <math>\alpha</math>-Lipoic acid, melatonin.</p>	10

	Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole. Functional foods for chronic disease prevention.	
<b>V</b>	Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals. Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods. Pharmacopeial Specifications for dietary supplements and nutraceuticals.	10
<b>Total</b>		<b>60</b>

### **Recommended Books: (Latest Editions)**

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K.T Agustian and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2<sup>nd</sup> Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors 2000 *Functional foods* Wood head Publ.Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition) Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger.

<b>Program</b>	<b>B. Pharm</b>
<b>Year/Semester</b>	<b>V Semester</b>
<b>Name of the course</b>	<b>Entrepreneurship Development</b>
<b>Course Code</b>	<b>BP511ET</b>
<b>Credits</b>	<b>4</b>
<b>Hours + Tutorial/week</b>	<b>3 hours (Lectures) &amp; 1 hour (Tutorial)</b>
<b>Pre/Co-requisite/s</b>	<b>Nil</b>

### **Course description**

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

### **Course outcomes**

On completion of this course, it is expected that students will be able to understand,

CO 1: The Role of enterprise in national and global economy

CO 2: Dynamics of motivation and concepts of entrepreneurship

CO 3: Demands and challenges of Growth Strategies and Networking

### **Course contents**

<b>Unit</b>	<b>Topic</b>	<b>Hours</b>
<b>1</b>	Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management	<b>12</b>
<b>2</b>	Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency –Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.	<b>12</b>
<b>3</b>	Launching and Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT	<b>12</b>

	Analysis. Resource mobilization - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.	
<b>4</b>	Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study	<b>12</b>
<b>5</b>	Preparing project proposal to start on new enterprise project work – Feasibility report; Planning, resource mobilization and implementation.	<b>12</b>
<b>Total</b>		<b>60</b>

#### References

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VI</b>
<b>Name of the course</b>	<b>Medicinal Chemistry III– Theory</b>
<b>Course Code</b>	<b>BP 601T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course description:** This subject designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

**Course Outcomes:** Upon completion of the course, student shall be able to

**CO 1:** Understand the importance of drug design and different techniques of drug design.

**CO 2:** Illustrate the chemistry of drugs with respect to their biological activity.

**CO 3:** Know the importance of SAR, metabolism, adverse effects and therapeutic value of drugs.

### Course Content

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<i>Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)</i>		
<b>I</b> <b>(3 Weeks)</b>	<b>Antibiotics</b> Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. <b>β- Lactam antibiotics:</b> Penicillin, Cephalosporins, β- Lactamase inhibitors, Monobactams	<b>12</b>
	<b>Aminoglycosides:</b> Streptomycin, Neomycin, Kanamycin	

	<b>Tetracyclines:</b> Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline	
<b>II</b> (3 Weeks)	<b>Antibiotics</b> Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. <b>Macrolide:</b> Erythromycin Clarithromycin, Azithromycin. <b>Miscellaneous:</b> Chloramphenicol*, Clindamycin.	<b>12</b>
	<b>Prodrugs:</b> Basic concepts and application of prodrugs design.	
	<b>Antimalarials:</b> Etiology of malaria. <b>Quinolines:</b> SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine. <b>Biguanides and dihydro triazines:</b> Cycloguanil pamoate, Proguanil. <b>Miscellaneous:</b> Pyrimethamine, Artesunate, Artemether, Atovaquone.	
<b>III</b> (3 Weeks)	<b>Anti-tubercular Agents</b> <b>Synthetic antitubercular agents:</b> Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.* <b>Anti-tubercular antibiotics:</b> Rifampicin, Rifabutin, Cycloserine Streptomycin, Capreomycin sulphate.	<b>12</b>
	<b>Urinary tract anti-infective agents</b> <b>Quinolones:</b> SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin <b>Miscellaneous:</b> Furazolidine, Nitrofurantoin*, Methanamine.	
	<b>Antiviral agents:</b> Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.	

<b>IV</b> <b>(3 Weeks)</b>	<p><b>Antifungal agents:</b></p> <p><b>Antifungal antibiotics:</b> Amphotericin-B, Nystatin, Natamycin, Griseofulvin.</p> <p><b>Synthetic Antifungal agents:</b> Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.</p>	<b>12</b>
	<p><b>Anti-protozoal Agents:</b> Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine. <b>Anthelmintics:</b> Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.</p>	
	<p><b>Sulphonamides and Sulfones</b></p> <p>Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.</p> <p><b>Folate reductase inhibitors:</b> Trimethoprim*, Cotrimoxazole.</p> <p><b>Sulfones:</b> Dapsone*.</p>	
<b>V</b> <b>(3 Weeks)</b>	<p><b>Introduction to Drug Design</b></p> <p>Various approaches used in drug design.</p> <p>Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter.</p>	<b>12</b>
	<p>Taft's steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques.</p>	
	<p><b>Combinatorial Chemistry:</b> Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.</p>	
<b>TOTAL</b>		<b>60</b>

**Learning Resources/Recommended Texts/Reference books/web resources**

1. William O. Foye, Textbook of Medicinal Chemistry, Lea Febiger, Philadelphia.

2. Graham. L. Patrick, an Introduction to Medicinal Chemistry, Oxford University publishers.
3. JH Block & JM Beale (Eds), Wilson& Griswold's textbook of organic Medicinal Chemistry and pharmaceutical chemistry, 11th Ed, Lipcolt, Raven, Philadelphia, 2004.
4. Rama Rao Nadendla, Medicinal Chemistry, Mc Millan Publishers.
5. Hansch, Comprehensive medicinal chemistry, Vol 1 – 6 Elsevier pergmon press, Oxford.
6. D. Abraham (Ed), Burger Medicinal chemistry and Drug discovery, Vol. 1 & 2, 6<sup>th</sup>Ed, John Wiley & Sons, New York 2003.
7. M. Atherden, Bentley and Driver's Textbook of Pharmaceutical Chemistry Ed: 1. Oxford University Press, Delhi.
8. Daniel lednicer, Strategies for Organic Drug Synthesis and Design, John Wiley, N. Y. 1998.
9. D. Lednicer, Organic drug synthesis, Vol, 1 – 6, J. Wiley N.Y.



<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VI</b>
<b>Name of the course</b>	<b>Pharmacology- III (Theory)</b>
<b>Course Code</b>	<b>BP602 T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** This course aimed to provide knowledge on pharmacological aspects like mechanism of action, pharmacokinetics, side effects, drug interactions, contraindications and indications of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chrono pharmacology

**Course Outcomes:** Upon successful completion of this course, the student should be able to:

CO1: Illustrates the general principles of chemotherapy

CO2: Apply the knowledge of chemotherapeutic agents for the management of infectious diseases

CO3: Describe the principles of animal toxicology and human toxicology

CO4: Explain the principles of chrono pharmacology in optimization of drug therapy

#### **Theory Course: Contents**

<b>Unit</b>	<b>Contents</b>	<b>Hours</b>
<b>I</b>	<b>Pharmacology of drugs acting on Respiratory system</b> Anti -asthmatic drugs Drugs used in the management of COPD Expectorants and antitussives Nasal decongestants Respiratory stimulants <b>Pharmacology of drugs acting on the Gastrointestinal Tract</b> Antiulcer agents. Drugs for constipation and diarrhea. Appetite stimulants and suppressants. Digestants and carminatives. Emetics and anti-emetics.	<b>12</b>

II	<b>Chemotherapy</b> a. General principles of chemotherapy. b. Sulfonamides and cotrimoxazole. c. Antibiotics: Penicillin's, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolones, tetracycline and aminoglycosides	12
III	<b>Chemotherapy</b> Antitubercular agents Antileprotic agents Anti-fungal agents Antiviral drugs Anthelmintics Antimalarial drugs Antiamoebic agents	12
IV	<b>Chemotherapy</b> Urinary tract infections and sexually transmitted diseases. Chemotherapy of malignancy. <b>Immunopharmacology</b> Immunostimulants Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars	12
V	<b>Principles of toxicology</b> Definition and basic knowledge of acute, subacute and chronic toxicity. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity General principles of treatment of poisoning Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.	12

	<b>Chrono pharmacology</b> Definition of rhythm and cycles. Biological clock and their significance leading to chronotherapy.	
	<b>Total</b>	<b>60</b>

**Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udapa and P.D. Gupta, Concepts in Chronopharmacology.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VI</b>
<b>Name of the course</b>	<b>Herbal Drug Technology (Theory)</b>
<b>Course Code</b>	<b>BP 603 T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, Nutraceuticals etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

**Course Learning Outcomes:** Upon completion of this course the student should be able to:

CO1: Understand raw material as source of herbal drugs from cultivation to herbal drug product

CO2: Know the WHO and ICH guidelines for evaluation of herbal drugs

CO3: Know the herbal cosmetics, natural sweeteners, Nutraceuticals

CO4: Appreciate patenting of herbal drugs, GMP.

#### **Theory Course: Contents**

<b>UNIT</b>	<b>Topic</b>	<b>Hours</b>
<b>I</b>	<b>Herbs as raw materials</b> Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs, Selection, identification and authentication of herbal materials Processing of herbal raw material <b>Biodynamic Agriculture</b> Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Bio pesticides/ Bio insecticides. <b>Indian Systems of Medicine</b> Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma	12
<b>II</b>	<b>Nutraceuticals</b> General aspects, Market, growth, scope and types of products	12

	<p>available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.</p> <p>Study of following herbs as health food: Alfalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina</p> <p><b>Herbal-Drug and Herb-Food Interactions:</b> General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypericum, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper &amp; Ephedra.</p>	
<b>III</b>	<p><b>Herbal Cosmetics</b></p> <p>Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colors, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.</p> <p><b>Herbal excipients:</b> Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors &amp; perfumes.</p> <p><b>Herbal formulations:</b> Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like Phytosomes</p>	12
<b>IV</b>	<p><b>Evaluation of Drugs</b> WHO &amp; ICH guidelines for the assessment of herbal drugs</p> <p>Stability testing of herbal drugs.</p> <p><b>Patenting and Regulatory requirements of natural products:</b></p> <p>Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma.</p> <p><b>Regulatory Issues</b> - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs &amp; Cosmetics Act for ASU drugs.</p>	12
<b>V</b>	<p><b>General Introduction to Herbal Industry</b></p> <p>Herbal drugs industry: Present scope and future prospects.</p>	12

	<p>A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.</p> <p><b>Schedule T–Good Manufacturing Practice of Indian systems of medicine:</b> Components of GMP (Schedule – T) and its objectives</p> <p>Infrastructural requirements, working space, storage area, machinery and equipment's, standard operating procedures, health and hygiene, documentation and records.</p>	
<b>Total</b>		60

**Recommended Books: (Latest Editions)**

1. W.C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), IstEdn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr. SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Pharmacognosy & Phytochemistry by V.D.Rangari
10. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
11. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
12. Pragi A, Varun A. A text book of Herbal Drug Technology
13. Satya S, Jaiganesh KP, Sudha P. Current trends in Herbal Drug Technology.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VI</b>
<b>Name of the course</b>	<b>Biopharmaceutics and Pharmacokinetics</b>
<b>Course Code</b>	<b>BP 604T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arising.

### Course outcome

At the end of the theory course, the student will be able to

- C704.1 Understand the concepts of Absorption, Distribution, Metabolism and Elimination of Drugs
- C704.2 Estimate various pharmacokinetic parameters of drugs following various compartment models with different routes of administration.
- C704.3 Understand the concepts of Design of Dosage Regimen
- C704.4 Demonstrate the understanding of Bioavailability and Bioequivalence

### Course Content

<b>Unit</b>	<b>Contents</b>	<b>Hours</b>
<b>I.</b>	<p><b>Introduction to Biopharmaceutics</b></p> <p><b>Absorption:</b> Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes,</p> <p><b>Distribution:</b> Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, <b>Protein binding of drugs:</b> plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drug</p>	12

<b>II.</b>	<p><b>Elimination:</b> Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Nonrenal routes of drug excretion of drugs</p> <p><b>Bioavailability and Bioequivalence:</b> Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, <i>in-vitro</i> drug dissolution models, <i>in-vitro-in-vivo</i> correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs</p>	12
<b>III.</b>	<p><b>Pharmacokinetics:</b></p> <p>Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a) Intravenous Injection (Bolus) (b) Intravenous infusion and (c) Extra vascular administrations.</p> <p><b>Pharmacokinetics parameters-</b> <math>K_E</math>, <math>t_{1/2}</math>, <math>V_d</math>, AUC, <math>K_a</math>, <math>Cl_T</math> and <math>CL_R</math>-definitions methods of eliminations, understanding of their significance and application</p>	12
<b>IV.</b>	<p><b>Multi compartment models:</b> Two compartment open model. IV bolus</p> <p><b>Dosage Regimens: Approaches to Design of Dosage Regimen:</b> Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.</p>	12
<b>V.</b>	<p><b>Nonlinear Pharmacokinetics:</b> a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.</p>	12
<b>Total</b>		60

#### Recommended reference Books

- 1 . Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- 2 . Biopharmaceutics and Pharmacokinetics; By Robert F Notari



3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU4thedition,Prentice-Hall Internationaledition.USA
4. Biopharmaceutics and Pharmacokinetics-A Treatise, By D.M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics:By MiloGlbaldi Donald, R. Mercel DekkerInc.
6. HandBook of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N.Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
11. BiopharmaceuticsandClinicalPharmacokinetics-Anintroduction4thedition Revised and expanded by Rebot F Notari Marcel Dekker Inn, New York and Basel,1987
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VI</b>
<b>Name of the course</b>	<b>Pharmaceutical Biotechnology-Theory</b>
<b>Course Code</b>	<b>BP605T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 hours (lectures) &amp; 1hour (Tutorial)</b>

**Course Description:** This course is dealing with the basic techniques of fermentation technology, rDNA technology, Enzyme immobilization, biotechnological based. This course will focus on the new developments in the production of biopharmaceuticals by rDNA technology and monoclonal antibodies.

**Course Learning Outcomes:** Upon completion of the subject student shall be able to;

CO 1: Compare the knowledge of interlinks of pharmaceutical sciences, with biotechnology by using living organisms, their products applying rDNA technology and immobilized enzymes in Pharmaceutical Industries

CO2: Expertise their skills for biotechnology concepts, tools and genetic engineering techniques.

CO3: Genetic engineering applications in relation to production of pharmaceuticals and vaccines.

CO4: Importance of Monoclonal antibodies in Industries.

CO5: Appreciate the use of microorganisms in fermentation technology.

#### **Course Contents**

<b>Unit</b>	<b>Contents</b>	<b>Hours</b>
I	Brief introduction to Biotechnology with reference to Pharmaceutical Sciences. Enzyme Biotechnology- Methods of enzyme immobilization and applications. Biosensors- Working and applications of biosensors in Pharmaceutical Industries. Brief introduction to Protein Engineering. Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. Basic principles of genetic engineering.	12
II	Study of cloning vectors, restriction endonucleases and DNA ligase. Recombinant DNA technology. Application of genetic engineering in medicine.	12

	Application of r DNA technology and genetic engineering in the production of: Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin. Brief introduction to PCR.	
III	Types of immunity- humoral immunity, cellular immunity Structure of Immunoglobulins, Structure and Function of MHC Hypersensitivity reactions, Immune stimulation and Immune suppressions. General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity. Storage conditions and stability of official vaccines Hybridoma technology- Production, Purification and Applications. Blood products and Plasma Substitutes.	12
IV	Immuno blotting techniques- ELISA, Western blotting, Southern blotting. Genetic organization of Eukaryotes and Prokaryotes. Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. Introduction to Microbial biotransformation and applications. Mutation: Types of mutation/mutants.	12
V	Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. Large scale production fermenter design and its various controls. Study of the production of - penicillin's, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.	12
<b>Total</b>		<b>60</b>

**Recommended Books (Latest edition):**

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldsby et. al.: Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal

Society of Chemistry.

5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.

6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific.

Publication

7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2<sup>nd</sup> edition, Aditya books Ltd., New Delhi.

8. Vyas SP, DixitVK. Pharmaceutical Biotechnology, 1<sup>st</sup>ed. India: CBS Publishers.

9. PrescottSC, DunnCG. Industrial Microbiology, 1<sup>st</sup>ed. UK: Mc.Graww Hill.

10. Kokate, Jalalpure, Hurakadle : Pharmaceutical Biotechnology, Elsevier India.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VI</b>
<b>Name of the course</b>	<b>Biostatistics and Research Methodology</b>
<b>Course Code</b>	<b>BP606T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 hours (Lecture)+ 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This course helps the students to understand the applications of Biostatistics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non-Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO1: Define Basics concepts of Statistics

CO2: Recognize types of clinical studies, types of data distribution, data graphics and statistical applications in Pharmacy.

CO3: Formulate parametric tests and non-parametric tests.

CO4: Able to the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)

#### **Theory Course: Contents**

<b>Unit</b>	<b>Topics</b>	<b>No. of hours</b>
<b>I</b>	<b>Introduction:</b> Statistics, Biostatistics, Frequency distribution <b>Measures of central tendency:</b> Mean, Median, Mode- Pharmaceutical examples <b>Measures of dispersion:</b> Dispersion, Range, standard deviation, Pharmaceutical problems <b>Correlation:</b> Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples	<b>13</b>
<b>II</b>	<b>Regression:</b> Curve fitting by the method of least squares, fitting the	

	<p>lines <math>y = a + bx</math> and <math>x = a + by</math>, Multiple regression, standard error of regression– Pharmaceutical Examples</p> <p><b>Probability:</b> Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties – problems</p> <p>Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples</p> <p><b>Parametric test:</b> t-test (Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference</p>	<b>13</b>
<b>III</b>	<p><b>Non-Parametric tests:</b> Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test</p> <p><b>Introduction to Research:</b> Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism</p> <p><b>Graphs:</b> Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph</p> <p><b>Designing the methodology:</b> Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.</p>	<b>13</b>
<b>IV</b>	<p>Blocking and confounding system for Two-level factorials</p> <p><b>Regression modeling:</b> Hypothesis testing in Simple and Multiple regression models</p> <p><b>Introduction to Practical components of Industrial and Clinical Trials Problems:</b> Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach</p>	<b>11</b>
<b>V</b>	<p><b>Design and Analysis of experiments:</b></p> <p><b>Factorial Design:</b> Definition, <math>2^2</math>, <math>2^3</math> design.</p>	<b>10</b>

	Advantage of factorial design <b>Response Surface methodology:</b> Central composite design, Historical design, Optimization Techniques	
	<b>Total</b>	<b>60</b>

**Learning Resources/Recommended Texts/Reference books/web resources**

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha.
3. Design and Analysis of Experiments –PHI Learning Private Limited, R.Pannerselvam.
4. Design and Analysis of Experiments –Wiley Students Edition, Douglas and C. Montgomery.
5. Text book of Statistical Methods and Computer applications by Dr. Ramakrishna Prasad.
6. Fundamentals of Biostatistics by Khan and Khanum.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VI</b>
<b>Name of the course</b>	<b>Medicinal Chemistry III – Practical</b>
<b>Course Code</b>	<b>BP 607P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** Medicinal Chemistry - III laboratory course aimed to train the students in chemical synthesis and purification process for few medicinal compounds. This course also provides the laboratory skills related to identification of impurities and percentage purity present in drug substances as per IP procedures.

**Course Outcomes:** Upon successful completion of this course, the student should be able to:

**CO 1:** Demonstrate the skills in synthesis of various medicinal compounds and intermediates.

**CO 2:** Perform quantitative estimations to determine the purity of drug substances.

**CO 3:** Know the physicochemical properties of drugs and Lipinski rule by *Insilico* drug design software.

<b>Week</b>	<b>TOPICS</b>
<b>I. Preparation of drugs and intermediates</b>	
1	Sulphanilamide
2	7-Hydroxy-4-methyl coumarin
3	Chlorobutanol
4	<b>Chalcone</b>
5	<b>Diazoamino benzene from aniline</b>
6	Hexamine
<b>II. Assay of drugs</b>	
7	Isonicotinic acid hydrazide
8	Chloroquine
9	<b>Albendazole</b>
10	Dapsone
11	Chlorpheniramine maleate



12	<b>Lactic acid/Acetazolamide</b>
13, 14	<b>III.</b> Preparation of medicinally important compounds or intermediates by Microwave irradiation technique
15, 16	<b>IV. Drawing structures and reactions using Chem Draw®</b> Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinski's RO5)

**Learning Resources/Recommended Texts/Reference books/web resources**

1. Vogel A. L. Vogel's Textbook of Practical Organic Chemistry, 5th ed. Pearson Prentice Hall: Dorling. Kindersley (India) Pvt, Ltd; 2007.
2. Mann F. G. & Saunders B. C. Practical Organic Chemistry, 4th ed.: Pearson Publishers; 2007.
3. Indian pharmacopoeia 2007/2010.
4. Burger's Medicinal Chemistry, Vol I to IV.
5. Introduction to principles of drug design- Smith and Williams.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VI</b>
<b>Name of the course</b>	<b>Pharmacology – III (Lab)</b>
<b>Course Code</b>	<b>BP 608 P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** The pharmacology laboratory course is aimed to skilled the students to perform the various toxicity tests according to respective guidelines. And also, expertise the students on biostatistics used in experimental pharmacology.

#### **Course Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Estimate the serum biochemical parameters by using semi-auto analyzer

CO2: Find out the LD50 of given compounds

CO 3: Apply the various Biostatistics methods in experimental pharmacology

#### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Dose calculation in pharmacological experiments
2	Anti-allergic activity by mast cell stabilization assay
3	Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4	Study of Antidiarrheal activity of drugs
5	Study of anti-helminthic activity
6	Estimation of serum biochemical parameters by using semi- autoanalyzer
7	Study of antioxidant activity ( <i>Invitro/ In vivo</i> ) Study of antidiabetic activity ( <i>In vitro/ In vivo</i> )
8	Test for pyrogens (rabbit method)
9	Determination of acute oral toxicity (LD50) of a drug from a given data
10	Determination of acute skin irritation / corrosion of a test substance

11	Determination of acute eye irritation / corrosion of a test substance
12	Calculation of pharmacokinetic parameters from a given data
13	Biostatistics methods in experimental pharmacology (student's t test, ANOVA).
14	Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

*\*Experiments are demonstrated by simulated experiments/videos*

### **Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VI</b>
<b>Name of the course</b>	<b>HERBAL DRUG TECHNOLOGY (Practical)</b>
<b>Course Code</b>	<b>BP 609 P</b>
<b>Credits</b>	<b>2</b>
<b>Hours /week</b>	<b>4 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** Herbal drug technology laboratory course is aimed to train the students regarding laboratory skills by preliminary phytochemical screening of crude drugs. This course also deals with laboratory-based experiments on preparation and evaluation herbal formulation.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Learn preliminary phytochemical screening of crude drugs.

CO 2: Illustrate cosmeceutical formulation and their evaluation.

CO3: Analysis herbal pharmaceutical formulations

#### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	To perform preliminary phytochemical screening of crude drugs.
2	Determination of the alcohol content of Asava and Arista
3	Evaluation of excipients of natural origin
4	Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5	Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopeial requirements.
6	Monograph analysis of herbal drugs from recent Pharmacopoeias
7	Determination of Aldehyde content
8	Determination of Phenol content
9	Determination of total alkaloids

#### **Recommended Books: (Latest Editions)**

1. W.C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.

2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), IstEdn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr. SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Pharmacognosy & Phytochemistry by V.D.Rangari
10. Pharmacopeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
11. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VII</b>
<b>Name of the course</b>	<b>Instrumental methods of analysis (Theory)</b>
<b>Course Code</b>	<b>BP701T</b>
<b>Credits</b>	<b>4</b>
<b>Hours/week</b>	<b>3 hours (lectures) + 1 (Tutorial)</b>
<b>Pre/co-requisite/s</b>	<b>Nil</b>

### Course Description

This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

**Course Learning Outcomes:** Upon completion of the course the student shall be able to

CO1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis

CO2. Understand the chromatographic separation and analysis of drugs.

CO3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

### Course content:

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I</b>	<p><b>UV Visible spectroscopy</b></p> <p>Introduction to Spectroscopy, Properties of Electromagnetic Radiation, Electromagnetic spectrum and its interaction with matter. Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.</p> <p>Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.</p> <p>Applications - Spectrophotometric titrations, Single component and multi component analysis</p> <p><b>Fluorimetry</b></p> <p>Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications</p>	<b>15</b>

<b>II</b>	<p><b>IR spectroscopy</b> Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations</p> <p>Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermistor, Pyroelectric detector and applications</p> <p><b>NMR, Mass Spectroscopy:</b> Basic introduction and applications</p> <p><b>Flame Photometry:</b> Principle, Interferences, Instrumentation and applications</p> <p><b>Atomic Absorption Spectroscopy:</b> Principle, Interferences, Instrumentation and applications</p> <p><b>Nepheloturbidometry-</b> Principle, instrumentation and applications</p>	<b>15</b>
<b>III</b>	<p><b>Introduction to chromatography</b> <b>Adsorption and partition column chromatography-</b> Methodology, advantages, disadvantages and applications.</p> <p><b>Thin layer chromatography-</b> Introduction, Principle, Methodology, R<sub>f</sub> values, advantages, disadvantages and applications.</p> <p><b>Paper chromatography-</b> Introduction, methodology, development techniques, advantages, disadvantages and applications.</p> <p><b>Electrophoresis-</b> Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications</p>	<b>10</b>
<b>IV</b>	<p><b>Gas chromatography -</b> Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications</p> <p><b>High performance liquid chromatography (HPLC)-</b> Introduction, theory, instrumentation, advantages and applications.</p>	<b>10</b>
<b>V</b>	<p><b>Ion exchange chromatography-</b> Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications</p> <p><b>Gel chromatography-</b> Introduction, theory, instrumentation and applications</p> <p><b>Affinity chromatography-</b> Introduction, theory, instrumentation and applications</p>	<b>10</b>
	<b>Total</b>	<b>60</b>

**Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein



<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	
<b>Name of the course</b>	<b>Industrial Pharmacy II</b>
<b>Course Code</b>	<b>BP 702 T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The Industrial Pharmacy II course is aimed to impart knowledge on techniques of pilot plant and scale up, quality management systems. It emphasizes the discussions on regulatory requirements and considerations for filing and approval process - NDA, IND. This course also deals with technology transfer process. It also enlightens the students to know different Laws and Acts that regulate pharmaceutical industry.

#### **Course outcome**

At the end of the theory course, the student will be able to

CO1: Define basic framework of regulatory affairs.

CO2: Identify the various regulatory requirements for filing process of IND and NDA

CO3: Describe the process of technology transfer from lab scale to commercial batch

CO4: Propose the regulatory environment by implementing regulatory practices

#### **Course Content**

<b>Unit</b>	<b>Contents</b>	<b>Hours</b>
<b>I</b>	<b>Pilot plant scale up techniques:</b> General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology.	12
<b>II</b>	<b>Technology development and transfer:</b> WHO guidelines for Technology Transfer(TT):Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients,	14

	finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation-confidentiality agreement, licensing, MoUs, legal issues.	
<b>III</b>	<p><b>Regulatory affairs:</b> Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals</p> <p><b>Regulatory requirements for drug approval:</b> Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.</p>	12
<b>IV</b>	<p><b>Quality management systems:</b> Quality management&amp; Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP.</p>	12
<b>V</b>	<p><b>Indian Regulatory Requirements:</b> Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.</p>	10
<b>Total</b>		60

## **Learning Resources/Recommended Texts/Reference books/web resources**

### **Text books**

1. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert
3. New Drug Approval process: Accelerating Global Registrations By Richard A Guarino,MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. Guarino RA. New Drug Approval Process (Drugs and the Pharmaceutical Sciences). Marcel Dekker Inc: USA; 198
7. ISBN-13: 978-0824773823.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VII</b>
<b>Name of the course</b>	<b>Pharmaceutical Quality Assurance</b>
<b>Course Code</b>	<b>BP703T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

The pharmaceutical quality assurance course provides the knowledge on various aspects related to pharmaceutical manufacturing industries. It covers the concepts and guidelines of quality assurance and quality management, Total Quality Management (TQM), ICH guidelines, Quality by Design (QbD), ISO 9000 & ISO 14000, NABL Accreditation and IPR. It deals with pharmaceutical aspects related to Organization and personnel, Premises, equipments and raw materials. The course offers the information on the activities like quality control, calibration and validation, warehousing and good laboratory practice (GLP). It also provides the quality assurance activities of complaints, recalls and document maintenance in pharmaceutical industry.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

- CO 1: Define the principles and concepts of TQM, ICH, QbD, ISO, GMP, GLP, calibration, validation, warehousing and IPR.
- CO 2: Distinguish the calibration and validation activities of QC and QA in Pharmaceutical manufacturing industry as per the regulatory authorities.
- CO 3: Evaluate the pharmaceutical manufacturing activities related to premises, organization, personnel, warehousing, equipments, raw materials, complaints, product recalls, and document maintenance.

### Theory Course: Contents

Unit	Topics	Hours
<b>I</b> <b>(4 Weeks)</b>	<b>Quality Assurance and Quality Management concepts:</b> Definition and concept of Quality control, Quality assurance and GMP. <b>Total Quality Management (TQM):</b> Definition, elements, philosophies.	<b>16</b>
	<b>ICH Guidelines:</b> purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines	
	<b>Quality by design (QbD):</b> Definition, overview, elements of QbD program, tools. <b>ISO 9000 &amp; ISO14000:</b> Overview and Benefits. <b>NABL accreditation:</b> Principles and procedures. <b>Intellectual property rights:</b> General principles, Concepts.	
<b>II</b> <b>(3 Weeks)</b>	<b>Organization and personnel:</b> Personnel responsibilities, training, hygiene and personal records.	<b>12</b>
	<b>Premises:</b> Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.	
	<b>Equipments and raw materials:</b> Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.	
<b>III</b> <b>(2 Weeks)</b>	<b>Quality Control:</b> Quality control test for containers, rubber closures and secondary packing materials.	<b>8</b>
	<b>Good Laboratory Practices:</b> General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	

<b>IV</b> <b>(3 Weeks)</b>	<b>Complaints:</b> Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. <b>Document maintenance in pharmaceutical industry:</b> Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.	<b>12</b>
<b>V</b> <b>(3 Weeks)</b>	<b>Calibration and Validation:</b> Introduction, definition and general principles of calibration and validation, importance and scope of validation, types of validation, validation master plan. Advantages of Validation. General principles of Analytical method Validation.	<b>12</b>
	<b>Qualification:</b> Introduction, definition, general principles and types.	
	<b>Warehousing:</b> Good warehousing practice, materials management	
<b>TOTAL</b>		<b>60</b>

#### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh.
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.
8. Good laboratory Practices – Marcel Deckker Series.
9. ICH guidelines, ISO 9000 and 14000 guidelines.
10. Saha CN, Bhattacharya S. Intellectual property rights: An overview and implications in pharmaceutical industry. J Adv Pharm Technol Res. 2011;2(2):88-93. doi:10.4103/2231-4040.82952

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VII</b>
<b>Name of the course</b>	<b>Novel Drug Delivery Systems</b>
<b>Course Code</b>	<b>BPH704T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This course is designed to impart knowledge on the area of novel drug delivery systems, their formulation, evaluation, and applications. The course also allows students to extend their knowledge in various approaches for development of novel drug delivery systems and criteria for selection of drugs and polymers for the development of Novel drug delivery systems and Targeted drug delivery systems.

#### **Course outcomes**

At the end of the theory course, the student will be able to

**CO1:** Understand the concepts, applications and criteria for selection of drugs and polymers for the development and formulation of Novel drug delivery systems.

**CO2:** Apply knowledge in designing and formulation, characterization of various novel formulations as per requirements.

**CO3:** Assess various evaluation parameters for oral, parenteral, topical etc. drug delivery systems.

**CO4** Originate novel current drug delivery technologies in development of dosage forms and differentiate them from conventional systems

#### **Course Content**

<b>Unit</b>	<b>Contents</b>	<b>Hours</b>
<b>I</b>	<b>Controlled drug delivery systems:</b> Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design-controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations. <b>Polymers:</b> Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.	12

<b>II</b>	<b>Microencapsulation:</b> Definition, advantages and disadvantages, microspheres/ microcapsules, microparticles, methods of microencapsulation, applications. <b>Mucosal Drug Delivery system:</b> Introduction, Principles of bio adhesion/ mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems. <b>Implantable Drug Delivery Systems:</b> Introduction, advantages and disadvantages, concept of implants and osmotic pump, <b>Design of Elementary osmotic pump, Alzet osmotic pump</b>	12
<b>III</b>	<b>Transdermal Drug Delivery Systems:</b> Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches, <b>Evaluation of TDDS</b> <b>Gastroretentive drug delivery systems:</b> Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high-density systems, inflatable and gastroadhesive systems and their applications, <b>Evaluation of GRDDS. Nasopulmonary drug delivery system:</b> Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers	12
<b>IV</b>	<b>Targeted drug Delivery:</b> Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications <b>and evaluation tests</b>	12
<b>V</b>	<b>Ocular Drug Delivery Systems:</b> Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and occuserts. <b>Intrauterine Drug Delivery Systems:</b> Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications.	12
<b>Total</b>		<b>60</b>



**Learning Resources:**

- 12.2 Y. W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- 12.3 S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances Vallabh Prakashan, New Delhi, First edition 2002.
- 12.4 N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors New Delhi, First edition 1997 (reprint in 2001).
- 12.5 Saltzman WM. Drug delivery: engineering principles for drug therapy. Oxford University Press; 2001.
- 12.6 Wang B, Hu L, Siahaan TJ. Drug delivery: principles and applications. John Wiley & Sons; 2016 Mar 9.
- 12.7 Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
- 12.8 Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VII</b>
<b>Name of the course</b>	<b>Instrumental Methods of Analysis (Practical)</b>
<b>Course Code</b>	<b>BP705P</b>
<b>Credits</b>	<b>2</b>
<b>Hours/week</b>	<b>4hours(lectures)</b>
<b>Pre/co-requisite/s</b>	<b>Nil</b>

**Course Outcomes:** Upon completion of the course the student shall be able to

**CO 1:** Handle UV-Vis Spectrophotometer.

**CO 2:** Analyze drugs by different techniques

**Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
<b>1</b>	Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
<b>2</b>	Estimation of dextrose by colorimetry
<b>3</b>	Estimation of sulfanilamide by colorimetry
<b>4</b>	Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy.
<b>5</b>	Assay of paracetamol by UV- Spectrophotometry
<b>6</b>	Estimation of quinine sulfate by fluorimetry
<b>7</b>	Study of quenching of fluorescence
<b>8</b>	Determination of sodium by flame photometry
<b>9</b>	Determination of potassium by flame photometry
<b>10</b>	Determination of chlorides and sulphates by nephelo turbidometry
<b>11</b>	Separation of amino acids by paper chromatography
<b>12</b>	Separation of amino acids by circular paper chromatography
<b>13</b>	Separation of sugars by thin layer chromatography
<b>14</b>	Separation of plant pigments by column chromatography
<b>15</b>	Demonstration experiment on HPLC

**Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>VIII</b>
<b>Name of the course</b>	<b>Pharmacy Practice</b>
<b>Course Code</b>	<b>BP801T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This course is designed based on the changing scenario of pharmacy practice in India. The course gives a brief description about the organization and classification of hospitals. The course describes various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. The course describes the activities of community pharmacy such as drug store management and inventory control, dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up. This course mentions the importance of clinical pharmacy concept and activities of the clinical pharmacist.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Define the professional practice like drug distribution and management skills in hospital pharmacy, community pharmacy and clinical pharmacy in association with respect to various committees of the hospitals.

CO 2: Assess the drug therapy of patient through drug therapy chart review, medication history interview; recognize and manage drug related problems effectively.

CO 3: Equip unbiased drug and poison information.

CO 4: Interpret the laboratory investigations of specific diseased states.

CO 5: Provide the pharmaceutical care services

**Theory Course: Contents**

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I</b>	<b>Hospital and it's organization</b> Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis,	

	<p>Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.</p> <p><b>Hospital pharmacy and its organization:</b> Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.</p> <p><b>Adverse drug reaction:</b> Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.</p> <p><b>Community Pharmacy:</b> Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.</p>	13
II	<p><b>Drug distribution system in a hospital</b></p> <p>Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.</p> <p><b>Hospital formulary:</b> Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.</p> <p><b>Therapeutic drug monitoring:</b> Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.</p> <p><b>Medication adherence:</b> Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.</p> <p><b>Patient medication history interview:</b> Need for the patient medication history interview, medication interview forms.</p>	13

	<b>Community pharmacy management</b> Financial, materials, staff, and infrastructure requirements.	
III	<b>Pharmacy and therapeutic committee</b> Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation. <b>Drug information services:</b> Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information. <b>Patient counseling:</b> Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist <b>Education and training program in the hospital</b> Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education. <b>Prescribed medication order and communication skills</b> Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.	13
IV	<b>Budget preparation and implementation</b> Budget preparation and implementation <b>Clinical Pharmacy:</b> Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern. <b>Over the counter (OTC) sales:</b> Introduction and sale of over the counter, and Rational use of common over the counter medications.	11
V	<b>Drug store management and inventory control</b> Organization of drug store, types of materials stocked and storage	

	<p>conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure</p> <p><b>Investigational use of drugs</b></p> <p>Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.</p> <p><b>Interpretation of Clinical Laboratory Tests</b></p> <p>Blood chemistry, hematology, and urinalysis</p>	<b>10</b>
	<b>Total</b>	<b>60</b>

#### **Learning Resources/Recommended Texts/Reference books/web resources**

1. William E Hassan. Hospital Pharmacy – 5<sup>th</sup> ed. Philadelphia: Lea and Febiger.
2. Merchant and Qadry's: Dr. J.S. Qadry. A textbook of Hospital Pharmacy 10<sup>th</sup> ed. B.S. Shah Prakashan.
3. David H Lawson, R Michael E. Richards. Clinical Pharmacy and Hospital Drug Management – 1982. Chapman and Hall.
4. Dr. H.P. Tipnis, Dr. Amrita Bajaj. Clinical Pharmacy – 1<sup>st</sup> ed. Career Publications.
5. Dr. G. Parthasarathi, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills – 2<sup>nd</sup> ed. University Press.
6. S. J. Carter. Cooper and Gunn's. Dispensing for Pharmaceutical students – 12<sup>th</sup> ed. CBS Publishers and Distributors.
7. Mary Lee. Basic skills in interpreting laboratory data – 5<sup>th</sup> ed. American Society of Health System Pharmacist®.
8. Susan Foran. Australian drug information -Procedure manual – 1996. Society of Hospital Pharmacists of Australia.
9. Parmar N.S. Health Education and Community Pharmacy- 18<sup>th</sup> ed. CBS Publishers and Distributors.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VIII</b>
<b>Name of the course</b>	<b>Social and Preventive Pharmacy</b>
<b>Course Code</b>	<b>BP802T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 hours (Lecture)+ 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO1: Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.

CO2: Develop skills of critical way of thinking based on current healthcare development.

CO3: Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

#### **Theory Course: Contents**

<b>Unit</b>	<b>Topics</b>	<b>No. of hours</b>
<b>I (3 Weeks)</b>	<b>Concept of health and disease</b> Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. <b>Social and health education</b> Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention. <b>Sociology and health</b> Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health	<b>13</b>



	<b>Hygiene and health</b> Personal hygiene and health care; avoidable habits	
<b>II</b> <b>( 3 Weeks)</b>	<b>Preventive medicine</b> General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse.	<b>13</b>
<b>III</b> <b>( 3 Weeks)</b>	<b>National health programs, its objectives, functioning and outcome of the following:</b> HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.	<b>13</b>
<b>IV</b> <b>( 3 Weeks )</b>	National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program.	<b>11</b>
<b>V</b> <b>(3 Weeks)</b>	Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.	<b>10</b>
	<b>Total</b>	<b>60</b>

**Learning Resources/Recommended Texts/Reference books/web resources**

1. Prabhakara GN. Short Textbook of Preventive and Social Medicine. 2<sup>nd</sup> Edition. 2010. Jaypee Publications. ISBN: 9789380704104.
2. Roy Rabindra Nath, Saha Indranil. Textbook of Preventive and Social Medicine (Mahajan and Gupta). 4<sup>th</sup> Edition, 2013. Jaypee Publications. ISBN: 9789350901878.
3. Jain Vivek. Review of Preventive and Social Medicine (Including Biostatistics). 6<sup>th</sup> Edition. 2014. Jaypee Publications. ISBN: 9789351522331.
4. Hiremath Lalita D, Hiremath Dhananjaya A. Essentials of Community Medicine—A Practical Approach. 2<sup>nd</sup> Edition. 2012. Jaypee Publications. ISBN: 9789350250440.
5. K Park. Park Textbook of Preventive and Social Medicine. 21<sup>st</sup> Edition. 2011. Banarsidas Bhanot Publishers. ISBN-14: 9788190128285.
6. Ramesh Adepu. Community Pharmacy Practice. BSP publishers, Hyderabad.
7. Research in Social and Administrative Pharmacy, Elsevier, Ireland. (Journal).

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VIII</b>
<b>Name of the course</b>	<b>Pharmaceutical Regulatory Science</b>
<b>Course Code</b>	<b>BP803ET</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO1: Understand the process of drug discovery and development

CO2: Discusses the scientific, regulatory, and legal considerations for the development of generic drug products and Outlines the ANDA regulatory approval process

CO3: Identify the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.

CO4: Understand the regulatory approval process and their registration in Indian and international markets

CO5: Understand, write and review Regulatory Documents.

#### **Theory Course: Contents**

<b>Unit</b>	<b>Topics</b>	<b>No. of hours</b>
<b>I (3 Weeks)</b>	<b>New Drug Discovery and development</b> Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.	<b>13</b>
<b>II</b>	<b>Regulatory Approval Process</b>	

<b>(3 Weeks)</b>	<p>Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.</p> <p><b>Regulatory authorities and agencies</b></p> <p>Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications).</p>	<b>13</b>
<b>III (3 Weeks)</b>	<p><b>Registration of Indian drug product in overseas market</b></p> <p>Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.</p>	<b>13</b>
<b>IV (3 Weeks)</b>	<p><b>Clinical trials</b></p> <p>Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors &amp; Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials</p>	<b>11</b>
<b>V (3 Weeks)</b>	<p><b>Regulatory Concepts</b></p> <p>Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book</p>	<b>10</b>
	<b>Total</b>	<b>60</b>

### **Learning Resources/Recommended Texts/Reference books/web resources**

1. David Machin, Simon Day, Sylvan Green. Textbook of Clinical Trials. John Wiley and Sons; 2005.
2. Giovanna Di Ignazio, Di Giovanna, Haynes. Principles of Clinical Research. Illustrated edition. University of Michigan. Wrightson Biomedical Publications; 2008. ISBN 1871816459, 9781871816457.
3. Sachin Itkar, Dr. N.S. Vyawahare. Drug Regulatory Affairs. Nirali Prakashan.
4. Ira R. Berry and Robert P. Martin. The Pharmaceutical Regulatory Process. Drugs and the Pharmaceutical Sciences, 2<sup>nd</sup> ed. Vol.185. Informa Health care Publishers.
5. Richard A Guarino, MD. New Drug Approval Process: Accelerating Global Registrations. Drugs and the Pharmaceutical Sciences. 5<sup>th</sup> edition. Vol.190.
6. John Wiley & Sons. Inc. Guidebook for drug regulatory submissions / Sandy Weinberg.
7. Douglas J. Pisano, David Mantus. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics.
8. Leon Shargel and Isader Kaufer. Generic Drug Product Development, Solid Oral Dosage forms. , Marcel Dekker series. Vol.143.
9. Fay A. Rozovsky and Rodney K. Adams. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance.
10. John I. Gallin and Frederick P. Ognibene. Principles and Practices of Clinical Research. 2<sup>nd</sup> ed.
11. Rick Ng. Drugs: From Discovery to Approval. 2<sup>nd</sup> ed.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VIII</b>
<b>Name of the course</b>	<b>Computer Aided Drug Design</b>
<b>Course Code</b>	<b>BP804ET</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course description:** This subject designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

**Course Outcomes:** Upon completion of the course, the student shall be able to

**CO 1:** Design and discovery of lead molecules

**CO 2:** Estimate the role of drug design in drug discovery process

**CO 3:** Apply the concept of QSAR, docking, molecular modeling software and various strategies to design & develop new drug like molecules.

#### Course Content

Unit	Topics	Hours
<b>I</b> <b>(3 Weeks)</b>	<b>Introduction to Drug Discovery and Development</b> Stages of drug discovery and development	<b>12</b>
	<b>Lead discovery and Analog Based Drug Design</b> Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.	
	<b>Analog Based Drug Design:</b> Bioisosterism, Classification, Bioisosteric replacement. Any three case studies	
<b>II</b> <b>(3 Weeks)</b>	<b>Quantitative Structure Activity Relationship (QSAR)</b> SAR versus QSAR, History and development of QSAR,	<b>12</b>
	Types of physicochemical parameters, experimental and theoretical approaches for the determination of Physico-chemical parameters such as Partition coefficient, Hammett's substituent constant and Tafts	

	steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.	
<b>III</b> <b>(3 Weeks)</b>	<b>Molecular Modeling and virtual screening techniques</b> <b>Virtual Screening techniques:</b> Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening, <b>Molecular docking:</b> Rigid docking, flexible docking, manual docking, Docking based screening. <i>De novo</i> drug design.	<b>12</b>
<b>IV</b> <b>(3 Weeks)</b>	<b>Informatics &amp; Methods in drug design</b> Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.	<b>12</b>
<b>V</b> <b>(3 Weeks)</b>	<b>Molecular Modeling:</b> Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination. Revision	<b>12</b>
<b>TOTAL</b>		<b>60</b>

### Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.
5. Koro I kovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VIII</b>
<b>Name of the course</b>	<b>Cell and Molecular Biology Theory</b>
<b>Course Code</b>	<b>BP805ET</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>

**Course Description:** Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function. This is done both on a microscopic and molecular level. Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO1: Summarize cell and molecular biology history.

CO2: Summarize cellular functioning and composition.

CO3: Describe the chemical foundations of cell biology.

CO4: Summarize the DNA properties of cell biology.

CO5: Describe protein structure and function.

CO6: Describe cellular membrane structure and function.

CO7: Describe basic molecular genetics mechanisms.

CO8: Summarize the Cell Cycle.

#### **Theory Course: Contents**

<b>Unit</b>	<b>Topic</b>	<b>Hours</b>
I	Cell and Molecular Biology: Definitions theory and basics and Applications. Cell and Molecular Biology: History and Summation. Properties of cells and cell membrane. Prokaryotic versus Eukaryotic, Cellular Reproduction Chemical Foundations – an Introduction and Reactions (Types)	12



II	DNA and the Flow of Molecular Information DNA Functioning DNA and RNA Types of RNA Transcription and Translation.	12
III	Proteins: Defined <b>and</b> Amino Acids Protein Structure Regularities in Protein Pathways Cellular Processes Positive Control and significance of Protein Synthesis	12
IV	Science of Genetics Transgenics and Genomic Analysis Cell Cycle analysis Mitosis and Meiosis Cellular Activities and Checkpoints	12
V	Cell Signals: Introduction Receptors for Cell Signals Signaling Pathways: Overview Mis regulation of Signaling Pathways Protein-Kinases: Functioning.	12
Total		60

**Recommended Books (latest edition):**

- 1.W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn. Industrial Microbiology, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
- 3.Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
- 4.Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
- 5.Rose: Industrial Microbiology.
- 6.Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
- 7.Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
- 8.Peppler: Microbial Technology.

9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly Company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
13. RA Goldshy et. al., Kuby Immunology.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VIII</b>
<b>Name of the course</b>	<b>Cosmetic Science– Theory</b>
<b>Course Code</b>	<b>BP806ET</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>

### Course Description:

This course is designed to impart a fundamental knowledge on various types of cosmetics products, their formulation and evaluations. This course also describes the importance of herbal cosmetics.

**Course Learning Outcomes:** Upon completion of this course the student should be able to:

CO 1: Define and classify various types of cosmetic and dermatological products.

CO 2: Discuss the principles involved in formulation and manufacturing of various cosmetic and dermatological products.

CO 3: Demonstrate ability to develop, validate and apply different instrumental analytical techniques to analyze various cosmetic and dermatological products.

### Theory Course Contents:

<b>Unit</b>	<b>Topic</b>	<b>Hours</b>
I	Classification of cosmetic and cosmeceutical products  Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs <b>Cosmetic excipients:</b> Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application <b>Skin:</b> Basic structure and function of skin. <b>Hair:</b> Basic structure of hair. Hair growth cycle. <b>Oral Cavity:</b> Common problem associated with teeth and gums.	14
II	<b>Principles of formulation and building blocks of skin care products:</b> Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of	16

	<p>cosmeceuticals.</p> <p><b>Antiperspirants&amp; deodorants-</b> Actives &amp; mechanism of action.</p> <p><b>Principles of formulation and building blocks of Hair care products:</b></p> <p>Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils.</p> <p>Chemistry and formulation of Para-phenylene diamine based hair dye.</p> <p><b>Principles of formulation and building blocks of oral care products:</b></p> <p>Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.</p>	
III	<p><b>Sun protection:</b> Classification of Sunscreens and SPF.</p> <p><b>Role of herbs in cosmetics:</b> Skin Care: Aloe and turmeric Hair care: Henna and amla. Oral care: Neem and clove</p> <p><b>Analytical cosmetics:</b> BIS specification and analytical methods for shampoo, skin-cream and toothpaste.</p>	12
IV	<p><b>Principles of Cosmetic Evaluation:</b> Principles of sebumeter, corneometer.</p> <p>Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps, and syndet bars. Evolution and skin benefits.</p>	8
V	<p>Oily and dry skin causes leading to dry skin, skin moisturization. Basic understanding of the terms Comedogenic, dermatitis.</p> <p><b>Cosmetic problems associated with Hair and scalp:</b> Dandruff, Hair fall causes</p> <p><b>Cosmetic problems associated with skin:</b> blemishes, wrinkles, acne, prickly heat and body odor.</p> <p><b>Antiperspirants and Deodorants-</b> Actives and mechanism of action.</p>	10
<b>Total</b>		60

**Recommended Books: (Latest Editions)**

1. Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2. Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4<sup>th</sup> Edition, Vandana Publications Pvt. Ltd., Delhi.
3. Text book of cosmeticology by Sanju Nanda &Roop K. Khar, Tata Publishers.

<b>Program</b>	<b>B. Pharmacy</b>
<b>Semester</b>	<b>VIII</b>
<b>Name of the course</b>	<b>Experimental Pharmacology</b>
<b>Course Code</b>	<b>BP807ET</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO1: Appreciate the applications of various commonly used laboratory animals.

CO2: Appreciate and demonstrate the various screening methods used in preclinical research

CO3: Appreciate and demonstrate the importance of biostatistics and research methodology

CO4: Design and execute a research hypothesis independently

#### **Theory Course: Contents**

<b>UNIT</b>	<b>Topic</b>	<b>Hours</b>
<b>I</b>	<b>Laboratory Animals:</b> Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	15
<b>II</b>	<b>Preclinical screening models</b> a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. b. <b>Study of screening animal models for</b> Diuretics, nootropics, anti-Parkinson's, antiasthmatics, c. <b>Preclinical screening models:</b> for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and	15

	hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease.	
<b>III</b>	<b>Preclinical screening models:</b> for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.	10
<b>IV</b>	<b>Preclinical screening models:</b> for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants. Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	10
<b>V</b>	<b>Research methodology and Bio-statistics</b> Selection of research topic, review of literature, research hypothesis and study design. Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data.	10
<b>Total</b>		<b>60</b>

**Recommended Books (latest edition):**

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

<b>Programme</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>VIII</b>
<b>Name of the course</b>	<b>Advanced Instrumentation Techniques-Theory</b>
<b>Course Code</b>	<b>BP808ET</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3hours (lectures) &amp; 1hour (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Scope:** This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

**Course Outcomes:** Upon completion of the course the student shall be able to

CO 1: Understand the advanced instruments used and its applications in drug analysis

CO 2: Perform the chromatographic separation and analysis of drugs.

CO 3: Perform the calibration of various analytical instruments

**Course Content:**

<b>Unit</b>	<b>Topics</b>	<b>Hours</b>
<b>I (4 Weeks)</b>	<b>Nuclear Magnetic Resonance spectroscopy</b> Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant,	<b>16</b>
	Spin - spin coupling, relaxation, instrumentation and applications	
	<b>Mass Spectrometry:</b> Principles, Fragmentation, Ionization techniques, Electron impact, chemical ionization, MALDI, FAB.	
	Analyzers-Time of flight and Quadrupole, instrumentation, applications.	
<b>II (3 Weeks)</b>	<b>Thermal Methods of Analysis:</b> Principles, instrumentation and applications of Thermogravimetric Analysis (TGA),	<b>12</b>
	Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)	

	<b>X-Ray Diffraction Methods:</b> Origin of X-rays, basic aspects of crystals, X-ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.	
<b>III</b> <b>(3 Weeks)</b>	<b>Calibration and validation</b> -as per ICH and USFDA guidelines	<b>12</b>
	<b>Calibration of following Instruments</b> Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,	
	<b>Calibration of following Instruments</b> Fluorimeter, Flame Photometer, HPLC and GC	
<b>IV</b> <b>(2 Weeks)</b>	<b>Radio immune assay:</b> Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay	<b>8</b>
	<b>Extraction techniques:</b> General principle and procedure involved in the solid phase extraction and liquid-liquid extraction.	
<b>V</b> <b>(3 Weeks)</b>	<b>Hyphenated techniques-LC-MS/MS</b>	<b>12</b>
	GC-MS/MS,	
	HPTLC-MS.	
<b>TOTAL</b>		<b>60</b>

#### **Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein.



<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>VIII</b>
<b>Name of the course</b>	<b>Quality Control and Standardization of Herbals</b>
<b>Course Code</b>	<b>BP809ET</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>3 Hours (Lectures) + 1 (Tutorial)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

**Course Learning Outcomes:**

Upon completion of the subject student shall be able to;

CO1: Know WHO guidelines for quality control of herbal drugs

CO2: Know Quality assurance in herbal drug industry

CO3: Know the regulatory approval process and their registration in Indian and international markets

CO4: Appreciate EU and ICH guidelines for quality control of herbal drugs

**Theory Course: Contents**

<b>Unit</b>	<b>Topic</b>	<b>Hours</b>
<b>I</b>	Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms, WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use.	10
<b>II</b>	<b>Quality assurance in herbal drug industry</b> of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.	12
<b>III</b>	EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines.	12

<b>IV</b>	Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.	12
<b>V</b>	Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in Pharmacovigilance systems Comparison of various Herbal Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products.	12
Total		60

**Recommended Books: (Latest Editions)**

1. W.C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
5. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
6. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
7. WHO Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998.
8. WHO Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

<b>Program</b>	<b>B. Pharm</b>
<b>Semester</b>	<b>VIII</b>
<b>Name of the course</b>	<b>Project Work</b>
<b>Course Code</b>	<b>BP810PW</b>
<b>Credits</b>	<b>6</b>
<b>Hours /week</b>	<b>12 Hours</b>

**Raghavendra Institute of Pharmaceutical Education and Research  
(RIPER)** (Conferred Autonomous status from the academic year 2021-22) Accorded  
under Sections 2 (f) and 12 (B) of UGC act 1956 and Accredited by National Board of  
Accreditation (NBA) and National Assessment & Accreditation Council (NAAC: A)  
Approved by PCI and AICTE, New Delhi

## **Academic Regulations, Program structure & Syllabus**

**Effective from ACY 2021-2022**

### **MASTER OF PHARMACY**



**(Applicable for the students admitted from 2021-2022)**

**: Awarding University:**

**Jawaharlal Nehru Technological University Anantapuramu (JNTUA)**

## Regulations

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## **CHAPTER– I:REGULATIONS**

### **1. Short Title and Commencement**

These regulations shall be called “The Revised Regulations for the Master of Pharmacy (M.Pharm) Degree Program-Choice Based Credit System (CBCS). They shall come into effect from the Academic Year 2021-22. The regulations framed are subject to modifications from time to time by the concerned authorities’ of the institution.

### **2. Minimum qualification for admission**

A. Pass in the following examinations

B.Pharm Degree examination of an Indian university established by law in India from an institution approved by the Pharmacy Council of India and has scored not less than 50 % of the maximum marks (aggregate of 4 years of B.Pharm.)

Admission to the M.Pharm programme shall be made subject to the eligibility, qualifications and specialization prescribed by the A.P. State Government/University for each programme, from time to time.

Admissions shall be made based on either the merit rank or Percentile obtained by the qualified student in the relevant qualifying GPAT Examination / the merit rank obtained by the qualified student in an entrance test conducted by A.P. State Government (APPGECET) for M. Pharm. Programmes / an entrance test conducted by the university/ based on any other exams approved by the University, subject to reservations as laid down by the Govt. from time to time.

### **3. Duration of the program**

The program of study for M.Pharm. Shall extend over a period of four semesters (two academic years). The curricular and syllabic for the programme shall be prescribed from time to time by the institute.

### **4. Medium of instruction and examinations**

Medium of instruction and examination shall be in English.

### **5. Working days in each semester**

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the months of June/July to November/December and the even semesters shall be conducted from December/January to May/June of every calendar year.

### **6. Attendance Requirements:**

- 6.1. A student shall be eligible to appear for the external examinations if he/she acquires a minimum 75% of attendance in aggregate of all the courses.
- 6.2. Condonation of shortage of attendance in aggregate up to 10% (65% and above and below 75%) in each semester may be granted by the College Academic Committee.
- 6.3. Condonation of shortage of attendance shall be granted only for genuine and valid reasons on representation by the candidate with supporting evidence
- 6.4. Students whose shortage of attendance is not condoned in any semester are not eligible to take their end examination of that class.

- 6.5. A stipulated fee shall be payable towards the condonation of a shortage of attendance.
- 6.6. A student will not be promoted to the next semester unless he satisfies the attendance requirements of the present semester. They may seek re-admission into that semester when offered next.
- 6.7. If any candidate fulfils the attendance requirement in the present semester, he shall not be eligible for readmission into the same class.
- 6.8. If the learning is carried out in a blended mode (both offline & online), then the total attendance of the student shall be calculated considering the offline and online attendance of the student.

## **7. Program/Course credit structure**

As per the philosophy of the Choice Based Credit System (CBCS) provides choice for students to select from the prescribed courses. Credit Based Semester System, certain quantum's of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week / per activity.

### **7.1. Credit assignment**

#### **7.1.1. Theory and Laboratory courses**

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory.

Credit is a unit by which the course work is measured. It determines the number of hours of instruction required per week. One credit is equivalent to one hour of teaching (Lecture/Tutorial) or two hours of practical work/field work per week.

Credit definition:

1 Hr. Lecture	1 credit
1 Hr. Tutorial	1 credit
1 Hr. Practical	0.5 credit
1 Hr. seminar/assignment	0.5 credit
1 Hr. research work	0.5 credit

### **7.2. Minimum credit requirements**

The minimum credit points required for the award of M. Pharm. degree is 100. However, based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Extra & Co-Curricular activities over the duration of our semesters. The credits are distributed semester-wise as shown in Table 10. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

## 8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, and Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

## 9. Course of study

The specializations in M.Pharm program is given in Table 1.

**Table-1: List of M.Pharm. Specializations and their Code**

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmacy Practice	MPP
7.	Pharmacology	MPL

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table — 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table—2 to 11.

## 10. Programme Pattern:

- 10.1. Total duration of the of M. Pharm. programme is two academic years
- 10.2. Each academic year of study is divided into two semesters.
- 10.3. Each Semester shall be of a minimum of 100 instructional days per semester.
- 10.4. The student shall not take more than four academic years to fulfil all the academic requirements for the award of M. Pharm. degree from the date of commencement of first year first semester, failing which the student shall forfeit the seat in M. Pharm. programme.
- 10.5. The medium of instruction of the programme (including examinations and project reports) will be in English only.
- 10.6. A faculty advisor/mentor shall be assigned to each specialization to advise students on the programme, its Course
- 10.7. Structure and Curriculum, Choice of Courses, based on his competence, progress, pre-requisites, and interest.
- 10.8. Preferably 40% course work for the theory courses in every semester may be conducted in the blended mode of learning.



**Table-2: Course of study for M.Pharm (Pharmaceutics)**

<b>Course Code</b>	<b>Course</b>	<b>Credit Hours</b>	<b>Credit Points</b>	<b>Hrs./wk</b>	<b>Marks</b>
<b>Semester I</b>					
MPH101T	Modern Pharmaceutical Analytical Techniques (AECC)	4	4	4	100
MPH102T	Drug Delivery System (CC)	4	4	4	100
MPH103T	Modern Pharmaceutics(CC)	4	4	4	100
MPH104T	Regulatory Affairs (CC)	4	4	4	100
MPH105P	Modern Pharmaceutical Analytical Techniques- practical(AECC)	6	3	6	75
MPH106P	Pharmaceutics Practical-I (CC)	6	3	6	75
MPH107S	Seminar/Assignment(SEC)	6	3	6	75
	<b>Audit course</b>	--	--	--	--
MPH108A1	<i>Yoga and stress management</i>				
MPH108A2	<i>Disaster management</i>				
MPH108A3	<i>Green initiatives</i>				
MPH108A4	<i>Human rights and responsibilities</i>				
<b>Total</b>		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>
<b>Semester II</b>					
MPH201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS) (CC)	4	4	4	100
MPH202T	Advanced Bio pharmaceutics& Pharmacokinetics(CC)	4	4	4	100
MPH203T	Computer Aided Drug Delivery System(CC)	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals(CC)	4	4	4	100
MPH205P	Pharmaceutics Practical-II (CC)	6	3	6	75
MPH206P	Pharmaceutics Practical-III (CC)	6	3	6	75
MPH207S	Seminar/Assignment (SEC)	6	3	6	75
	<b>Audit course</b>	--	--	--	--
MPH208A1	<i>Constitution of India</i>				
MPH208A2	<i>Bhagavad-Gita for personality development</i>				
MPH208A3	<i>Water conservation</i>				
MPH208A4	<i>Waste management</i>				
<b>Total</b>		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>

**Table-3: Course of study for M.Pharm (Industrial Pharmacy)**

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
<b>Semester-I</b>					
MIP101T	Modern Pharmaceutical Analytical Techniques (AECC)	4	4	4	100
MIP102T	Pharmaceutical Formulation Development(CC)	4	4	4	100
MIP103T	Novel drug delivery systems (CC)	4	4	4	100
MIP104T	Intellectual Property Rights(CC)	4	4	4	100
MIP105P	Modern Pharmaceutical Analytical Techniques- practical(AECC)	6	3	6	75
MIP106P	Industrial Pharmacy Practical-I (CC)	6	3	6	75
MIP107S	Seminar/Assignment (SEC)	6	3	6	75
	<b>Audit course</b> (Need to choose anyone)	--	--	--	--
MIP108A1	Yoga and stress management				
MIP108A2	Disaster management				
MIP108A3	Green initiatives				
MIP108A4	Human rights and responsibilities				
<b>Total</b>		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>
<b>Semester-II</b>					
MIP201T	Advanced Bio pharmaceuticals and Pharmacokinetics (CC)	4	4	4	100
MIP202T	Scale up and Technology Transfer (CC)	4	4	4	100
MIP203T	Pharmaceutical Production Technology(CC)	4	4	4	100
MIP204T	Entrepreneurship Management(AECC)	4	4	4	100
MIP205P	Industrial Pharmacy Practical-II(CC)	6	3	6	75
MIP206P	Industrial Pharmacy Practical-III(CC)	6	3	6	75
MIP207S	Seminar/Assignment (SEC)	6	3	6	75
	<b>Audit course</b> (Need to choose anyone)	--	-	--	--
MIP208A1	Constitution of India				
MIP208A2	Bhagavad-Gita for personality development				
MIP208A3	Water conservation				
MIP208A4	Waste management				
	<b>Total</b>	<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>

**Table–4:CourseofstudyforM.Pharm (Pharmaceutical Chemistry)**

<b>Course Code</b>	<b>Course</b>	<b>Credit Hours</b>	<b>Credit Points</b>	<b>Hrs./wk</b>	<b>Marks</b>
<b>Semester I</b>					
MPC101T	Modern Pharmaceutical Analytical Techniques (AECC)	4	4	4	100
MPC102T	Advance Organic Chemistry-I (CC)	4	4	4	100
MPC103T	Advance Medicinal Chemistry(CC)	4	4	4	100
MPC104T	Chemistry of Natural Products(CC)	4	4	4	100
MPC105P	Modern Pharmaceutical Analytical Techniques (CC)	6	3	6	75
MPC106P	Pharmaceutical Chemistry Practical-I (CC)	6	3	6	75
MPC107S	Seminar Assignment (SEC)	6	3	6	75
<b>Audit course</b> (Need to choose anyone)		--	--	--	--
MPC108A1	Yoga and stress management				
MPC108A2	Disaster management				
MPC108A3	Green initiatives				
MPC108A4	Human rights and responsibilities				
<b>Total</b>		<b>35</b>	<b>25</b>	<b>34</b>	<b>625</b>
<b>Semester II</b>					
MPC201T	Advance spectral analysis (CC)	4	4	4	100
MPC202T	Advanced Organic Chemistry-II(CC)	4	4	4	100
MPC203T	Computer Aided Drug Design(CC)	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry (CC)	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical-II (CC)	6	3	6	75
MPC206P	Pharmaceutical Chemistry Practical-III(CC)	6	3	6	75
MPC207S	Seminar/Assignment (SEC)	6	3	6	75
<b>Audit course</b> (Need to choose anyone)		--	--	--	--
MPC208A1	Constitution of India				
MPC208A2	Bhagavad-Gita for personality development				
MPC208A3	Water conservation				
MPC208A4	Waste management				
<b>Total</b>		<b>35</b>	<b>25</b>	<b>34</b>	<b>625</b>

**Table–5:CourseofstudyforM.Pharm (Pharmaceutical Analysis)**

<b>Course Code</b>	<b>Course</b>	<b>Credit Hours</b>	<b>Credit Points</b>	<b>Hrs./wk</b>	<b>Marks</b>
<b>Semester I</b>					
MPA101T	Modern Pharmaceutical Analytical Techniques (CC)	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis (CC)	4	4	4	100
MPA103T	Quality Control and Quality Assurance (CC)	4	4	4	100
MPA104T	Food Analysis (CC)	4	4	4	100
MPA105P	Modern Pharmaceutical Analytical Techniques Lab(CC)	6	3	6	75
MPA106P	Pharmaceutical Analysis Practical- I (CC)	6	3	6	75
MPA107S	Seminar/Assignment (SEC)	6	3	6	75
	<b>Audit course</b> (Need to choose anyone)	--	--	--	--
MPA108A1	Yoga and stress management				
MPA108A2	Disaster management				
MPA108A3	Green initiatives				
MPA108A4	Human rights and responsibilities				
<b>Total</b>		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>
<b>Semester II</b>					
MPA201T	Advanced Instrumental Analysis (CC)	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques(CC)	4	4	4	100
MPA203T	Pharmaceutical Validation(CC)	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis(CC)	4	4	4	100
MPA205P	Pharmaceutical Analysis Practical- II(CC)	6	3	6	75
MPA206P	Pharmaceutical Analysis Practical- II (CC)	6	3	6	75
MPA207S	Seminar/Assignment (SEC)	6	3	6	75
	<b>Audit course</b> (Need to choose anyone)	--	--	--	--
MPA208A1	Constitution of India				
MPA208A2	Bhagavad-Gita for personality development				
MPA208A3	Water conservation				
MPA208A4	Waste management				
<b>Total</b>		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>

**Table–6: Course of study for M.Pharm (Pharmaceutical Quality Assurance)**

<b>Course Code</b>	<b>Course</b>	<b>Credit Hours</b>	<b>Credit Points</b>	<b>Hrs./wk</b>	<b>Marks</b>
<b>Semester I</b>					
MQA101T	Modern Pharmaceutical Analytical Techniques (AECC)	4	4	4	100
MQA102T	Quality Management system(CC)	4	4	4	100
MQA103T	Quality Control and Quality Assurance(CC)	4	4	4	100
MQA104T	Product development and Technology transfer(CC)	4	4	4	100
MQA105P	Modern Pharmaceutical Analytical Techniques Lab(AECC)	6	3	6	75
MQA106P	Pharmaceutical Quality Assurance Practical-I (CC)	6	3	6	75
MQA107S	Seminar/Assignment (SEC)	6	3	6	75
	<b>Audit course</b> (Need to choose anyone)	--	--	--	--
MQA108A1	Yoga and stress management				
MQA108A2	Disaster management				
MQA108A3	Green initiatives				
MQA108A4	Human rights and responsibilities				
<b>Total</b>		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>
<b>Semester II</b>					
MQA201T	Hazard and safety Management (CC)	4	4	4	100
MQA202T	Pharmaceutical Manufacturing Technology (CC)	4	4	4	100
MQA203T	Pharmaceutical validation (CC)	4	4	4	100
MQA204T	Audits and Regulatory Compliance (CC)	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical-II (CC)	6	3	6	75
MQA206P	Pharmaceutical Quality Assurance Practical-III (CC)	6	3	6	75
MQA207S	Seminar/Assignment (SEC)	6	3	6	75
	<b>Audit course</b> (Need to choose anyone)	--	--	--	--
MQA208A1	Constitution of India				
MQA208A2	Bhagavad-Gita for personality development				
MQA208A3	Water conservation				
MQA208A4	Waste management				
<b>Total</b>		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>

**Table–7:CourseofstudyforM.Pharm (Pharmacy Practice)**

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
<b>Semester I</b>					
MPP101T	Clinical Pharmacy Practice (CC)	4	4	4	100
MPP102T	Pharmacotherapeutics I (CC)	4	4	4	100
MPP103T	Hospital and Community Pharmacy(CC)	4	4	4	100
MPP104T	Clinical Research(CC)	4	4	4	100
MPP105P	Pharmacy Practice Practical-I (CC)	6	3	6	75
MPP106P	Pharmacy Practice Practical-II (CC)	6	3	6	75
MPP107S	Seminar/Assignment (SEC)	6	3	6	75
	<b>Audit course</b> (Need to choose anyone)	--	--	--	--
MPP108A1	Yoga and stress management				
MPP108A2	Disaster management				
MPP108A3	Green initiatives				
MPP108A4	Human rights and responsibilities				
Total		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>
<b>Semester II</b>					
MPP201T	Principles of Quality Use of Medicines (CC)	4	4	4	100
MPP202T	Pharmacotherapeutics II(CC)	4	4	4	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring(CC)	4	4	4	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics(CC)	4	4	4	100
MPP205P	<b>Pharmacy Practice Practical-III(CC)</b>	6	3	6	75
MPP206P	<b>Pharmacy Practice Practical-IV(CC)</b>	6	3	6	75
MPP207S	Seminar/Assignment (SEC)	6	3	6	75
	<b>Audit course</b> (Need to choose anyone)	--	--	--	
MPP208A1	Constitution of India				
MPP208A2	Bhagavad-Gita for personality development				
MPP208A3	Water conservation				
MPP208A4	Waste management				
Total		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>

**Table–8:CourseofstudyforM.Pharm (Pharmacology)**

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
<b>Semester I</b>					
MPL101T	Modern Pharmaceutical Analytical Techniques (AECC)	4	4	4	100
MPL 102T	Advanced Pharmacology-I(CC)	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I(CC)	4	4	4	100
MPL 104T	Cellular and Molecular Pharmacology(CC)	4	4	4	100
MPL105P	Modern Pharmaceutical Analytical Techniques Practical(AECC)	6	3	6	75
MPL 106P	Pharmacology Practical-I(CC)	6	3	6	75
MPL107P	Seminar/Assignment (SEC)	6	3	6	75
	Audit course (Need to choose anyone)				
MPL108A1	Yoga and stress management				
MPL108A2	Disaster management				
MPL108A3	Green initiatives				
MPL108A4	Human rights and responsibilities				
<b>Total</b>		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>
<b>Semester II</b>					
MPL201T	Advanced Pharmacology II (CC)	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods-II(CC)	4	4	4	100
MPL203T	Principles of Drug Discovery(CC)	4	4	4	100
MPL204T	Clinical research and Pharmacovigilance (CC)	4	4	4	100
MPL205P	Pharmacology Practical-II (CC)	6	3	6	75
MPL206P	Pharmacology Practical-III (CC)	6	3	6	75
MPL207P	Seminar/Assignment(SEC)	6	3	6	75
	Audit courses (Need to choose anyone)				
MPL208A1	Constitution of India				
MPL208A2	Bhagavad-Gita for personality development				
MPL208A3	Water conservation				
MPL208A4	Waste management				
<b>Total</b>		<b>34</b>	<b>25</b>	<b>34</b>	<b>625</b>

**Table-9: Course of study for M.Pharm III. Semester  
(Common for All Specializations)**

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
<b>Semester III</b>					
MRM301T	Research Methodology & IPR (AECC)	4	4	4	100
	<b>Elective (Need to choose anyone)</b>	4	4	4	100
MRM303P	Discussion/Presentation (SEC)	2	2	2	50
MRM304P	Research Work	28	14	14	350
<b>Total</b>		<b>38</b>	<b>24</b>	<b>24</b>	<b>600</b>

CC : Core Course.

AECC : Ability Enhancement Compulsory course.

DSE : Discipline Specific Elective

SEC : Skill Enhancement Course

**Table-10: Course of study for M.Pharm.IV Semester  
(Common for All Specializations)**

Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
MRM401P	Journal Club (SEC)	1	1	1	25
MRM403P	Discussion/Final Presentation (SEC)	3	3	3	75
MRM402P	Research Work	32	16	32	400
<b>Total</b>		<b>36</b>	<b>20</b>	<b>36</b>	<b>500</b>

**Table-11: Extra-curricular and Co-curricular Activities**

S. No.	Name of the Category	Credits
1.	*Add-on Courses-compulsory credit- 1	1
2.	NSS, NCC and other social service activities- Compulsory credit- 1	1
3.	Achievements- Compulsory credits- 3	3
4.	<b>6<sup>th</sup> Credit can be any one of the above</b>	1
	<b>Total</b>	<b>6</b>



**Table–12: Semester wise credits distribution**

<b>Semester</b>	<b>Credit Points</b>
<b>I</b>	<b>25</b>
<b>II</b>	<b>25</b>
<b>III</b>	<b>24</b>
<b>IV</b>	<b>20</b>
<b>Extra-curricular and Co-curricular Activities</b>	<b>06</b>
<b>Total Credit Points</b>	<b>100</b>

**Extra-curricular and Co-curricular Activities: 6 Credits**

### **Rules and Regulations**

#### **Categories**

1. \*Add on courses **(1 credit)**
2. NSS, NCC and other social service activities **(1 credit)**
3. Achievements **(3 credits)**
4. **6<sup>th</sup> credit can be any one of the above.**

#### **1. Add on courses (1 credit Compulsory) (In campus / Off-campus) (Offline/online)**

**One credit** -Each short-term course certificate as per UGC norms for add on courses. (30hrs Duration/8 weeks)

**Two credits**- Diploma course certificate as per UGC norms for add on courses (60hrs Duration/16 weeks)

Other's discretion of Director of Academics/CE/Principal

#### **2. NSS, NCC and other social service activities (1 credit Compulsory)**

(10 hours for one credit. 20 hours for two credits)

#### **Calculation of Hours**

- A. Two Commemoration Day celebrations/Any other day celebration participation=1 hr (i.e., -Independence Day, Republic Day, Gandhi Jayanti, etc)
- B. One Participation in Rally = 2 hrs
- C. For one day camp participation= 3 hrs
- D. One day Yoga/training involving learn and practice participation =2 hrs
- E. One session of Plantation Day- 2 hrs
- F. Donating blood donation at Blood donation camp at college or hospital- 5 hrs (Maximum one per year allowed. Certificate is required in case in outside of the College)

- G. One day participation in Clean India like activities at outside -5 hrs
- H. Three Awareness program participation-1 hr
- I. One Street play performance/flash mob performance -3 hrs
- J. Four audience participation in programs (Discretion of NSS Officer/CE/Principal)- 1 hr
- K. Any performance in any of the events which are not listed here (Discretion of NSS officer/CE/Principal)-2 hrs
- L. One Social service merit certificate (Lion's club/Rotary club/Traffic police/Police Volunteers / Other Govt. Organizations)-1 credit
- M. Other's discretion of NSS officer/CE/Principal

### **3. Achievements (3 credits Compulsory)**

#### **Research Scholar Initiatives**

- A. One Indexed Publications (Scopus/WOS)-1 credit
- B. One Indexed publications (SCI, SCIE) -2 credit
- C. One IPC/equivalent Participation-1 credit
- D. One IPC/equivalent presentation (Oral/Poster)-2 Credits
- E. Local chapters like IPA/ISPOR/RSC publications or presentations-1 credit
- F. One Presentation at seminars/conferences in India-1 credit
- G. One Presentation at seminars/conferences at outside India-2 credits
- H. Two national level Conferences/seminars/workshops Participation -1credit
- I. One International Level Conferences/seminars/workshops Participation at India – 1credit
- J. One International Conferences/seminars/workshops Participation at outside India -2 credit
- K. Other's discretion of R&D Director/CE/Principal

#### **Certificates for Achievements (Sports/cultural/others)**

- A. One National/State/District/University level certificate-2 credits (winner/runner)
- B. One National/State/District/University level certificate-1 credit (only when Participation certificate received)
- C. One Non-government/affiliated institution Merits/own institute level certificate 1 Credit (winner/runner)
- D. Other's discretion of NSS officer/CE/Principal

Note: International Conference: Held outside India International Journal: The Editorial Board outside India

\*The credit points assigned for extracurricular and or co-curricular activities shall be given by the principal of the college and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

#### **Evaluation of course**

Report must be submitted by the student to the department guide, which shall be forwarded to the external evaluator

### **11. Program Committee**

1. The M.Pharm. Programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:  
A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:
  - Periodically reviewing the progress of the classes.
  - Discussing the problems concerning curriculum, syllabus, and the conduct of classes.
  - Discussing with the course teachers on the nature and scope of assessment for the Course and the same shall be announced to the student's at the beginning of respective Semesters.
  - Communicating its recommendation to the Head of the institution on academic matters.
  - The Programme Committee shall meet at least twice in a semester preferably at the End of each sessional exam

### **12. Examinations/Assessments**

The schemes for internal assessment and end semester examinations are given in Table—16.

#### **12.1. End semester examinations**

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the institution.

Tables–13: Schemes for internal assessments and end semester examinations  
(Pharmaceutics-MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Contin uous Mode	Sessional Exams		To tal	Ma rks	Dura tion	
			Ma rks	Dura tion				
SEMESTER I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPH102T	Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
MPH103T	Modern Pharmaceutics	10	15	1Hr	25	75	3Hrs	100
MPH104T	Regulatory Affair	10	15	1Hr	25	75	3Hrs	100
MPH105P	Modern Pharmaceutical Analytical Techniques- practical	10	15	6Hrs	25	50	6hrs	75
MPH106P	Pharmaceutics Practical-I	10	15	6Hrs	25	50	6hrs	75
MPH107S	Seminar/Assignment	-	-	-	-	-	-	75
	*Audit course							
MPH108A1	Yoga and stress management							
MPH108A2	Disaster management							
MPH108A3	Green initiatives							
MPH108A4	Human rights and responsibilities							
Total								625

<b>SEMESTER II</b>								
<b>MPH201T</b>	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1Hr	25	75	3Hrs	100
<b>MPH202T</b>	Advanced Biopharmaceutics& Pharmacokinetics	10	15	1Hr	25	75	3Hrs	100
<b>MPH203T</b>	Computer Aided Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
<b>MPH204T</b>	Cosmetic and Cosmeceuticals	10	15	1Hr	25	75	3Hrs	100
<b>MPH205P</b>	Pharmaceutics Practical-II	10	15	6Hrs	25	50	6Hrs	75
<b>MPH206P</b>	Pharmaceutics Practical-III	10	15	6Hrs	25	50	6Hrs	75
<b>MPH207S</b>	Seminar/Assignment	-	-	-	-	-	-	75
	<b>*Audit course</b>							
<b>MPH208A1</b>	Constitution of India							
<b>MPH208A2</b>	Bhagavad-Gita for personality development							
<b>MPH208A3</b>	Water conservation							
<b>MPH208A4</b>	Waste management							
							Total	625

Tables–14: Schemes for internal assessments and end semester examinations (Industrial Pharmacy- MIP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MIP101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MIP102T	Pharmaceutical Formulation Development	10	15	1Hr	25	75	3Hrs	100
MIP103T	Novel drug delivery systems	10	15	1Hr	25	75	3Hrs	100
MIP104T	Intellectual Property Rights	10	15	1Hr	25	75	3Hrs	100
MIP105P	Modern Pharmaceutical Analytical Techniques-practical	10	15	6Hrs	25	50	6hrs	75
MIP106P	Industrial Pharmacy-practical-I	10	15	6Hrs	25	50	6hrs	75
MIP107S	Seminar /Assignment	-	-	-	-	-	-	75
	*Audit course(Need to choose anyone)							
MIP108A1	Yoga and stress management							
MIP108A2	Disaster management							
MIP108A3	Green initiatives							
MIP108A4	Human rights and responsibilities							
Total								625

<b>SEMESTER II</b>								
<b>MIP201T</b>	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1Hr	25	75	3Hrs	100
<b>MIP202T</b>	Scale up and Technology Transfer	10	15	1Hr	25	75	3Hrs	100
<b>MIP203T</b>	Pharmaceutical Production Technology	10	15	1Hr	25	75	3Hrs	100
<b>MIP204T</b>	Entrepreneurship Management	10	15	1Hr	25	75	3Hrs	100
<b>MIP205P</b>	Industrial Pharmacy-practical-II	10	15	6Hrs	25	50	6Hrs	75
<b>MIP206P</b>	Industrial Pharmacy-practical-III	10	15	6Hrs	25	50	6Hrs	75
<b>MIP207S</b>	Seminar /Assignment	-	-	-	-	-	-	75
	<b>*Audit course</b> (Need to choose anyone)							
<b>MIP208A1</b>	Constitution of India							
<b>MIP208A2</b>	Bhagavad-Gita for personality development							
<b>MIP208A3</b>	Water conservation							
<b>MIP208A4</b>	Waste management							
							Total	625

Tables-15: Schemes for internal assessments and end semester examinations  
(Pharmaceutical Chemistry-MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPC101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPC102T	Advance Organic Chemistry-1	10	15	1Hr	25	75	3Hrs	100
MPC103T	Advance Medicinal Chemistry	10	15	1Hr	25	75	3Hrs	100
MPC104T	Chemistry of Natural Products	10	15	1Hr	25	75	3Hrs	100
MPC105P	Modern Pharmaceutical Analytical Techniques-practical	10	15	6Hrs	25	50	6hrs	75
MPC106P	Pharmaceutical Chemistry Practical- I	10	15	6Hrs	25	50	6hrs	75
MPC107S	Seminar/Assignment	-	-	-	-	-	-	75
	*Audit course							
MPC108A1	Yoga and stress management							
MPC108A2	Disaster management							
MPC108A3	Green initiatives							
MPC108A4	Human rights and responsibilities							
Total								625



<b>SEMESTER II</b>								
<b>MPC201T</b>	Advance spectral analysis	10	15	1Hr	25	75	3Hrs	100
<b>MPC202T</b>	Advanced Organic Chemistry- II	10	15	1Hr	25	75	3Hrs	100
<b>MPC203T</b>	Computer Aided Drug Design	10	15	1Hr	25	75	3Hrs	100
<b>MPC204T</b>	Pharmaceutical Process Chemistry	10	15	1Hr	25	75	3Hrs	100
<b>MPC205P</b>	Pharmaceutical Chemistry Practical- II	10	15	6Hrs	25	50	6Hrs	75
<b>MPC206P</b>	Pharmaceutical Chemistry Practical- III	10	15	6Hrs	25	50	6Hrs	75
<b>MPC207S</b>	Seminar/Assignment	-	-	-	-	-	-	75
	<b>*Audit course</b>							
<b>MPC208A1</b>	Constitution of India							
<b>MPC208A2</b>	Bhagavad-Gita for personality development							
<b>MPC208A3</b>	Water conservation							
<b>MPC208A4</b>	Waste management							
							Total	625

Tables–16: Schemes for internal assessments and end semester examinations (Pharmaceutical Analysis-MPA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1Hr	25	75	3Hrs	100
MPA103T	Quality Control And Quality Assurance	10	15	1Hr	25	75	3Hrs	100
MPA104T	Food Analysis	10	15	1Hr	25	75	3Hrs	100
MPA105P	Modern Pharmaceutical Analytical Techniques Lab	10	15	6Hrs	25	50	6hrs	75
MPA106P	Pharmaceutical Analysis Practical- I	10	15	6Hrs	25	50	6hrs	75
MPA107S	Seminar/Assignment	-	-	-	-	-	-	75
	*Audit course(Need to choose anyone)							
MPA108A1	Yoga and stress management							
MPA108A2	Disaster management							
MPA108A3	Green initiatives							
MPA108A4	Human rights and responsibilities							
Total								625

<b>SEMESTER II</b>								
<b>MPA201T</b>	Advanced Instrumental Analysis	10	15	1Hr	25	75	3Hrs	100
<b>MPA202T</b>	Modern Bio-Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
<b>MPA203T</b>	Pharmaceutical Validation	10	15	1Hr	25	75	3Hrs	100
<b>MPA204T</b>	Herbal and Cosmetic Analysis	10	15	1Hr	25	75	3Hrs	100
<b>MPA205P</b>	Pharmaceutical Analysis Practical- II	10	15	6Hrs	25	50	6Hrs	75
<b>MPA206P</b>	Pharmaceutical Analysis Practical- III	10	15	6Hrs	25	50	6Hrs	75
<b>MPA207S</b>	Seminar/Assignment	-	-	-	-	-	-	75
	<b>*Audit course</b> (Need to choose anyone)							
<b>MPA208A1</b>	Constitution of India							
<b>MPA208A2</b>	Bhagavad-Gita for personality development							
<b>MPA208A3</b>	Water conservation							
<b>MPA208A4</b>	Waste management							
							Total	625

Tables–17: Schemes for internal assessments and end semester examinations  
(Pharmaceutical Quality Assurance-MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuo us Mode	Sessional Exams		Tot al	Mar ks	Durati on	
			Mar ks	Durati on				
SEMESTER I								
MQA101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MQA102T	Quality Management system	10	15	1Hr	25	75	3Hrs	100
MQA103T	Quality Control And Quality Assurance	10	15	1Hr	25	75	3Hrs	100
MQA104T	Product development and Technology transfer	10	15	1Hr	25	75	3Hrs	100
MQA105P	Modern Pharmaceutical Analytical Techniques Lab	10	15	6Hrs	25	50	6hrs	75
MQA106P	Pharmaceutical Quality Assurance Practical-I	10	15	6Hrs	25	50	6hrs	75
MQA107S	Seminar/Assign ment	-	-	-	-	-	-	75
	*Audit course(Need to choose anyone)							
MQA108A1	Yoga and stress management							
MQA108A2	Disaster management							
MQA108A3	Green initiatives							
MQA108A4	Human rights and responsibilities							
Total								625

<b>SEMESTER II</b>								
<b>MQA201T</b>	Hazard and safety Management	10	15	1Hr	25	75	3Hrs	100
<b>MQA202T</b>	Pharmaceutical Manufacturing Technology	10	15	1Hr	25	75	3Hrs	100
<b>MQA203T</b>	Pharmaceutical validation	10	15	1Hr	25	75	3Hrs	100
<b>MQA204T</b>	Audits and Regulatory Compliance	10	15	1Hr	25	75	3Hrs	100
<b>MQA205P</b>	Pharmaceutical Quality Assurance Practical-II	10	15	6Hrs	25	50	6Hrs	75
<b>MQA206P</b>	Pharmaceutical Quality Assurance Practical-III	10	15	6Hrs	25	50	6Hrs	75
<b>MQA207S</b>	Seminar/Assignment	-	-	-	-	-	-	75
	<b>*Audit course</b> (Need to choose anyone)							
<b>MQA208A1</b>	Constitution of India							
<b>MQA208A2</b>	Bhagavad-Gita for personality development							
<b>MQA208A3</b>	Water conservation							
<b>MQA208A4</b>	Waste management							
							Total	625

Tables–18: Schemes for internal assessments and end semester examinations (Pharmacy Practice - MPP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPP101T	Clinical Pharmacy Practice	10	15	1Hr	25	75	3Hrs	100
MPP102T	Pharmacotherapeutics I	10	15	1Hr	25	75	3Hrs	100
MPP103T	Hospital and Community Pharmacy	10	15	1Hr	25	75	3Hrs	100
MPP104T	Clinical Research	10	15	1Hr	25	75	3Hrs	100
MPP105P	Pharmacy Practice practical-I	10	15	6Hrs	25	50	6hrs	75
MPP106P	Pharmacy Practice practical-II	10	15	6Hrs	25	50	6hrs	75
MPP107S	Seminar/Assignment	-	-	-	-	-	-	75
	*Audit course(Need to choose anyone)							
MPP108A1	Yoga and stress management							
MPP108A2	Disaster management							
MPP108A3	Green initiatives							
MPP108A4	Human rights and responsibilities							
Total								625

<b>SEMESTER II</b>								
MPP201T	Principles of Quality Use of Medicines	10	15	1Hr	25	75	3Hrs	100
MPP202T	Pharmacotherapeutics II	10	15	1Hr	25	75	3Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1Hr	25	75	3Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1Hr	25	75	3Hrs	100
MPP205P	Pharmacy Practice practical-III	10	15	6Hrs	25	50	6Hrs	75
MPP206P	Pharmacy Practice practical-IV	10	15	6Hrs	25	50	6Hrs	75
MPP207S	Seminar/Assignment	-	-	-	-	-	-	75
	*Audit course (Need to choose anyone)							
MPP208A1	Constitution of India							
MPP208A2	Bhagavad-Gita for personality development							
MPP208A3	Water conservation							
MPP208A4	Waste management							
							Total	625

Tables–19: Schemes for internal assessments and end semester examinations (Pharmacology - MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPL 102T	Advanced Pharmacology-I	10	15	1Hr	25	75	3Hrs	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I	10	15	1Hr	25	75	3Hrs	100
MPL 104T	Cellular and Molecular Pharmacology	10	15	1Hr	25	75	3Hrs	100
MPL105P	Modern Pharmaceutical Analytical Techniques Practical	10	15	6Hrs	25	50	6hrs	75
MPL 106P	Pharmacology practical-I	10	15	6Hrs	25	50	6hrs	75
MPL107P	Seminar/Assignment	-	-	-	-	-	-	75
	*Audit course(Need to choose anyone)							
MPL108A1	Yoga and stress management							
MPL108A2	Disaster management							
MPL108A3	Green initiatives							
MPL108A4	Human rights and responsibilities							
Total								625



<b>SEMESTER II</b>								
MPL201T	Advanced Pharmacology II	10	15	1Hr	25	75	3Hrs	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	10	15	1Hr	25	75	3Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1Hr	25	75	3Hrs	100
MPL204T	Clinical research and Pharmacovigilance	10	15	1Hr	25	75	3Hrs	100
MPL205P	Pharmacology practical-II	10	15	6Hrs	25	50	6Hrs	75
MPL206P	Pharmacology practical-III	10	15	6Hrs	25	50	6Hrs	75
MPL207P	Seminar/Assignment	-	-	-	-	-	-	75
	<b>*Audit course</b> (Need to choose anyone)							
MPL208A1	Constitution of India							
MPL208A2	Bhagavad-Gita for personality development							
MPL208A3	Water conservation							
MPL208A4	Waste management							
							Total	<b>625</b>

Tables–20: Schemes for internal assessments and end semester examinations (SemesterIII)  
(Common for all specializations)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM301T	Research Methodology & IPR	10	15	1Hr	25	75	3Hrs	100
	Elective	10	15	1Hr	25	75	3Hrs	100
MRM303P	Discussion /Presentation(Proposal Presentation)	-	-	-	50	-	-	50
MRM304P	Research work*	-	-	-	-	350	1Hr	350
Total								600

Tables–21: Schemes for internal assessments and end semester examinations (SemesterIII)  
(Electives)

**Pharmaceutics**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
	Elective (Need to choose anyone)	10	15	1Hr	25	75	3Hrs	100
MPH302E1	Biological Screening methods							
MPH302E2	Quality by Design in formulation development							
MPH302E3	Scientific writing							

Tables–22: Schemes for internal assessments and end semester examinations (SemesterIII)  
(Electives)

**Industrial Pharmacy**

Course Code	Course	Internal Assessment				End Exams	Semester	Total Marks
		Continuo us Mode	Sessional Exams		Tota l	Mark s	Duratio n	
			Mark s	Duratio n				
SEMESTER III								
	Elective (Need to choose anyone)	10	15	1Hr	25	75	3Hrs	100
MIP302E1	Biological Screening methods							
MIP302E2	Quality by Design in formulation developme nt							
MIP302E3	Scientific writing							

Tables–23: Schemes for internal assessments and end semester examinations (Semester III)  
(Electives)

**Pharmaceutical Analysis**

Course Code	Course	Internal Assessment				End Exams	Semester	Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
	Elective (Need to choose anyone)	10	15	1Hr	25	75	3Hrs	100
MPA302E1	Biological Screening methods							
MPA302E2	Analytical QbD							
MPA302E3	Scientific writing							

Tables–24: Schemes for internal assessments and end semester examinations (Semester III)  
(Electives)

**Pharmaceutical Quality Assurance**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
	Elective (Need to choose anyone)	10	15	1Hr	25	75	3Hrs	100
MQA302E1	Biological Screening methods							
MQA302E2	Analytical QbD							
MQA302E3	Scientific writing							

Tables–25: Schemes for internal assessments and end semester examinations (Semester III)  
(Electives)

**Pharmacology**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
	Elective (Need to choose anyone)	10	15	1Hr	25	75	3Hrs	100
MPL302E1	Clinical Pharmacokinetics and Therapeutic Drug Monitoring							
MPL302E2	Clinical pharmacy practice							
MPL302E3	Scientific writing							

Tables–26: Schemes for internal assessments and end semester examinations (Semester III)  
(Electives)

**Pharmacy Practice**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Mark s	Duration				
SEMESTER III								
	Elective (Need to choose anyone)	10	15	1Hr	25	75	3Hrs	100
MPP302E1	Biological Screening Methods							
MPP302E2	Entrepreneurship Management							
MPP302E3	Scientific writing							

Tables–27: Schemes for internal assessments and end semester examinations (Semester III)  
(Electives)

**Pharmaceutical Chemistry**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
	Elective to choose anyone)	10	15	1Hr	25	75	3Hrs	100
MPC302E1	Biological Screening methods							
MPC302E2	Quality by Design in pharmaceutical chemistry							
MPC302E3	Scientific writing							

Tables–28: Schemes for internal assessments and end semester examinations (Semester IV)  
(Common for all specializations)

<b>SEMESTER IV</b>								
MRM401P	Journal club	-	-	-	25	-	-	25
MRM402P	Discussion /Presentation(Proposal Presentation)	-	-	-	75	-	-	75
MRM403P	Research work and Colloquium	-	-	-	-	400	1Hr	400
<b>Total</b>								<b>500</b>

**\*Non-University Examination**

**12.2 Internal assessment: Continuous mode**

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table–29: Scheme for awarding internal exam (Theory)

<b>I mid exam</b>	<b>Marks</b>	<b>II Mid exam</b>	<b>Marks</b>
Conducted for 30M reduced to 15M	15	Conducted for 30M reduced to 15M	15
Note: 80% marks from the better exam and 20% from the other.			
Continuous assessment (Group discussion 5M: Problem solving 5M)			10
<b>Total</b>			<b>25M</b>

Table– 30:Scheme for awarding internal exam (Practical)

<b>I mid exam</b>	<b>Marks</b>	<b>II Mid exam</b>	<b>Marks</b>
Conducted for 30M reduced to 15M	15	Conducted for 30M reduced to 15M	15
Note: 80% marks from the better exam and 20% from the other.			
Continuous assessment (viva 5M: Problem solving 5M)			10
<b>Total</b>			<b>25M</b>

### **12.3. Internal exams (Theory)**

The following pattern shall be followed in the internal Examination (theory):

- 10 MCQs all to be answered in PART-A (Each of 1M) **-10M**
- 2 questions to be answered from a set of 3 questions in PART-B (Each of 10M)-**20M**

### **12.4. Internal exams (Practical)**

The following pattern shall be followed in the internal Examination (Practical): **30M**

- Synopsis 5M
- Minor experiment 8M
- Major experiment 12M
- Viva & record 5M

### **12.5. End exams (Theory)**

The following pattern shall be followed in the End Examination:

- 5 questions to be answered from a set of 7 questions in PART-A (Each of 5M)-**25M**
- 5 questions to be answered from a set of 8 questions in PART-B (Each of 10M)-**50M**

### **12.6. End exams (Practical)**

The following pattern shall be followed in the end Examination (Practical): **-50M**

- Synopsis 10M
- Minor experiment 10M
- Major experiment 20M
- Viva & record 10M

## **13. Promotion and award of grades**

A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 50% of marks in End Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together.

In case the candidate does not secure the minimum academic requirement in any of the Subjects he/she must reappear for the Semester Examination either supplementary or Regular in that subject or repeat the course when next offered or do any other specified Subject as may be required.

## **14. Carry forward of marks**

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However, his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

### **15. Improvement of internal assessment**

A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and has failed in the end examination

- The candidate should have passed all the subjects for which the Internal Evaluation marks secured are more than 50%. Out of the subjects, if the candidate has failed in the examination due to Internal Evaluation marks secured being less than 50%, the candidate shall be given one chance for each Theory subject and for a maximum of **three** Theory subjects for Improvement of Internal evaluation marks.
- The candidate has to re-register for the chosen subjects and fulfill the academic requirements.
- For registration the candidates must apply to the college by paying the requisite fees and get approval before the start of the semester in which re-registration is required
- In the event of availing the Improvement of Internal evaluation marks, the internal evaluation marks as well as the End Examinations marks secured in the previous attempt(s) for the reregistered subjects stand cancelled.

### **16. Advanced supply examination**

Advanced supply examination shall be conducted for the failed students. The exact dates of examinations shall be notified from time to time immediately after the release of semester end regular examinations results.

17. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II. Semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

### **18. Grading of performances**

#### **18.1. Letter grades and grade points allocations:**

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table — 32.



## 18.2. Structure of Grading of Academic Performance

**Table-31: Grading point assigned**

Range in which the marks in the subject fall	Grade	Grade points Assigned
$\geq 90$	S (Superior)	10
$\geq 80 < 90$	A (Excellent)	9
$\geq 70 < 80$	B (Very Good)	8
$\geq 60 < 70$	C (Good)	7
$\geq 50 < 60$	D (Pass)	6
$< 50$	F (Fail)	0
Absent	Ab (Absent)	0

- A student obtaining Grade 'F' or Grade 'Ab' in a subject shall be considered failed and will be required to reappear for that subject when it is offered the next supplementary examination.
- For noncredit \*Audit courses, "Satisfactory" or "Unsatisfactory" shall be indicated instead of the letter grade and this will not be counted for the computation of SGPA/CGPA.

### 19. The Semester grade point average(SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then

Students' SGPA is equal to:

$$\text{SGPA} = \frac{C1G1 + C2G2 + C3G3 + C4G4}{C1 + C2 + C3 + C4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example, if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$\text{SGPA} = \frac{C1G1 + C2G2 + C3G3 + C4 * \text{ZERO}}{C1 + C2 + C3 + C4}$$

### 20. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s)

is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA.

Shall only reflect the new grade and not the failure grades earned earlier. The CGPA is calculated as:

$$CGPA = \frac{C1S1 + C2S2 + C3S3 + C4S4}{C1 + C2 + C3 + C4}$$

Where C1, C2, C3, .... Is the total number of credits for semester I, II, III.... and S1, S2, S3,....is the SGPA of semester I,II,III,....

## 21. Declaration of class

After a student has satisfied the requirements prescribed for the completion of the program and is eligible for the award of M. Pharm. Degree, he shall be placed in one of the following four classes:

Class Awarded	Percentage of Marks to be secured
First Class with Distinction	$\geq 70\%$
First Class	$< 70\% \geq 60\%$
Pass Class	$< 60\% \geq 50\%$

## 22. Evaluation of Project/Dissertation Work:

The Project work shall be initiated at the beginning of the III Semester and the duration of the Project is of two semesters. Evaluation of Project work is for 400 marks with 250 marks for internal evaluation and 150 marks for external evaluation.

A Project Review Committee (PRC) shall be constituted with the Head of the Department as Chairperson, Project Supervisor and one senior faculty member of the department offering the M. Pharm. programme.

- Registration of Project Work: A candidate is permitted to register for the Project Work in III Semester after satisfying the attendance requirement in all the subjects, both theory and laboratory (in I & II semesters).
- The Project work shall be initiated at the beginning of the III Semester and the duration of the Project is of two semesters.
- A candidate is permitted to submit Project dissertation with the approval of PRC.
- The candidate must pass all the theory, practical and other courses before submission of the dissertation.
- Continuous assessment of Project Work - I and Project Work – II during the

Semester(s) will be monitored by the PRC.

- The candidate shall submit status report by giving seminars in three different phases (Two in III semester and one in IV semester) during the project work period. These seminar reports must be approved by the PRC before submission of the Project dissertation.
- After registration, a candidate must present in Project Work Review - I, in consultation with his Project Supervisor, the title, objective, and plan of action of his Project work to the PRC for approval within four weeks from the commencement of III Semester.
- Only after obtaining the approval of the PRC can the student initiate the project work.
- The Supervisor and PRC will examine the Problem Definition, Objectives,
- Scope of Work, Literature Survey in the same domain and progress of the Project Work.
- A candidate must secure a minimum of 50% of marks to be declared successful in Project Work Review - II. Only after successful completion of Project Work
- Review – II, candidate shall be permitted for Project Work Review – III in IV Semester. The unsuccessful students in Project Work Review - II shall reappear for it at the time of subsequent Project Work Reviews as and when conducted.
- The Project Work Review - III in IV semester carries 100 internal marks.
- Evaluation should be done by the PRC for 50 marks and the Supervisor will evaluate it for the other 50 marks. The PRC will examine the overall progress of the Project Work and decide whether eligible for final submission.
- A candidate must secure a minimum of 50% of marks to be declared successful in Project Work Review - III. If he fails to obtain the required minimum marks, he must reappear for Project Work Review - III after a month.
- For the approval of PRC, the candidate shall submit the draft copy of dissertation to the Head of the Department and make an oral presentation before the PRC.
- After approval from the PRC, a soft copy of the dissertation should be submitted for Plagiarism check and the plagiarism report should be included in the final dissertation.
- The dissertation will be accepted for submission if the similarity index is less than 30%.
- If the similarity index has more than the required percentage, the student is advised to modify accordingly and re-submit the soft copy of the dissertation.
- After successful plagiarism check three copies of the dissertation certified by the supervisor and HOD shall be submitted to the college.
- The dissertation shall be adjudicated by an external examiner selected by the Institution. For this, the HOD of the concerned department shall submit a panel of three examiners. However, the dissertation will be adjudicated by one examiner nominated by the principal.
- If the report of the examiner is not satisfactory, the candidate shall revise and resubmit the dissertation, in the time frame as decided by the PRC. If the report of the examiner is unfavorable again, the dissertation shall be summarily rejected. The

candidate must reregister for the project and complete the project within the stipulated time after taking the approval from the institute.

- If the report of the examiner is satisfactory, the Head of the Department shall coordinate and decide for the conduct of Project Viva-Voce examination.
- The Project Viva-Voce examinations shall be conducted by a board consisting of the Supervisor, Head of the Department and the external examiner who adjudicated the dissertation.
- If he fails to fulfill the requirements as specified, he will reappear for the Project
- Viva-Voce examination only after three months. In the reappeared examination also, if he fails to fulfill the requirements, he will not be eligible for the award of the degree.

### **23. Evaluation of Extracurricular and co curricular activities**

The external examiner appointed for the Project evaluation must check the genuineness of the certificates provided for attainment of 6 credits for Extracurricular and co curricular activities.

### **24. Award of Ranks**

Ranks and Medals shall be awarded based on final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

### **25. Award of degree**

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

### **26. Duration for completion of the program of study**

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students must pass within the said period, otherwise they have to get fresh Registration.

### **27. Revaluation/Re totaling of answer papers**

The candidate's can apply for revaluation /re totaling by paying prescribed fee.

### **28. Re-admission after break of study**

Candidate who seeks re-admission to the program after break of study has to get the approval from the institute by paying a condonation fee.

## 29. Rules for disciplinary action for malpractices / improper conduct in examinations

	<b>Nature of Malpractices/Improper conduct</b>	<b>Punishment</b>
	If the candidate:	
1.(a)	Possesses or keeps accessible in examination hall, any paper, note-book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The Hall Ticket of the candidate is to be cancelled.

3.	<p>Impersonates any other candidate in connection with</p> <p>The examination.</p>	<p>The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred for four consecutive semesters from class work and all examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the subjects of the examination (including practical's and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for four consecutive semesters from class work and all examinations if his involvement is established. Otherwise, the candidate is debarred for two consecutive semesters from class work and all examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.</p>
4.	<p>Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.</p>	<p>Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.</p>
5.	<p>Uses objectionable, abusive, or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.</p>	<p>Cancellation of the performance in that subject only.</p>
6.	<p>Refuses to obey the orders of the Chief Superintendent /Assistant - Superintendent /any officer on duty or misbehaves or creates disturbance of any kind in and around the examination</p>	<p>In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared</p>

	hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. If the candidate physically assaults the invigilator/ officer-in-charge of the Examinations, then the candidate is also debarred and forfeits his/her seat. In case of outsiders, they will be handed over to the police and a police case is registered against them.
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
9.	If student, who is not a candidate for the particular examination, or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The

		candidate is also debarred and forfeits the seat. Person (s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.
11.	Copying detected based on internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject only or in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester / year examinations, depending on the recommendation of the committee.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the institute for further action to award suitable punishment.	

1. Malpractices identified by squad or special invigilators
2. Punishments to the candidates as per the above guidelines.

**Note:**

Whenever the performance of a student is cancelled in any subject/subjects due to Malpractice, he must register for End Examinations in that subject/subjects consequently and must fulfill all the norms required for the award of Degree.



# **PHARMACEUTICS**

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MPH101T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description**

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

#### **Course Outcomes:**

C101.1	Discuss the principle of various modern analytical technique involved in the analysis of drugs using spectroscopy, chromatography, electrophoresis, x-ray methods.
C101.2	Apply the modern analytical techniques in the identification and quantification of drugs in dosage forms.
C101.3	Interpret the analytical data and spectral data to draw the conclusion of quality of pharmaceuticals.

#### **THEORY**

**60 hours**

<b>1</b>	<p>a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.</p> <p>b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.</p> <p>c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.</p> <p>d. Flame emission spectroscopy and Atomic absorption spectroscopy:</p>	<b>10hrs</b>
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	Principle, Instrumentation, Interferences and Applications.	
<b>2</b>	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup> C NMR. Applications of NMR spectroscopy.	<b>10hrs</b>
<b>3</b>	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	<b>10hrs</b>
<b>4</b>	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: <ul style="list-style-type: none"> <li>• Thin Layer chromatography</li> <li>• High Performance Thin Layer Chromatography</li> <li>• Ion exchange chromatography</li> <li>• Column chromatography</li> <li>• Gas chromatography</li> <li>• High Performance Liquid chromatography</li> <li>• Ultra High Performance Liquid chromatography</li> <li>• Affinity chromatography</li> <li>• Gel Chromatography</li> </ul>	<b>10hrs</b>
<b>5</b>	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: <p>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing</p> <p>b. X ray Crystallography: Production of X rays, Different X ray methods,</p>	<b>10hrs</b>

	Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	
<b>6</b>	<p>a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.</p> <p>b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.</p>	<b>10hrs</b>

#### REFERENCES

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<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Drug Delivery Systems</b>
<b>Course Code</b>	<b>MPH102T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description**

This course is designed to impart knowledge on the area of Sustained, and control delivery systems. It imparts students with knowledge on various polymers used in Sustained, and control delivery. This course also adds note on personalised medicines, advances in novel drug delivery systems.

#### **Course outcome**

At the end of the theory course, the student will be able to

C102.1	Discuss the various approaches for development of novel drug delivery systems.
C102.2	Identify the criteria for selection of drugs and polymers for the development of delivering system.
C102.3	Design and evaluation of Novel drug delivery systems.

#### **THEORY**

**60 hours**

<b>1</b>	Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine. Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	<b>10hrs</b>
<b>2</b>	Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems: Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals	<b>10 hrs</b>
<b>3</b>	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	<b>10hrs</b>
<b>4</b>	Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	<b>6 hrs</b>
<b>5</b>	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation, and evaluation. Implants: Formulation consideration and Evaluation	<b>10hrs</b>
<b>6</b>	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	<b>8hrs</b>
<b>7</b>	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	<b>6hrs</b>

## REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutics-Theory</b>
<b>Course Code</b>	<b>MPH103T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course Description

The Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries.

### Course outcome

At the end of the theory course, the student will be able to

C103.1	List the elements of preformulation studies.
C103.2	Enumerate the process of Generic drug Product development
C103.3	Demonstrate Industrial Management and GMP Considerations.
C103.4	Explain optimization techniques & Pilot Plant Scale Up techniques
C103.5	Explain stability Testing, sterilization process & packaging of dosage forms

### Course Content

**60 hours**

<b>1</b>	a. Preformation Concepts – Drug Excipient interactions -different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS), Concepts of preformulation in parenteral products	<b>10hrs</b>
<b>2</b>	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot	<b>15 hrs</b>
<b>3</b>	Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs, and application in formulation	<b>15 hrs</b>
<b>4</b>	Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipment, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	<b>10 hrs</b>
<b>5</b>	CGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment, and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	<b>10hrs</b>

## REFERENCES

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred Martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.



<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Regulatory Affairs Theory</b>
<b>Course Code</b>	<b>MPH104T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course Description

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

### Course outcomes:

C104.1	Discuss the concepts of innovator and generic drugs in drug development process
C104.2	Analyze the post approval regulatory requirements for actives and drug products and submission of global documents in Common Technical Document / eCTD formats
C104.3	Identify regulatory procedures involved in non-clinical and clinical drug development
C104.4	Apply the principles of regulatory affairs in drug development process, filing and approval, non-clinical and clinical drug development in global scenario

### Course Content

**60 hours**

<b>1</b>	a. Documentation in Pharmaceutical industry: Masterformula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	<b>12hrs</b>
<b>2</b>	CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry, and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	<b>12 hrs</b>
<b>3</b>	Nonclinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD)and investigator brochure (IB).	<b>12hrs</b>
<b>4</b>	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. Recent developments and amendments in clinical trials rules & regulations. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. Medical devices-Regulatory Considerations	<b>12 hrs</b>

## References

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargeland IsaderKaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R.Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons, Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
7. [www.ich.org/](http://www.ich.org/)
8. [www.fda.gov/](http://www.fda.gov/)
9. [europa.eu/index\\_en.htm](http://europa.eu/index_en.htm)
10. <https://www.tga.gov.au/tga-basics>

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MPH105P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

At the end of the practical course of experiments, the student will be able to

C105.1	Demonstrate the skill to adopt standard operating procedure to handle modern analytical technique like spectroscopy, chromatography, electrophoresis, x-ray methods.
C105.2	Conduct experiments using modern analytical techniques for the analysis of dosage forms.
C105.3	Elucidate the chemical structure from the spectral data by applying the principles of spectroscopy.

## PRACTICALS

1. Calibration of glass wares as per I.P
2. Calculation of dilution and dilution factor
3. Construction of Linear curve and determination of Regression co efficient.
4. Study of auxo-chrome effect by UV-Visible spectrum
5. Assay of Metformin tablets by A (1%, 1 cm) method as per IP 2014
6. Assay of Ciprofloxacin injection using ferric chloride by Colorimetric method
7. Assay of Riboflavin tablets by Fluorimetry
8. Assay of FDC using simultaneous method by UV Spectrophotometer in drug dosage form
9. Identification of substance by IR and UV spectrum
10. Assay of caffeine by RP-HPLC method (Calibration curve method)
11. Determination of composition of volatile oil (lemon oil/ cinnamon oil) by GC (area normalization method)
12. Calculation of system suitability parameters for HPLC chromatograph
13. Determination of R<sub>f</sub>, R<sub>m</sub>, R<sub>x</sub> value for amino-acids /sugars/ analogue by PC/TLC
14. Isolation of  $\beta$ -carotene by preparative TLC method
15. Experiments on column packing and elution (Demo)
16. Workshop on Spectral interpretation (IR and <sup>1</sup>H NMR)
17. Problem based exercise /Revision (Woodward Fieser rule)

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Pharmaceutics-Practical-I (MPH 106P)</b>
<b>Course Code</b>	<b>MPH106P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

1. To carry out preformulation studies
2. To study the effect of compressional force on tablets disintegration time.
3. To study Micromeritic properties of powders and granulation.
4. To study the effect of particle size on dissolution of a tablet.
5. To study the effect of binders on dissolution of a tablet.
6. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of transdermal patches.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Molecular Pharmaceutics (Nano Technology &amp; Targeted DDS) (NTDS)</b>
<b>Course Code</b>	<b>MPH201T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description**

This course is designed to impart knowledge on the area of advances in novel drug delivery systems, their formulation, evaluation, and applications. The course also allows students to extend their knowledge in various approaches for development of novel drug delivery systems and criteria for selection of drugs and polymers for the development of Novel drug delivery systems and Targeted drug delivery systems.

#### **Course outcomes**

At the end of the theory course, the student will be able to

C201.1	Explain the various approaches for development of novel drug delivery systems.
C201.2	Identify the criteria for selection of Polymer for the development of Novel targeted drug delivering systems.
C201.3	Discuss the formulation and evaluation of novel & targeted drug delivery systems.

#### **Course Content**

**60 hours**

<b>1</b>	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	<b>12hrs</b>
<b>2</b>	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation, and evaluation.	<b>12 hrs</b>
<b>3</b>	Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation, and application of Niosomes, Aquasomes, Phytosomes, Electrosomes	<b>12hrs</b>
<b>4</b>	Pulmonary Drug Delivery Systems: Aerosols, propellents, Container Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation, and evaluation.	<b>12 hrs</b>
<b>5</b>	Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene delivery systems (viral and nonviral gene vectors). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics knowledge of therapeutic antisense molecules and aptamers as drugs of future.	<b>12hrs</b>

#### **References:**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors New Delhi, First edition 1997 (reprint in 2001).
4. Saltzman WM. Drug delivery: engineering principles for drug therapy. Oxford University Press; 2001.
5. Wang B, Hu L, Siahaan TJ. Drug delivery: principles and applications. John Wiley & Sons; 2016 Mar 9.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Advanced Biopharmaceutics &amp; Pharmacokinetics</b>
<b>Course Code</b>	<b>MPH202T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course Description

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

### Course outcome

At the end of the theory course, the student will be able to

CO201.1	Explain the basic concepts in Biopharmaceutics and pharmacokinetics.
CO201.2	Demonstrated use of raw data and derive the pharmacokinetic models and parameters the best describes the process of drug absorption, distribution, metabolism and elimination.
CO201.3	Evaluate Biopharmaceutics studies involving drug product equivalency.
CO201.4	Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutical parameters
CO201.5	Application of basics of pharmacokinetics to solve clinical pharmacokinetic problems

### Course Content

**60 hours**

<b>1</b>	Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup, and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	<b>12hrs</b>
<b>2</b>	Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.	<b>12 hrs</b>
<b>3</b>	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modelling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in	<b>12hrs</b>

	brief, non-linear pharmacokinetics: cause of non-linearity, Michael is – Menten equation, estimation of k and v. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, druginteractions linked to transporters.	
4	Drug Product Performance, in vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Bio pharmaceuticals classification system, methods. Permeability: In-vitro, in-situ, and In-vivo methods. generic biologics (bio similar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 hrs
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12hrs

#### REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4<sup>th</sup> edition, Philadelphia, Lea and Febiger, 1991.
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2<sup>nd</sup> edition, Connecticut Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R.Hiremath, Prism Book.
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2<sup>nd</sup> edition, MarcelDekker Inc., New York, 1982.
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970.
7. Clinical Pharmacokinetics, Concepts and Applications 3<sup>rd</sup> edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4<sup>th</sup> edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York, and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1<sup>st</sup> edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1<sup>st</sup> edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Computer Aided Drug Development</b>
<b>Course Code</b>	<b>MPH203T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course Description

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

### Course outcome

At the end of the theory course, the student will be able to

C203.1	Describe the History of Computers Computational, Modelling of Drug Disposition
C203.2	explain the use of Computers in Preclinical Development, Optimization Techniques in Pharmaceutical Formulation
C203.3	Explain the Optimization Techniques in Pharmaceutical Formulation, Computers in Market Analysis. And Computers in Clinical Development,
C203.4	Apprise the Artificial Intelligence (AI) and Robotics and Computational fluid dynamics(CFD)

### Course Contents

**60 hours**

<b>1</b>	Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. Quality-by-Design in Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, scientifically based QbD - examples of application.	<b>12hrs</b>
<b>2</b>	Computational Modeling of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	<b>12 hrs</b>
<b>3</b>	Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	<b>12hrs</b>
<b>4</b>	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in-vitro-in-vivo correlation, Biowaiver considerations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics:	<b>12 hrs</b>



	Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems	
<b>5</b>	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	<b>12hrs</b>

### References

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1 Edition, Jelena Djuris, Woodhead Publishing.
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James G. Boylan, Marcel Dekker Inc, New York, 1996.
4. Karri V V S Narayana Reddy, Gowthamarajan Kupusamy, and Arun R. Computer Aided Drug Development. PV Books 2021.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Cosmetics And Cosmeceuticals</b>
<b>Course Code</b>	<b>MPH204T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description**

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

#### **Course outcome**

At the end of the theory course, the student will be able to

CO204.1	List the key ingredients used in cosmetics and cosmeceuticals.
CO204.2	Enumerate Key building blocks for various formulations.
CO204.3	Explain the current technologies in the market
CO204.4	Describe the various key ingredients and basic science to develop cosmetics and cosmeceuticals
CO204.5	Explain the scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

#### **Course Content**

**60 hours**

<b>1</b>	Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics. Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics—Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	<b>12hrs</b>
<b>2</b>	Cosmetics - Biological aspects: Structure of skin and relating problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eyelids, lips, hands, feet, nail, scalp, neck, body and under-arm.	<b>12hrs</b>
<b>3</b>	Formulation Building blocks, Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobials their merits and demerits. Factors affecting microbial preservative efficacy. Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxin.	<b>12hrs</b>
<b>4</b>	Design of cosmeceutical products: sun screens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, and dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	<b>12hrs</b>
<b>5</b>	Herbal Cosmetics: Herbal ingredients used in Hair care, skincare and Oral care. Review of guidelines for herbal cosmetics by private bodies	<b>12hrs</b>

#### **REFERENCES**

1. Harry's Cosmeticology. 8<sup>th</sup> edition.
2. Poucher's perfume cosmetics and Soaps, 10<sup>th</sup> edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4<sup>th</sup> edition Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3<sup>rd</sup> edition

4. Cosmetic and Toiletries recent suppliers catalogue.
5. CTFA directory.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Pharmaceutics Practical-II</b>
<b>Course Code</b>	<b>MPH205P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Outcomes**

C205.1	Understand various techniques of making Novel dosage forms
C205.2	Evaluate various dosage forms
C205.3	Evaluate various cosmetic preparations

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
6. Preparation of antiseptic cream
7. Development and evaluation of Cold Cream, Varnishing Creams
8. Development and evaluation of Shampoo (liquid shampoo, Cream Shampoo)
9. Development and evaluation of Tooth powder and Toothpaste
10. To incorporate herbal and chemical actives to develop products
11. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Pharmaceutics Practical-III</b>
<b>Course Code</b>	<b>MPH206P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>
<b>Course Outcomes:</b>	
C206.1	Understand various techniques of biopharmaceutical evaluation of dosage forms
C206.2	Evaluate various pharmacokinetic parameters
C206.3	Design experiments based on QbD for optimization of drug delivery

1. Protein binding studies of a highly protein bound drug & poorly protein bound drug
2. Determination of Pharmacokinetic Parameter after iv bolus and iv infusion (OCOM)
3. Determination of Pharmacokinetic Parameter after iv bolus, two compartmental analysis.
4. Determination of Pharmacokinetic Parameter after extra vascular administration.
5. Determination of Rate constant from Urinary Data
6. Bioavailability & Bioequivalence studies of Paracetamol in animals.
7. Pharmacokinetic and IVIVC data analysis by PK Solver
8. In vitro cell studies for permeability and metabolism
9. Quality-by-Design in Pharmaceutical Development
10. DoE Using Design Expert® Software
11. Formulation data analysis Using Design Expert® Software
12. Computer Simulations in Pharmacokinetics and Pharmacodynamics
13. Computational Modelling of Drug Disposition
14. To develop Clinical Data Collection manual
15. To carry out Sensitivity Analysis, and Population Modelling.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Research Methodology &amp; IPR</b>
<b>Course Code</b>	<b>MRM301T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

The course was designed to make the students understand the research problem, perform literature surveys, to understand the ethics of research and plagiarism. The course also helps student in understanding importance of biostatistics in interpreting the scientific data, ethics of animal experiments and to analyze the nature of intellectual property rights and new developments and patent rights

#### **Course Outcomes:**

At the end of this course, students will be able to

CO301.1	Understand research problem formulation.
CO301.2	Analyze research related information
CO301.3	Follow research ethics
CO301.4	Understand new ideas, concept, and creativity.
CO301.5	Understanding about Intellectual Property Right to be promoted among students in general & engineering.

#### **Course Content**

**60 Hours**

<b>Unit</b>	<b>Content</b>	<b>Hours</b>
1	General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, approaches, analysis, Plagiarism, Research ethics	12h
2	Effective technical writing, how to write report, Paper Developing a Research Proposal. Citation of references in the manuscript. Format of research proposal.	12h
3	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (Students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	12h
4	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, Quarantine, surveillance, diagnosis, treatment, and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia. Declaration of Helsinki: History, introduction, basic principles for all medical Research.	
5	Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT. Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies.	

**TEXT BOOKS:**

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"
3. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
4. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
5. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New Technological Age", 2016
6. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008
7. Indrayan A, Satyanarayana L. Biostatistics for medical, nursing and pharmacy students. PHI Learning Pvt. Ltd.; 2006.
8. Monamy V. Animal experimentation: A guide to the issues. Cambridge University Press; 2017 Feb 23.
9. Beauchamp TL, DeGrazia D. Principles of animal research ethics. Oxford University Press; 2019 Dec 30.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Biological Screening methods</b>
<b>Course Code</b>	<b>MPH302E1</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

The students are going to study about various techniques for screening of drugs for various pharmacological activities and guidelines for handling animals and human and animal ethics for screening of drugs.

#### **Course Outcomes**

On completion of this course, it is expected that students will be able to understand,

C302E1.1	Understand handling of animals, usage
C302E1.2	Screening of dosage forms in animals
C302E1.3	Understand about Pharmacological procedures

#### **Course Content**

**60 Hours**

<b>Unit</b>	<b>Content</b>	<b>Hours</b>
1	Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.	12h
2	Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbits Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.	12h
3	Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.	12h
4	Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.	12h
5	Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.	12h

#### **TEXT BOOKS:**

1. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springer-Verlag, Berlin Heidelberg
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi
4. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
5. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.



<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Quality by Design of Dosage forms</b>
<b>Course Code</b>	<b>MPH302E2</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The objective of Quality by Design is a modern, approach that formalizes product design, automates manual testing and streamlines trouble shooting. It uses a systemic approach to ensure quality by developing a thorough understanding of the compatibility of a finished product to all the components and processes involved in manufacturing that product.

### Course Outcomes

On completion of this course it is expected that students will be able to understand,

C302E2.1	Analyze QbD concepts
C302E2.2	Optimize dosage forms by QbD
C302E2.3	Understand about Process Analytical Techniques

### Course Contents

**60 Hours**

1	<b>Overview of QbD</b> Introduction, history of QbD, Regulatory aspects of QbD, Pharmaceutical quality by testing, Elements of QbD, benefits of QbD and current state of QbD.	12h
2	<b>Aspects of QbD to product development:</b> Introduction, Quality Target Product Profile (QTPP), Critical Quality Attributes (CQAs), Critical process parameters, risk assessment, design space, control strategy, product lifecycle management and continual improvement.	12h
3	<b>DOE, PAT and RTRT:</b> Design of Experiment (DOE), Process Analytical Techniques (PAT), Real Time Release Testing (RTRT).	12h
4	<b>Implementation of QbD in product development (case studies):</b> Introduction, Implementation of QbD in tablet formulation, implementation of QbD in pellet formulation.	12h
5	<b>Implementation of QbD in product development (case studies):</b> Implementation of QbD in emulsion formulation, Implementation of QbD in powder formulation and Implementation of QbD in Liposomes formulation.	12h

### REFERENCES:

1. Introduction to Quality by Design for Pharmaceuticals by Nilesh Desai and Manohar A. Potdar
2. Quality by Design (QbD): A new concept for Development of quality Pharmaceuticals by Patil.A.S. and Pethe

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Scientific Writing</b>
<b>Course Code</b>	<b>MPH302E3</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The objective of scientific writing is to formalize the students to communicate and get the research work published.

### Course Outcomes

On completion of this course, it is expected that students will be able to understand,

C303E2.1	Analyze scientific writing concepts
C303E2.2	Understand the concept of publication
C303E2.3	Evaluate the journals and the work for publication

### Course Content

**60 Hours**

1	<b>Introduction skills:</b> Getting ideas, designing the research work, Types of papers, Structure of a typical paper, how to write an introduction, essentials of language and academic editing	12h
2	<b>Effective Literature Review:</b> Databases (Medline, Science direct, Springer, PubMed, Google Scholar, and others), Collection of the information, Inclusion, and sequencing of authors based on their roles, Preparation of title and abstract of manuscript, Discussion, and conclusion,	12h
3	<b>Skills in writing Methodology:</b> Purpose of the Methods section, Preparation of Experimental Design, Conventions regarding style, Designing and labeling tables, how to use Excel for graphs, how to use Pivot Tables in Excel	12h
4	<b>Results and discussion:</b> Purpose of the Results, how to write the results, Purpose of the discussion, Preparation of Experimental Design How to write the discussion and conclusion <b>References:</b> Referencing styles: Vancouver, others, Referencing software: EndNote, Zotero etc. <b>Ethics:</b> Copyright, Plagiarism, Conflict of interest and disclosure. <b>English in writing skills:</b> Errors in grammar, punctuation.	12h
5	<b>Communication:</b> How to write an abstract, Graphical abstract/Image representation Selection of journal, Guide for SCOPUS/WOS/SCI Journals and Predatory Journals, Respond to the reviewer's comments	12h

### References

1. Lebrun JL. Scientific writing: a reader and writer's guide. World Scientific; 2007 Apr 5.
2. Gitlin L, Kolanowski A, Lyons KJ. Successful grant writing: Strategies for health and human service professionals. Springer Publishing Company; 2020 May 26.
3. Markovac J, Kleinman M, Englesbe M, editors. Medical and scientific publishing: author, editor, and reviewer perspectives. Academic Press; 2017 Nov 13.
4. Diskin S. The 21st Century Guide to Writing Articles in the Biomedical Sciences. World Scientific; 2018 Mar 9.
5. Joubert PH, Rogers SM. Strategic Scientific and Medical Writing. Berlin: Springer; 2015.
6. [https://cactus-editorial.teachable.com/p/bet\\_open](https://cactus-editorial.teachable.com/p/bet_open)

# **INDUSTRIAL PHARMACY**

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MIP101T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course Description

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

### Course Outcomes:

C101.1	Discuss the principle of various modern analytical technique involved in the analysis of drugs using spectroscopy, chromatography, electrophoresis, x-ray methods.
C101.2	Apply the modern analytical techniques in the identification and quantification of drugs in dosage forms.
C101.3	Interpret the analytical data and spectral data to draw the conclusion of quality of pharmaceuticals.

### THEORY

**60 hours**

<b>1</b>	<p>a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.</p> <p>b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.</p> <p>c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.</p> <p>d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.</p>	<b>10hrs</b>
<b>2</b>	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR	<b>10hrs</b>

	signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup> C NMR. Applications of NMR spectroscopy.	
<b>3</b>	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	<b>10hrs</b>
<b>4</b>	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: <ul style="list-style-type: none"> <li>• Thin Layer chromatography</li> <li>• High Performance Thin Layer Chromatography</li> <li>• Ion exchange chromatography</li> <li>• Column chromatography</li> <li>• Gas chromatography</li> <li>• High Performance Liquid chromatography</li> <li>• Ultra-High-Performance Liquid chromatography</li> <li>• Affinity chromatography</li> <li>• Gel Chromatography</li> </ul>	<b>10hrs</b>
<b>5</b>	a. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: <p>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing</p> <p>b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg 's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.</p>	<b>10hrs</b>
<b>6</b>	a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. <p>b. Thermal Techniques: Principle, thermal transitions, and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.</p>	<b>10hrs</b>

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Pharmaceutical Formulation Development</b>
<b>Course Code</b>	<b>MIP 102T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

### Course Outcome

On completion of this course, it is expected that students will be able to understand-

C102.1	Understand the scheduled activities in a pharmaceutical firm.
C102.2	Perform the pre formulation studies of pilot batches of pharmaceutical industry
C102.3	Analyze significance of dissolution and product stability

### THEORY

60 Hrs

1	Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.	12h
2	Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.	12h
3	Solubility: Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotrophy.	12h
4	Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevant media, in-vitro and in-vivo correlations, levels of correlations.	12h
5	Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf-life assessment. Stability protocols, reports, and ICH guidelines.	12h

## REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice Of Industrial Pharmacy, 3<sup>rd</sup> ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5<sup>th</sup> ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms:tablets Vol. I-III, 2<sup>nd</sup> ed., CBS Publishers & distributors, New Delhi, 2005.
4. Connors KA. A Textbook of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3<sup>rd</sup> ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3<sup>rd</sup> ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4<sup>th</sup> ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4<sup>th</sup> ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation : The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.



<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Novel Drug Delivery Systems</b>
<b>Course Code</b>	<b>MIP 103T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

This course is designed to impart knowledge and skills necessary to train the students in novel drug delivery systems.

### Course Outcome

On completion of this course, it is expected that students will be able to understand,

C103.1	Understand the principles and mechanisms of controlled drug delivery systems.
C103.2	Formulate and evaluate the novel drug delivery systems

### THEORY

60 Hrs

1	Concept & Models for NDDS: Classification of rate-controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release. Carriers for Drug Delivery: Polymers / co-polymers- introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.	12h
2	Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems	12h
3	Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. <b>Sub-Micron Cosmeceuticals:</b> Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects.	12h
4	<b>Targeted Drug Delivery Systems:</b> Importance, concept, biological process, and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting— nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions— multiple emulsions, micro-emulsions. <b>Protein / Peptide Drug Delivery Systems:</b> Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.	12h
5	<b>Biotechnology in Drug Delivery Systems:</b> Brief review of major areas— recombinant DNA technology, monoclonal antibodies, gene therapy. <b>New trends for Personalized Medicine:</b> Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.	12h

## REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P. Tyle, Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Intellectual Property Rights</b>
<b>Course Code</b>	<b>MIP 104T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

### Course Outcome

On completion of this course, it is expected that students will be able to understand,

C104.1	Understand the Regulatory Audit process.
C104.2	Establish regulatory guidelines for drug and drug products
C104.3	Assist in the Regulatory requirements in the firms

### THEORY

60 Hrs

1	Definition, need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Filing of patents. The essential elements of patent; Guidelines for preparation of laboratory notebook, Non-obviousness in Patent.	12h
2	Role of GATT, TRIPS, and WIPO	12h
3	Brief introduction to Trademark protection and WHO Patents. IPR's and its types,	12h
4	Major bodies regulating pharmaceutical sector: CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA	12h
5	Regulatory requirements for contract research organization. Regulations for Biosimilars.	12h

### REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2<sup>nd</sup> Edition
2. Applied Production and Operation Management by Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MIP105P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

At the end of the practical course of experiments, the student will be able to

C105.1	Demonstrate the skill to adopt standard operating procedure to handle modern analytical technique like spectroscopy, chromatography, electrophoresis, x-ray methods.
C105.2	Conduct experiments using modern analytical techniques for the analysis of dosage forms.
C105.3	Elucidate the chemical structure from the spectral data by applying the principles of spectroscopy.

## PRACTICALS

18. Calibration of glass wares as per I.P
19. Calculation of dilution and dilution factor
20. Construction of Linear curve and determination of Regression co efficient.
21. Study of auxo-chrome effect by UV-Visible spectrum
22. Assay of Metformin tablets by A (1%, 1 cm) method as per IP 2014
23. Assay of Ciprofloxacin injection using ferric chloride by Colorimetric method
24. Assay of Riboflavin tablets by Fluorimetry
25. Assay of FDC using simultaneous method by UV Spectrophotometer in drug dosage form
26. Identification of substance by IR and UV spectrum
27. Assay of caffeine by RP-HPLC method (Calibration curve method)
28. Determination of composition of volatile oil (lemon oil/ cinnamon oil) by GC (area normalization method)
29. Calculation of system suitability parameters for HPLC chromatograph
30. Determination of R<sub>f</sub>, R<sub>m</sub>, R<sub>x</sub> value for amino-acids /sugars/ analogue by PC/TLC
31. Isolation of  $\beta$ -carotene by preparative TLC method
32. Experiments on column packing and elution (Demo)
33. Workshop on Spectral interpretation (IR and <sup>1</sup>H NMR)
34. Problem based exercise /Revision (Woodward Fieser rule)

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Industrial Pharmacy- Practical-I</b>
<b>Course Code</b>	<b>MIP 106P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course description**

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in making dosage forms and their evaluation

### **Course Outcomes**

C106.1	Formulation and evaluation of drug delivery systems
C106.2	Evaluate Stability studies of drugs in dosage forms
C106.3	Evaluate and compare marketed dosage forms

1. Formulation and evaluation of tablets
2. Formulation and evaluation of capsules
3. Formulation and evaluation of injections
4. Formulation and evaluation of suspension.
5. Formulation and evaluation of enteric coating tablets.
6. Comparative evaluation of 4 different brands of tablets
7. Comparative evaluation of 4 different brands of capsules
8. To study the effect of compressional force on tablet disintegration time
9. To study the effect of binders on dissolution of tablets

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / II semester</b>
<b>Name of the course</b>	<b>Advanced Biopharmaceutics &amp; Pharmacokinetics</b>
<b>Course Code</b>	<b>MIP 201T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

### Course outcomes

On completion of this course, it is expected that students will be able to understand,

C201.1	Analyze and derive the pharmacokinetic models and parameters the best describes the process of drug absorption, distribution, metabolism, and elimination
C201.2	Evaluate Bio pharmaceutics studies involving drug product equivalency.
C201.3	Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutical parameters.

### THEORY

60 Hrs

1	Drug Absorption from The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH-partition theory, Formulation, and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup, and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ, and In-vivo methods.	12h
2	Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate- Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: In Vitro-In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.	12h
3	Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation,	12h

	Estimation K <sub>max</sub> and V <sub>max</sub> . Drug interactions: Introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.	
4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.	12h
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic– pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12h

#### REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmkar and Sunil B.J aishwal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / II semester</b>
<b>Name of the course</b>	<b>Scale Up and Technology Transfer</b>
<b>Course Code</b>	<b>MIP 202T</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

#### **Course Outcomes**

On completion of this course, it is expected that students will be able to understand,

C202.1	Analyze and manage the scale up process in pharmaceutical industry.
C202.2	Understand and assist in technology transfer.
C202.3	Create and establish safety guidelines, which prevent industrial hazards.

#### **THEORY**

60 Hrs

1	Pilot plant design and scale up: Basic requirements for design, facility, equipment selection, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, parenteral and semisolid preparations. Problems encountered during transfer of technology	12h
2	Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.	12h
3	Equipment Qualification: Importance, IQ, OQ, PQ for equipment – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.	12h
4	Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.	12h
5	Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.	12h

#### **REFERENCES**

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production, and Management, 2007, Vallabh Prakashan, Dehli.



<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / II semester</b>
<b>Name of the course</b>	<b>PHARMACEUTICAL PRODUCTION TECHNOLOGY</b>
<b>Course Code</b>	<b>MIP 203T</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

### Course outcomes

On completion of this course, it is expected that students will be able to understand,

C203.1	Understand and handle the scheduled activities in a pharmaceutical firm.
C203.2	Analyze and manage the production of large batches of pharmaceutical formulations.

### THEORY

60 Hrs

1	Improved Tablet Production: Tablet production process, unit operation improvements, granulation and pelletization equipment, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipment. Problems encountered. Coating Technology: Process, equipment, particle coating, fluidized bed coating, Problems encountered.	12h
2	Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures, and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering, and maintenance.	12h
3	Lyophilization & Spray drying Technology: Principles, process, freeze-drying, and spray drying equipment.	12h
4	Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered. Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipment including fine solids dispersion, problems encountered.  Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.	12h
5	Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI.	12h

## REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industry, Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / II semester</b>
<b>Name of the course</b>	<b>Entrepreneurship Management</b>
<b>Course Code</b>	<b>MIP 204T</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

#### **Course Outcomes**

On completion of this course, it is expected that students will be able to understand,

C204.1	Understand the Role of enterprise in national and global economy
C204.2	Create dynamics of motivation and concepts of entrepreneurship
C204.3	Analyze the demands and challenges of Growth Strategies And Networking

#### **THEORY**

60 Hrs

1	Conceptual Framework: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.	12h
2	Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency –Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.	12h
3	Launching And Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site, and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.	12h
4	Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measure, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination, and feasibility study.	12h
5	Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilisation and implementation.	12h

#### **REFERENCES**

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII. ed., CBS Publishers & distributors, New Delhi,

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / II semester</b>
<b>Name of the course</b>	<b>Industrial Pharmacy-Practical-II</b>
<b>Course Code</b>	<b>MIP 205P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course description**

This course is designed to impart knowledge and skills necessary to train the students to be on par in making various novel dosage forms and cosmetics

### **Course outcomes**

On completion of this course, it is expected that students will be able to understand,

C205.1	Understand various techniques of making Novel dosage forms
C205.2	Evaluate various dosage forms
C205.3	Evaluate various cosmetic preparations

1. Preparation and evaluation Fast dissolving tablets
2. Preparation and evaluation Floating tablets
3. Formulation and evaluation of Mucoadhesive tablets.
4. Formulation and evaluation of microspheres
5. Formulation and evaluation of liposomes/niosomes
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Preparation and evaluation of a freeze-dried formulation.
8. DoE Using Design Expert® Software
9. Development and evaluation of Shampoo
10. Preparation and evaluation of cream

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / II semester</b>
<b>Name of the course</b>	<b>Industrial Pharmacy-Practical-III</b>
<b>Course Code</b>	<b>MIP 206P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course description**

This course is designed to impart knowledge and skills necessary to train the students to be on par in biopharmaceutical aspects of dosage forms and validate and qualification of pharmaceutical equipment.

### **Course outcomes**

On completion of this course, it is expected that students will be able to understand,

C205.1	Understand various techniques of biopharmaceutical evaluation of dosage forms
C205.2	Evaluate various pharmacokinetic parameters
C205.3	Evaluate and validate pharmaceutical equipment

1. Protein binding studies of a highly protein bound drug
2. Protein binding studies of a poorly protein bound drug
3. Pharmacokinetic and IVIVC data analysis
4. Calculation of Urinary Pharmacokinetics
5. Calculation of Bioavailability and Bioequivalence Studies
6. Calculation of pharmacokinetics parameters of one compartment oral data and two compartment IV data.
7. To plot various pharmacokinetic plots
8. Validation of friabilator
9. Validation of disintegration apparatus

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Research Methodology and IPR</b>
<b>Course Code</b>	<b>MRM 301T</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

## **II YEAR I Semester**

### **Course description**

- To understand the research problem
- To know the literature studies, plagiarism, and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

### **Course Outcomes:**

At the end of this course, students will be able to

CO301T-1	Understand research problem formulation.
CO301T-2	Analyze research related information
CO301T-3	Follow research ethics
CO301T-4	Understand new ideas, concept, and creativity.
CO301T-5	Understanding about Intellectual Property Right to be promoted among students in general & engineering.

1	General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, approaches, analysis, Plagiarism, Research ethics	12h
2	Effective technical writing, how to write report, Paper Developing a Research Proposal. Citation of references in the manuscript. Format of research proposal.	12h
3	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (tudent's "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	12h
4	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment, and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia. Declaration of Helsinki: History, introduction, basic principles for all medical Research.	12h
5	Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT. Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies.	12h

**TEXT BOOKS:**

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

**REFERENCES:**

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step-by-Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New Technological Age", 2016.
7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Biological screening methods (Elective)</b>
<b>Course Code</b>	<b>MIP 302 E1</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The students are going to study about various techniques for screening of drugs for various pharmacological activities and guidelines for handling animals and human and animal ethics for screening of drugs.

### Course Outcomes

On completion of this course, it is expected that students will be able to understand,

C302E1.1	Understand handling of animals, usage
C302E1.2	Screening of dosage forms in animals
C302E1.3	Understand about Pharmacological procedures

### Course Content

**60 Hours**

Unit	Content	Hours
1	Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.	12h
2	Bioassays: Basic principles of biological standardization: Methods used in the bio-assay of Rabbits Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.	12h
3	Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.	12h
4	Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.	12h
5	Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.	12h

### TEXT BOOKS:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
- 2 Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springer-Verlag, Berlin Heidelberg
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi
4. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
5. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.



<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Quality By Design of Dosage Forms (Elective)</b>
<b>Course Code</b>	<b>MIP 302 E2</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The objective of Quality by Design is a modern, approach that formalizes product design, automates manual testing and streamlines trouble shooting. It uses a systemic approach to ensure quality by developing a thorough understanding of the compatibility of a finished product to all the components and processes involved in manufacturing that product.

### Course Outcomes

On completion of this course it is expected that students will be able to understand,

C302E2.1	Analyze QbD concepts
C302E2.2	Optimize dosage forms by QbD
C302E2.3	Understand about Process Analytical Techniques

### Course Content

**60 Hours**

1	<b>Overview of QbD</b> Introduction, history of QbD, Regulatory aspects of QbD, Pharmaceutical quality by testing, Elements of QbD, benefits of QbD and current state of QbD.	12h
2	<b>Aspects of QbD to product development:</b> Introduction, Quality Target Product Profile (QTPP), Critical Quality Attributes (CQAs), Critical process parameters, risk assessment, design space, control strategy, product lifecycle management and continual improvement.	12h
3	<b>DOE, PAT and RTRT:</b> Design of Experiment (DOE), Process Analytical Techniques (PAT), Real Time Release Testing (RTRT).	12h
4	<b>Implementation of QbD in product development (case studies):</b> Introduction, Implementation of QbD in tablet formulation, implementation of QbD in pellet formulation.	12h
5	<b>Implementation of QbD in product development (case studies):</b> Implementation of QbD in emulsion formulation, Implementation of QbD in powder formulation and Implementation of QbD in Liposomes formulation.	12h

### REFERENCES:

1. Introduction to Quality by Design for Pharmaceuticals by Nilesh Desai and Manohar A. Potdar
2. Quality by Design (QbD): A new concept for Development of quality Pharmaceuticals by Patil.A.S. and Pethe

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Scientific Writing (Elective)</b>
<b>Course Code</b>	<b>MIP 302 E3</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The objective of scientific writing is to formalize the students to communicate and get the research work published

### Course Outcomes

On completion of this course, it is expected that students will be able to understand,

C303E2.1	Analyze scientific writing concepts
C303E2.2	Understand the concept of publication
C303E2.3	Evaluate the journals and the work for publication

### Course Content

**60 Hours**

1	<b>Introduction skills:</b> Getting ideas, designing the research work, Types of papers, Structure of a typical paper, how to write an introduction, essentials of language and academic editing	12h
2	<b>Effective Literature Review:</b> Databases (Medline, Science direct, Springer, PubMed, Google Scholar, and others), Collection of the information, Inclusion, and sequencing of authors based on their roles, Preparation of title and abstract of manuscript, Discussion, and conclusion,	12h
3	<b>Skills in writing Methodology:</b> Purpose of the Methods section, Preparation of Experimental Design, Conventions regarding style, Designing and labeling tables, how to use Excel for graphs, how to use Pivot Tables in Excel	12h
4	<b>Results and discussion:</b> Purpose of the Results, how to write the results, Purpose of the discussion, Preparation of Experimental Design How to write the discussion and conclusion <b>References:</b> Referencing styles: Vancouver, others, Referencing software: EndNote, Zotero etc. <b>Ethics:</b> Copyright, Plagiarism, Conflict of interest and disclosure. <b>English in writing skills:</b> Errors in grammar, punctuation.	12h
5	<b>Communication:</b> How to write an abstract, Graphical abstract/Image representation Selection of journal, Guide for SCOPUS/WOS/SCI Journals and Predatory Journals, Respond to the reviewer's comments	12h

## References

7. Lebrun JL. Scientific writing: a reader and writer's guide. World Scientific; 2007 Apr 5.
8. Gitlin L, Kolanowski A, Lyons KJ. Successful grant writing: Strategies for health and human service professionals. Springer Publishing Company; 2020 May 26.
9. Markovac J, Kleinman M, Englesbe M, editors. Medical and scientific publishing: author, editor, and reviewer perspectives. Academic Press; 2017 Nov 13.
10. Diskin S. The 21st Century Guide to Writing Articles in the Biomedical Sciences. World Scientific; 2018 Mar 9.
11. Joubert PH, Rogers SM. Strategic Scientific and Medical Writing. Berlin: Springer; 2015.
12. [https://cactus-editorial.teachable.com/p/bet\\_open](https://cactus-editorial.teachable.com/p/bet_open)

# **PHARMCEUTICAL ANALYSIS**

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MPA101T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course Description

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

### Course Outcomes:

C101.1	Discuss the principle of various modern analytical technique involved in the analysis of drugs using spectroscopy, chromatography, electrophoresis, x-ray methods.
C101.2	Apply the modern analytical techniques in the identification and quantification of drugs in dosage forms.
C101.3	Interpret the analytical data and spectral data to draw the conclusion of quality of pharmaceuticals.

### THEORY

**60 hours**

<b>1</b>	a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	<b>10hrs</b>
<b>2</b>	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double	<b>10hrs</b>

	resonance, Brief outline of principles of FT-NMR and <sup>13</sup> C NMR. Applications of NMR spectroscopy.	
<b>3</b>	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	<b>10hrs</b>
<b>4</b>	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: <ul style="list-style-type: none"> <li>• Thin Layer chromatography</li> <li>• High Performance Thin Layer Chromatography</li> <li>• Ion exchange chromatography</li> <li>• Column chromatography</li> <li>• Gas chromatography</li> <li>• High Performance Liquid chromatography</li> <li>• Ultra High Performance Liquid chromatography</li> <li>• Affinity chromatography</li> <li>• Gel Chromatography</li> </ul>	<b>10hrs</b>
<b>5</b>	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	<b>10hrs</b>
<b>6</b>	a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	<b>10hrs</b>

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>ADVANCED PHARMACEUTICAL ANALYSIS</b>
<b>Course Code</b>	<b>MPA102T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:** This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

### **Course Objectives**

C102.1	Able to Know Appropriate analytical skills required for the analytical method development.
C102.2	Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
C102.3	Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

### **THEORY**

**60 hours**

<b>1</b>	<p><b>Impurity and stability studies:</b> Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines</p> <p><b>Impurities in new drug products:</b> Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products</p> <p><b>Impurities in residual solvents:</b> General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents</p>	<b>10hrs</b>
<b>2</b>	<p><b>Elemental impurities:</b> Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation &amp; C, H, N and S analysis</p> <p><b>Stability testing protocols:</b> Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH,</p>	<b>10hrs</b>



	buffering species ionic strength and dielectric constant etc. on the reaction rates with practical considerations.	
<b>3</b>	<b>Impurity profiling and degradants characterization:</b> Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products	<b>10hrs</b>
<b>4</b>	<b>Stability testing of phytopharmaceuticals:</b> Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.	<b>10hrs</b>
<b>5</b>	<b>Biological tests and assays of the following:</b> a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, Types of PCR, Applications. Instrumentation (Principle and Procedures)	<b>10hrs</b>
<b>6</b>	<b>Immunoassays (IA)</b> Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.	<b>10hrs</b>

## REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4<sup>th</sup> Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.102
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2<sup>nd</sup> edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2<sup>nd</sup> edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Quality Control and Quality Assurance (QC&amp;QA)</b>
<b>Course Code</b>	<b>MPA103T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>

**Course Description:** This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

**Course Outcomes:** Upon completion of this course the student should be able to

C103.1	Understand the cGMP aspects in a pharmaceutical industry
C103.2	Appreciate the importance of documentation
C103.3	To understand the scope of quality certifications applicable to pharmaceutical industries
C103.4	Understand the responsibilities of QA & QC departments.

## **THEORY**

**60 hours**

<b>1</b>	Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	<b>12hrs</b>
<b>2</b>	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice?	<b>12 hrs</b>
<b>3</b>	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenteral, ophthalmic and surgical products (How to refer pharmacopoeias).	<b>12hrs</b>
<b>4</b>	Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents.	<b>12hrs</b>

	Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.	
5	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.	12hrs

## REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

<b>Program</b>	<b>M. Pharmacy</b>
<b>Year /Semester</b>	<b>First year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Food Analysis</b>
<b>Course Code</b>	<b>MPA 104T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

#### **Course Objectives**

C104.1	Understand the QC tests for food products.
C104.2	Able to determine the additives used in food products
C104.3	Able to Determine the pesticides used in food products
C104.4	Understand the rules and regulations of foods

<b>Unit</b>	<b>Topic</b>	<b>No. of hours</b>
1	Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates  Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.	12
2	Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.  Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.	12

3	Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavours, flavour enhancers, stabilizers, thickening and jelling agents.  Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.	12
4	General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.  Analysis of fermentation products like wine, spirits, beer and vinegar.	12
5	Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.  Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.	12

## REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

<b>Program</b>	<b>M. Pharmacy</b>
<b>Year /Semester</b>	<b>First year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques Practical</b>
<b>Course Code</b>	<b>MPA 105P</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

At the end of the practical course of experiments, the student will be able to

C105.1	Demonstrate the skill to adopt standard operating procedure to handle modern analytical technique like spectroscopy, chromatography, electrophoresis, x-ray methods.
C105.2	Conduct experiments using modern analytical techniques for the analysis of dosage forms.
C105.3	Elucidate the chemical structure from the spectral data by applying the principles of spectroscopy.

#### **PRACTICALS**

<b>Week</b>	<b>Duration</b>	<b>Description of Activity /Experiments</b>
1	6h	Calibration of glass wares as per I.P
2	6h	Calculation of dilution and dilution factor
3	6h	Construction of Linear curve and determination of Regression co efficient.
4	6h	Study of auxo-chrome effect by UV-Visible spectrum
5	6h	Assay of Metformin tablets by A (1%, 1 cm) method as per IP 2014
6	6h	Assay of Ciprofloxacin injection using ferric chloride by Colorimetric method
7	6h	Assay of Riboflavin tablets by Fluorimetry
8	6h	Assay of FDC using simultaneous method by UV Spectrophotometer in drug dosage form
9	6h	Identification of substance by IR and UV spectrum
10	6h	Assay of caffeine by RP-HPLC method (Calibration curve method)
11	6h	Determination of composition of volatile oil (lemon oil/ cinnamon oil) by GC (area normalization method)
12	6h	Calculation of system suitability parameters for HPLC chromatograph
13	6h	Determination of R <sub>f</sub> , R <sub>m</sub> , R <sub>x</sub> value for amino-acids /sugars/ analogue by PC/TLC
14	6h	Isolation of $\beta$ -carotene by preparative TLC method

15	6h	Experiments on column packing and elution (Demo)
16	6h	Workshop on Spectral interpretation (IR and $^1\text{H}$ NMR)
17	6h	Problem based exercise /Revision (Woodward Fieser rule)



<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Quality Control and Quality Assurance Practical</b>
<b>Course Code</b>	<b>MPA106P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

At the end of the practical course of experiments, the student will be able to

C106.1	Perform the quality control tests for various dosage forms
C106.2	Understand the regulatory aspects of dosage forms
C106.3	Understand the role of QA persons in Pharma Industry.

<b>Week</b>	<b>Duration</b>	<b>Description of Activity /Experiments</b>	<b>Type</b>
1	6h	Quality control tests for tablets	Experiment
2	6h	Quality control tests for capsules	Experiment
3	6h	Quality control tests for Injectables	Experiment
4	6h	Determination of total reducing sugar	Experiment
5	6h	Determination of Density and specific gravity of food product	
6	6h	Determination of proteins	Experiment
7	6h	Analysis of Milk	
8	6h	Determination of saponification value, Iodine value,	Experiment
9	6h	Peroxide value, Acid value in food products	Experiment
10	6h	Determination of fat content and rancidity in food products	Experiment
11	6h	Determination of preservatives in food	Experiment
12	6h	Determination of pesticide residue in food products	Experiment
13	6h	Microbiological assay of any two Antibiotics official in IP	Experiment
14	6h	Quality control tests for glass containers	Experiment

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Advanced instrumental Analysis</b>
<b>Course Code</b>	<b>MPA 201T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Program</b>	<b>M.Pharm</b>

**Course Description:** This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

**Course Outcome:** By the completion of topics the students will come out with the thorough knowledge of

C201.1	various spectral aspects of CE, IR, MS, NMR etc
C202.2	Various types of HPLC
C203.3	Spectral interpretation of drugs

#### **THEORY**

**60 hours**

<b>1</b>	HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes,  capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.	<b>12hrs</b>
<b>2</b>	Bio-chromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.  Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.	<b>12 hrs</b>
<b>3</b>	Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.  Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and	<b>12hrs</b>

	modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis.CE-MS hyphenation.	
<b>4</b>	Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact,chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems(Tandem: QqQ, TOF-TOF;Q-IT, QTOF, LTQ-FT, LTQ-Orbitrap.	<b>12hrs</b>
<b>5</b>	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to <sup>13</sup> CNMR:Spin spin and spin lattice relaxation phenomenon. <sup>13</sup> C NMR, 1-Dand 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LCNMR hyphenations.	<b>12hrs</b>

#### REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein,Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P DSethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson,Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Modern Bioanalytical Techniques</b>
<b>Course Code</b>	<b>MPA 202T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>

**Course description:**

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

**Course outcomes:**

Upon completion of the course, the student shall be able to understand

C202.1	Extraction of drugs from biological samples
C202.2	Separation of drugs from biological samples using different techniques
C202.3	Guidelines for BA/BE studies.

<b>Unit</b>	<b>Topics</b>	<b>No.of hours</b>
<b>I</b>	<b>Extraction of drugs and metabolites from biological matrices:</b>  General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach. Bioanalytical method validation: USFDA and EMEA guidelines.	<b>12</b>
<b>II</b>	<b>Biopharmaceutical Considerations:</b>  Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, Bio relevant media, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.	<b>12</b>
<b>III</b>	<b>Pharmacokinetics and Toxicokinetics:</b>  Basic consideration, Drug interaction (PK-PD interactions), the effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.	<b>12</b>

<b>IV</b>	<b>Cell culture techniques:</b>  Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays) SRB (Sulfo rhodamine) assay, Principles and applications of flow cytometry.	<b>12</b>
<b>V</b>	<b>Metabolite Identification:</b>  In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes. Drug Product Performance, In Vivo: Bioavailability and  <b>Bioequivalence:</b>  Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.	<b>12</b>
	<b>Total</b>	<b>60</b>

**Recommended Books: (Latest Editions)**

- Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
- Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
- Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
- Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
- Practical HPLC method Development – Snyder, Kirkland, Glaich, 2<sup>nd</sup> Edition, John Wiley & Sons, New Jercey. USA.
- Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2<sup>nd</sup> Edition, Marcel Dekker, Newyork, USA. 1997.
- Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercey, USA. 2007.
- Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
- Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
- ICH, USFDA & CDSCO Guidelines.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Pharmaceutical Validation</b>
<b>Course Code</b>	<b>MPA 203T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>

**Course Description:** The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

**Course Outcomes:** At completion of this course, it is expected that students will be able to understand

1. The concepts of calibration, qualification and validation
2. The qualification of various equipment's and instruments
3. Process validation of different dosage forms
4. Validation of analytical method for estimation of drugs
5. Cleaning validation of equipment's employed in the manufacture of pharmaceuticals

#### **THEORY**

**60 hours**

<b>1</b>	<p>Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification &amp; Validation process and Validation Master Plan.</p> <p>Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status-Calibration Preventive Maintenance, Change management).</p>	<b>10hrs</b>
<b>2</b>	<p>Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.</p> <p>Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.</p>	<b>10hrs</b>
<b>3</b>	<p>Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus</p> <p>Validation of Utility systems: Pharmaceutical water system &amp; pure steam, HVAC system, Compressed air and nitrogen.</p>	<b>10hrs</b>
<b>4</b>	<p>Process Validation: Concept, Process and documentation of Process</p>	<b>10hrs</b>

	<p>Validation. Prospective, Concurrent &amp; Retrospective Validation, Revalidation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.</p> <p>Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.</p>	
<b>5</b>	<p>Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Validation of facilities in sterile and non-sterile plant.</p> <p>Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP</p>	<b>10hrs</b>
<b>6</b>	<p>General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types</p> <p>patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.</p>	<b>10hrs</b>

## REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press



<b>Program</b>	<b>M. Pharmacy</b>
<b>Year /Semester</b>	<b>First year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Herbal &amp; cosmetic technology</b>
<b>Course Code</b>	<b>MPA204T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

### Objectives

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

<b>Unit</b>	<b>Topic</b>	<b>No. of hours</b>
1	Herbal remedies- Toxicity and Regulations: Herbals Vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.	12
2	Adulteration and Deterioration:  Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.	12
3	Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.	12

	<p>Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.</p> <p>Chromatographic techniques used in analysis of herbs and their constituents</p>	
4	<p>Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, biodrug-drug and biodrug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.</p>	12
5	<p>Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.</p> <p>Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skincare products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.</p>	12

## REFERENCES

- a. Pharmacognosy by Trease and Evans
- b. Pharmacognosy by Kokate, Purohit and Gokhale
- c. Quality Control Methods for Medicinal Plant, WHO, Geneva
- d. Pharmacognosy & Pharmacobiotechnology by AshutoshKar
- e. Essential of Pharmacognosy by Dr.S.H.Ansari
- f. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt.Ltd., Delhi
- g. Indian Standard specification, for raw materials, BIS, New Delhi.
- h. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
- i. Harry's Cosmeticology, 8th edition
- j. Suppliers catalogue on specialized cosmetic excipients
- k. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
- l. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

<b>Program</b>	<b>M. Pharmacy</b>
<b>Year /Semester</b>	<b>First year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Advanced Instrumental Analysis lab</b>
<b>Course Code</b>	<b>MPA205P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

## **PAPER 1**

### **PRACTICALS**

1. Interpretation of organic compounds by FT-IR
2. Interpretation of organic compounds by NMR
3. Interpretation of organic compounds by MS
4. Determination of purity by DSC in pharmaceuticals
5. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
6. Protocol preparation and performance of analytical/Bioanalytical method validation.
7. Fingerprint analysis of HPTLC.
8. Analysis of volatile compound by GC.
9. Sample preparation techniques for biological
10. Determination of LLOQ, ULOQ, LQC, MQC, HQC.

<b>Program</b>	<b>M. Pharmacy</b>
<b>Year /Semester</b>	<b>First year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Pharmaceutical Validation</b>
<b>Course Code</b>	<b>MPA206P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

1. Qualitative & quantitative analysis of rancidity in hair oil
2. Qualitative & quantitative analysis of rancidity in lipstick
3. Determination of Total Fatty Matter in soap
4. Determination of Total Fatty Matter in Hair Gel
5. Foaming capacity in shampoo
6. Validation of an analytical method for a drug
7. Cleaning validation of one equipment.
8. Calibration of UV Vis Spectrophotometer.
9. Calibration of FT-IR Spectrophotometer.
10. Calibration of pH meter.
11. Calibration of HPLC
12. Calibration of Dissolution apparatus.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Biological screening methods (Elective)</b>
<b>Course Code</b>	<b>MPA 302 E1</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The students are going to study about various techniques for screening of drugs for various pharmacological activities and guidelines for handling animals and human and animal ethics for screening of drugs.

### Course Outcomes

On completion of this course, it is expected that students will be able to understand,

C302E1.1	Understand handling of animals, usage
C302E1.2	Screening of dosage forms in animals
C302E1.3	Understand about Pharmacological procedures

### Course Content

**60 Hours**

Unit	Content	Hours
1	Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.	12h
2	Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbits Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.	12h
3	Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.	12h
4	Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.	12h
5	Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.	12h

**TEXT BOOKS:**

6. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
7. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springer-Verlag, Berlin Heidelberg
8. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi
9. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
10. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

<b>Program</b>	<b>M. Pharmacy</b>
<b>Year /Semester</b>	<b>Second year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Analytical QbD ( Elective)</b>
<b>Course Code</b>	<b>MPA302E2</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

The objective of Analytical Quality by Design is a modern, approach that optimize the method development conditions for any analytical method. It uses a systemic approach to ensure quality by developing and understanding the system to develop robust method.

#### **Course Outcomes**

On completion of this course it is expected that students will be able to understand,

C302E2.1	Analyze QbD concepts
C302E2.2	Optimize method development conditions by A QbD
C302E2.3	Understand about DoE and Critical Attributes.

<b>Unit</b>	<b>Content</b>	<b>Hours</b>
Unit-I	Introduction to Analytical Quality by Design: AQbD principles and fundamentals, Regulatory stand points of AQbD Potential applications of AQbD in analytical settings.	12
Unit-II	Analytical Quality by Design for gas chromatographic method development. Introduction, need for QbD in GC process development, Methodological aspects, Implimentation of QbD in GC, Statistical tools supporting GC-QbD, Experimental design, Method control strategy, validation.	12
Unit-III	Analytical Quality by Design for liquid chromatographic method development. Introduction, need for QbD in HPLC development, Methodological aspects, selection of method variables & Response variables, Optimization of method factors, Implimentation of QbD from design space, validation.	12
Unit-IV	Risk assessment and design space consideration in AQbD: Rewards of AQbD Approach to analytical methods, Regulatory perspectives of AQbD, Risk assessment in analytical method, Design space, MODR, Contour plots: 2 dimentional and 3 dimentional.	12
Unit-V	Design of experiments Application for analytical method development: Fundamentals of applying design of experiments, Key principles of DOE, Steps in performing DOE, Application of DoE in Analytical development.	12

## References

1. Hand book of Analytical Quality by design- Sarwar beg, Md saquib Hasnain. 1<sup>st</sup> edition, Elsevier publication, 2021.
2. International Conference on Harmonization (ICH) Q8(R2): Pharmaceutical Development (August 2009)
3. International Conference on Harmonization (ICH) Q9: Quality Risk Management (November 2005).
4. Ahuja, S. and Jespersen, N. Modern Instrumental Analysis, Elsevier, Amsterdam, 2006.



<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Scientific Writing (Elective)</b>
<b>Course Code</b>	<b>MPA 302 E3</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

The objective of scientific writing is to formalize the students to communicate and get the research work published

#### **Course Outcome**

On completion of this course, it is expected that students will be able to understand,

C303E2.1	Analyze scientific writing concepts
C303E2.2	Understand the concept of publication
C303E2.3	Evaluate the journals and the work for publication

1	<b>Introduction skills:</b> Getting ideas, designing the research work, Types of papers, Structure of a typical paper, how to write an introduction, essentials of language and academic editing	12h
2	<b>Effective Literature Review:</b> Databases (Medline, Science direct, Springer, PubMed, Google Scholar, and others), Collection of the information, Inclusion, and sequencing of authors based on their roles, Preparation of title and abstract of manuscript, Discussion, and conclusion,	12h
3	<b>Skills in writing Methodology:</b> Purpose of the Methods section, Preparation of Experimental Design, Conventions regarding style, Designing and labeling tables, how to use Excel for graphs, how to use Pivot Tables in Excel	12h
4	<b>Results and discussion:</b> Purpose of the Results, how to write the results, Purpose of the discussion, Preparation of Experimental Design How to write the discussion and conclusion <b>References:</b> Referencing styles: Vancouver, others, Referencing software: EndNote, Zotero etc. <b>Ethics:</b> Copyright, Plagiarism, Conflict of interest and disclosure. <b>English in writing skills:</b> Errors in grammar, punctuation.	12h
5	<b>Communication:</b> How to write an abstract, Graphical abstract/Image representation Selection of journal, Guide for SCOPUS/WOS/SCI Journals and Predatory Journals, Respond to the reviewer's comments	12h

## References

1. Lebrun JL. Scientific writing: a reader and writer's guide. World Scientific; 2007 Apr 5.
2. Gitlin L, Kolanowski A, Lyons KJ. Successful grant writing: Strategies for health and human service professionals. Springer Publishing Company; 2020 May 26.
3. Markovac J, Kleinman M, Englesbe M, editors. Medical and scientific publishing: author, editor, and reviewer perspectives. Academic Press; 2017 Nov 13.
4. Diskin S. The 21st Century Guide to Writing Articles in the Biomedical Sciences. World Scientific; 2018 Mar 9.
5. Joubert PH, Rogers SM. Strategic Scientific and Medical Writing. Berlin: Springer; 2015.
6. [https://cactus-editorial.teachable.com/p/bet\\_open](https://cactus-editorial.teachable.com/p/bet_open)

# **PHARMACEUTICAL QUALITY ASSURANCE**

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MPA101T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course Description

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

### Course Outcomes:

C101.1	Discuss the principle of various modern analytical technique involved in the analysis of drugs using spectroscopy, chromatography, electrophoresis, x-ray methods.
C101.2	Apply the modern analytical techniques in the identification and quantification of drugs in dosage forms.
C101.3	Interpret the analytical data and spectral data to draw the conclusion of quality of pharmaceuticals.

### THEORY

**60 hours**

<b>1</b>	a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	<b>10hrs</b>
<b>2</b>	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup> C NMR. Applications of NMR spectroscopy.	<b>10hrs</b>
<b>3</b>	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	<b>10hrs</b>
<b>4</b>	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients,	<b>10hrs</b>

	data interpretation and applications of the following: <ul style="list-style-type: none"> <li>• Thin Layer chromatography</li> <li>• High Performance Thin Layer Chromatography</li> <li>• Ion exchange chromatography</li> <li>• Column chromatography</li> <li>• Gas chromatography</li> <li>• High Performance Liquid chromatography</li> <li>• Ultra High Performance Liquid chromatography</li> <li>• Affinity chromatography</li> <li>• Gel Chromatography</li> </ul>	
<b>5</b>	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	<b>10hrs</b>
<b>6</b>	a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	<b>10hrs</b>

#### REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Quality Management System (QMS)</b>
<b>Course Code</b>	<b>MQA102T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

#### **Course Outcomes:**

At completion of this course it is expected that students will be able to understand-

1. The importance of quality
2. ISO management systems
3. Tools for quality improvement
4. Analysis of issues in quality
5. Quality evaluation of pharmaceuticals
6. Stability testing of drug and drug substances
7. Statistical approaches for quality

#### **THEORY**

**60 hours**

<b>1</b>	<p>Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality</p> <p>Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality</p> <p>Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers.</p> <p>Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, optimizing costs, Preventing cost of quality.</p>	<b>12hrs</b>
<b>2</b>	<p>Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Sixsigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.</p>	<b>12hrs</b>
<b>3</b>	<p>Six Sigma Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system.</p> <p>Concept of self-inspection.</p> <p>Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Corrective Actions &amp; Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/</p>	<b>12hrs</b>

	Line clearance.	
<b>4</b>	Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	<b>12hrs</b>
<b>5</b>	Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	<b>8hrs</b>
<b>6</b>	Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	<b>4hrs</b>

## REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Quality Control and Quality Assurance (QC&amp;QA)</b>
<b>Course Code</b>	<b>MQA103T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>

**Course Description:**

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

**Course Outcomes:**

Upon completion of this course the student should be able to

1. Understand the cGMP aspects in a pharmaceutical industry
2. To appreciate the importance of documentation
3. To understand the scope of quality certifications applicable to pharmaceutical industries
4. To understand the responsibilities of QA & QC departments.

**THEORY**

**60 hours**

<b>1</b>	Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	<b>12hrs</b>
<b>2</b>	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice?	<b>12 hrs</b>
<b>3</b>	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenteral, ophthalmic and surgical products (How to refer pharmacopoeias).	<b>12hrs</b>
<b>4</b>	Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical	<b>12hrs</b>



	Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.	
<b>5</b>	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.	<b>12hrs</b>

#### REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Product Development and Technology Transfer (PDTT)</b>
<b>Course Code</b>	<b>MQA104T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>

#### **Course Description:**

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

#### **Course Outcomes:**

Upon completion of this course the student should be able to

1. To understand the new product development process
2. To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
3. To elucidate necessary information to transfer technology of existing products between various manufacturing places

#### **THEORY**

**60 hours**

<b>1</b>	Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.	<b>12 h</b>
<b>2</b>	Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.	<b>12 h</b>
<b>3</b>	Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	<b>12 h</b>
<b>4</b>	Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.	<b>12 h</b>
<b>5</b>	Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models, Significance of Technology Transfer Documentation in technology transfer: Development report, technology transfer plan and Exhibit.	<b>12 h</b>

## REFERENCES

1. The process of new drug discovery and development. I and II Edition(2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevala. John I. Disouza. Maharukh T. Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remington's Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn. (1995) Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A. Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MQA105P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

At the end of the practical course of experiments, the student will be able to

C105.1	Demonstrate the skill to adopt standard operating procedure to handle modern analytical technique like spectroscopy, chromatography, electrophoresis, x-ray methods.
C105.2	Conduct experiments using modern analytical techniques for the analysis of dosage forms.
C105.3	Elucidate the chemical structure from the spectral data by applying the principles of spectroscopy.

### **PRACTICALS**

<b>Week</b>	<b>Duration</b>	<b>Description of Activity /Experiments</b>
1	6h	Calibration of glass wares as per I.P
2	6h	Calculation of dilution and dilution factor
3	6h	Construction of Linear curve and determination of Regression co efficient.
4	6h	Study of auxo-chrome effect by UV-Visible spectrum
5	6h	Assay of Metformin tablets by A (1%, 1 cm) method as per IP 2014
6	6h	Assay of Ciprofloxacin injection using ferric chloride by Colorimetric method
7	6h	Assay of Riboflavin tablets by Fluorimetry
8	6h	Assay of FDC using simultaneous method by UV Spectrophotometer in drug dosage form
9	6h	Identification of substance by IR and UV spectrum
10	6h	Assay of caffeine by RP-HPLC method (Calibration curve method)
11	6h	Determination of composition of volatile oil (lemon oil/ cinnamon oil) by GC (area normalization method)
12	6h	Calculation of system suitability parameters for HPLC chromatograph
13	6h	Determination of $R_f$ , $R_m$ , $R_x$ value for amino-acids /sugars/ analogue by PC/TLC
14	6h	Purification of $\beta$ -carotene by preparative TLC method
15	6h	Experiments on column packing and elution (Demo)
16	6h	Workshop on Spectral interpretation (IR and $^1\text{H}$ NMR)
17	6h	Problem based exercise /Revision (Woodward Fieser rule)

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Quality control &amp; Quality Assurance practical</b>
<b>Course Code</b>	<b>MQA106P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

At the end of the practical course of experiments, the student will be able to

C105.1	Perform the quality control tests for various dosage forms
C105.2	Understand the regulatory aspects of dosage forms
C105.3	Understand the role of QA persons in Pharma Industry.

- Case studies on
  - Total Quality Management
  - Six Sigma
  - Change Management/ Change control. Deviations
  - Out of Specifications (OOS)
  - Out of Trend (OOT)
  - Corrective & Preventive Actions (CAPA)
- Standard Operating Procedure for Fluorimetry and calibration procedure for of Fluorimetry
- Quality control test for Tablets
- Quality control test for Capsules
- Quality control test for Primary and Secondary packaging materials
- Testing of related and foreign substances in raw material 1 (IPQC test for raw materials-1 Talc)
- Testing of related and foreign substances in raw material 2 (IPQC test for raw materials-2 Starch)
- Improvement the solubility of drugs by using Co solvent
- Improvement of Solubility of drugs by using surfactant systems

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Hazards and Safety Management (H&amp;SM)</b>
<b>Course Code</b>	<b>MQA 201T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Program</b>	<b>M.Pharm</b>

**Course Description:** This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

**Course Outcomes:** At completion of this course it is expected that students will be able to

1. Understand about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the industry environment.
4. Ensure safety standards in pharmaceutical industry
5. Provide comprehensive knowledge on the safety management
6. Empower an ideas to clear mechanism and management in different kinds of hazard management system
7. Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

#### **THEORY**

**60 hours**

<b>1</b>	Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems,  a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources  Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes	<b>12hrs</b>
<b>2</b>	Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area,  Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system	<b>12 hrs</b>
<b>3</b>	Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard,  Management of over-Exposure to chemicals and TLV concept.	<b>12hrs</b>

4	<p>Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates.</p> <p>Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers</p>	12hrs
5	<p>Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools</p> <p>Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.</p>	12hrs

## REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. “Quantitative Risk Assessment in Chemical Process Industries” American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Pharmaceutical Validation</b>
<b>Course Code</b>	<b>MQA 202T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>

**Course Description:** The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

**Course Outcomes:** At completion of this course, it is expected that students will be able to understand

6. The concepts of calibration, qualification and validation
7. The qualification of various equipment's and instruments
8. Process validation of different dosage forms
9. Validation of analytical method for estimation of drugs
10. Cleaning validation of equipment's employed in the manufacture of pharmaceuticals

#### **THEORY**

**60 hours**

<b>1</b>	<p>Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification &amp; Validation process and Validation Master Plan.</p> <p>Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status-Calibration Preventive Maintenance, Change management).</p>	<b>10hrs</b>
<b>2</b>	<p>Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.</p> <p>Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.</p>	<b>10hrs</b>
<b>3</b>	<p>Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus</p> <p>Validation of Utility systems: Pharmaceutical water system &amp; pure steam, HVAC system, Compressed air and nitrogen.</p>	<b>10hrs</b>
<b>4</b>	<p>Process Validation: Concept, Process and documentation of Process</p>	<b>10hrs</b>



	<p>Validation. Prospective, Concurrent &amp; Retrospective Validation, Revalidation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.</p> <p>Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.</p>	
<b>5</b>	<p>Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Validation of facilities in sterile and non-sterile plant.</p> <p>Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP</p>	<b>10hrs</b>
<b>6</b>	<p>General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types</p> <p>patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.</p>	<b>10hrs</b>

## REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco,
5. (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Audits and Regulatory Compliance</b>
<b>Course Code</b>	<b>MQA 203T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>

**Course Description:** This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

**Course Outcomes:** Upon completion of this course the student should be able to

1. To understand the importance of auditing
2. To understand the methodology of auditing
3. To carry out the audit process
4. To prepare the auditing report
5. To prepare the check list for auditing

### **THEORY**

**60 hours**

<b>1</b>	Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	<b>12h</b>
<b>2</b>	Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.	<b>12h</b>
<b>3</b>	Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit,  Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	<b>12h</b>
<b>4</b>	Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	<b>12h</b>
<b>5</b>	Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	<b>12h</b>

### **REFERENCES**

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

<b>Program</b>	<b>M.Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Pharmaceutical Manufacturing Technology (PMT)</b>
<b>Course Code</b>	<b>MQA 204T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>

**Course Description:** This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

**Course Outcomes:** At completion of this course it is expected that students will be able to understand,

1. The common practice in the pharmaceutical industry developments, plant layout and production planning
2. Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
3. Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

#### **THEORY**

**60 hours**

<b>1</b>	<p>Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing.</p> <p>Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.</p> <p>Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.</p>	<b>12hrs</b>
<b>2</b>	<p>Aseptic process technology: Manufacturing, manufacturing flowcharts,</p> <p>Advanced sterile product manufacturing technology: Area planning &amp; environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities&amp; utilities equipment location, engineering and maintenance.</p> <p>Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals &amp; Large Volume Parenterals (SVP &amp; LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).</p> <p>Lyophilization technology: Principles, process, equipment.</p>	<b>12 hrs</b>
<b>3</b>	<p>Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed &amp; coated), Capsules</p>	<b>12hrs</b>

	<p>(Hard &amp; Soft).</p> <p>Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, Rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.</p> <p>Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.</p>	
<b>4</b>	<p>Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil /plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.</p>	<b>12hrs</b>
<b>5</b>	<p>Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP, CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.</p>	<b>12hrs</b>

## REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Goodman manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New York.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Wiley and Sons, New Jersey, 2008.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Pharmaceutical Manufacturing lab</b>
<b>Course Code</b>	<b>MPQ205P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

At the end of the practical course of experiments, the student will be able to

C205.1	Compare the sterile area and normal production area
C205.2	Understand the concept of selection of vendor
C205.3	Understand plant layout.

1. Check list for Bulk Pharmaceutical Chemicals vendors
2. Check list for tableting production.
3. Check list for sterile production area
4. Check list for Water for injection.
5. Design of plant layout: Sterile and non-sterile
6. Optimization of QbD
7. Protocol Development for Accelerated Stability Studies
8. Determination of P<sub>ka</sub> and Log P of drugs
10. To study the effect of P<sup>H</sup> on the solubility of drugs

<b>Program</b>	<b>M. Pharmacy</b>
<b>Year /Semester</b>	<b>First year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Pharmaceutical Validation lab</b>
<b>Course Code</b>	<b>MPA206P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

1. Estimation of Metallic contaminants by Flame photometer
2. Validation of an analytical method for a drug
3. Cleaning validation of one equipment.
4. Calibration of UV Vis Spectrophotometer.
5. Calibration of FT-IR Spectrophotometer.
6. Calibration of pH meter.
7. Calibration of HPLC
8. Calibration of Dissolution apparatus.
  
9. Qualification of following Pharma equipment
  - a) Autoclave
  - b) Tablet Compression Machine
  - c) Dissolution test apparatus
  - d) Friability
  - e) Disintegration



<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Biological screening methods (Elective)</b>
<b>Course Code</b>	<b>MQA 302 E1</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The students are going to study about various techniques for screening of drugs for various pharmacological activities and guidelines for handling animals and human and animal ethics for screening of drugs.

### Course Outcomes

On completion of this course, it is expected that students will be able to understand,

C302E1.1	Understand handling of animals, usage
C302E1.2	Screening of dosage forms in animals
C302E1.3	Understand about Pharmacological procedures

### Course Content

**60 Hours**

<b>Unit</b>	<b>Content</b>	<b>Hours</b>
1	Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.	12h
2	Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbits Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.	12h
3	Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.	12h
4	Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.	12h
5	Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.	12h

**TEXT BOOKS:**

11. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
12. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springer-Verlag, Berlin Heidelberg
13. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi
14. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
15. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

<b>Program</b>	<b>M. Pharmacy</b>
<b>Year /Semester</b>	<b>Second year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Analytical QbD ( Elective)</b>
<b>Course Code</b>	<b>MQA302E2</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The objective of Analytical Quality by Design is a modern, approach that optimize the method development conditions for any analytical method. It uses a systemic approach to ensure quality by developing and understanding the system to develop robust method.

### Course Outcomes

On completion of this course it is expected that students will be able to understand,

C302E2.1	Analyze QbD concepts
C302E2.2	Optimize method development conditions by A QbD
C302E2.3	Understand about DoE and Critical Attributes.

<b>Unit</b>	<b>Content</b>	<b>Hours</b>
Unit-I	Introduction to Analytical Quality by Design: AQbD principles and fundamentals, Regulatory stand points of AQbD Potential applications of AQbD in analytical settings.	12
Unit-II	Analytical Quality by Design for gas chromatographic method development. Introduction, need for QbD in GC process development, Methodological aspects, Implimentation of QbD in GC, Statistical tools supporting GC-QbD, Experimental design, Method control strategy, validation.	12
Unit-III	Analytical Quality by Design for liquid chromatographic method development. Introduction, need for QbD in HPLC development, Methodological aspects, selection of method variables & Response variables, Optimization of method factors, Implimentation of QbD from design space, validation.	12
Unit-IV	Risk assessment and design space consideration in AQbD: Rewards of AQbD Approach to analytical methods, Regulatory perspectives of AQbD, Risk assessment in analytical method, Design space, MODR, Contour plots: 2 dimentional and 3 dimentional.	12
Unit-V	Design of experiments Application for analytical method development: Fundamentals of applying design of experiments, Key principles of DOE, Steps in performing DOE, Application of DoE in Analytical development.	12

## References

5. Hand book of Analytical Quality by design- Sarwar beg, Md saquib Hasnain. 1<sup>st</sup> edition, Elsevier publication, 2021.
6. International Conference on Harmonization (ICH) Q8(R2): Pharmaceutical Development (August 2009)
7. International Conference on Harmonization (ICH) Q9: Quality Risk Management (November 2005).
8. Ahuja, S. and Jespersen, N. Modern Instrumental Analysis, Elsevier, Amsterdam, 2006.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Scientific Writing (Elective)</b>
<b>Course Code</b>	<b>MQA 302 E3</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The objective of scientific writing is to formalize the students to communicate and get the research work published

### Course Outcomes

On completion of this course, it is expected that students will be able to understand,

C303E2.1	Analyze scientific writing concepts
C303E2.2	Understand the concept of publication
C303E2.3	Evaluate the journals and the work for publication

1	<b>Introduction skills:</b> Getting ideas, designing the research work, Types of papers, Structure of a typical paper, how to write an introduction, essentials of language and academic editing	12h
2	<b>Effective Literature Review:</b> Databases (Medline, Science direct, Springer, PubMed, Google Scholar, and others), Collection of the information, Inclusion, and sequencing of authors based on their roles, Preparation of title and abstract of manuscript, Discussion, and conclusion,	12h
3	<b>Skills in writing Methodology:</b> Purpose of the Methods section, Preparation of Experimental Design, Conventions regarding style, Designing and labeling tables, how to use Excel for graphs, how to use Pivot Tables in Excel	12h
4	<b>Results and discussion:</b> Purpose of the Results, how to write the results, Purpose of the discussion, Preparation of Experimental Design How to write the discussion and conclusion <b>References:</b> Referencing styles: Vancouver, others, Referencing software: EndNote, Zotero etc. <b>Ethics:</b> Copyright, Plagiarism, Conflict of interest and disclosure. <b>English in writing skills:</b> Errors in grammar, punctuation.	12h
5	<b>Communication:</b> How to write an abstract, Graphical abstract/Image representation Selection of journal, Guide for SCOPUS/WOS/SCI Journals and Predatory Journals, Respond to the reviewer's comments	12h

## References

1. Lebrun JL. Scientific writing: a reader and writer's guide. World Scientific; 2007 Apr 5.
2. Gitlin L, Kolanowski A, Lyons KJ. Successful grant writing: Strategies for health and human service professionals. Springer Publishing Company; 2020 May 26.
3. Markovac J, Kleinman M, Englesbe M, editors. Medical and scientific publishing: author, editor, and reviewer perspectives. Academic Press; 2017 Nov 13.
4. Diskin S. The 21st Century Guide to Writing Articles in the Biomedical Sciences. World Scientific; 2018 Mar 9.
5. Joubert PH, Rogers SM. Strategic Scientific and Medical Writing. Berlin: Springer; 2015.
6. [https://cactus-editorial.teachable.com/p/bet\\_open](https://cactus-editorial.teachable.com/p/bet_open)

# PHARMACOLOGY

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MLP101T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description**

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

#### **Course Outcomes:**

C101.1	Discuss the principle of various modern analytical technique involved in the analysis of drugs using spectroscopy, chromatography, electrophoresis, x-ray methods.
C101.2	Apply the modern analytical techniques in the identification and quantification of drugs in dosage forms.
C101.3	Interpret the analytical data and spectral data to draw the conclusion of quality of pharmaceuticals.

#### **THEORY**

**60 hours**

<b>1</b>	a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorptions spectroscopy: Principle, Instrumentation, Interferences and Applications.	<b>10hrs</b>
<b>2</b>	NMR spectroscopy: Quantum numbers and their role in NMR, Principle,	<b>10 hrs</b>



	Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup> C NMR. Applications of NMR spectroscopy.	
<b>3</b>	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	<b>10hrs</b>
<b>4</b>	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: <ul style="list-style-type: none"> <li>• Thin Layer chromatography</li> <li>• High Performance Thin Layer Chromatography</li> <li>• Ion exchange chromatography</li> <li>• Column chromatography</li> <li>• Gas chromatography</li> <li>• High Performance Liquid chromatography</li> <li>• Ultra High Performance Liquid chromatography</li> <li>• Affinity chromatography</li> <li>• Gel Chromatography</li> </ul>	<b>10hrs</b>
<b>5</b>	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	<b>10hrs</b>
<b>6</b>	a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, Derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	<b>10hrs</b>

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>ADVANCED PHARMACOLOGY – I</b>
<b>Course Code</b>	<b>MPL 102T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

#### **Course Outcomes:**

C102.1	Discuss the pathophysiology and pharmacotherapy of certain diseases
C102.2	Explain the mechanism of drug actions at cellular and molecular level
C103.3	Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of disease

Theory

60hrs

<b>1</b>	General Pharmacology a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Significance of Protein binding. b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.	<b>12hrs</b>
<b>2</b>	Neurotransmission a. General aspects and steps involved in neurotransmission. b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetylcholine). c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine). d. Non adrenergic non cholinergic transmission (NANC). Cotransmission Systemic Pharmacology	<b>12 hrs</b>

	A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems Autonomic Pharmacology Para sympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction	
<b>3</b>	Central nervous system Pharmacology General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety, Depression, psychosis, mania, epilepsy, neurodegenerative Diseases, Narcotic and non-narcotic analgesics.	<b>12hrs</b>
<b>4</b>	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Anticoagulants, fibrinolytics and antiplatelet drugs	<b>12hrs</b>
<b>5</b>	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	<b>12hrs</b>

#### REFERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. K.D. Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications – Malcolm Rowland and Thomas N. Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I</b>
<b>Course Code</b>	<b>MPL 103T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

#### **Course Outcomes:**

<b>C103.1</b>	Appraise the regulations and ethical requirement for the usage of experimental animals.
<b>C103.2</b>	Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
<b>C103.3</b>	Describe the various newer screening methods involved in the drug discovery process
<b>C103.4</b>	Appreciate and correlate the preclinical data to humans

Theory

60hrs

<b>1</b>	Laboratory Animals Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications. Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals.	<b>12hrs</b>
<b>2</b>	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.	<b>12 hrs</b>
<b>3</b>	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergies. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: antiulcer, anti -emetic, antidiarrheal and	<b>12hrs</b>

	laxatives.	
<b>4</b>	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.	<b>12hrs</b>
<b>5</b>	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. immunomodulators, Immunosuppressants and immunostimulants, General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogeneous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin. Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans	<b>12hrs</b>

#### REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N. Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K. Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK. Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK. Kulkarni, 3rd Edition.
12. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A. Turner.
14. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>CELLULAR AND MOLECULAR PHARMACOLOGY</b>
<b>Course Code</b>	<b>MPL 104T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

#### **Course Outcomes:**

<b>C104.1</b>	Explain the receptor signal transduction processes.
<b>C104.2</b>	Explain the molecular pathways affected by drugs.
<b>C104.3</b>	Explain the molecular pathways affected by drugs.
<b>C104.4</b>	Demonstrate molecular biology techniques as applicable for pharmacology.

Theory

60hrs

<b>1</b>	Cell biology Structure and functions of cell and its organelles, Genome organization. Gene expression and its regulation, importance of siRNA and microRNA. Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.	<b>12hrs</b>
<b>2</b>	Cell signaling Intercellular and intracellular signaling pathways. Detailed study of following intracellular signaling pathways: cyclicAMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.	<b>12 hrs</b>
<b>3</b>	Principles and applications of genomic and proteomic tools, DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy. Basic principles of	<b>12hrs</b>

	recombinant DNA technology-Restrictionenzymes, various types of vectors. Applications of recombinantDNA technology.Gene therapy-Various types of gene transfer techniques, clinicalapplications and recent advances in gene therapy.	
<b>4</b>	Pharmacogenomics Gene mapping and cloning of disease gene.Genetic variation and its role in health/ pharmacologyPolymorphisms affecting drug metabolism. Genetic variation in drug transporters, Genetic variation in G protein coupled receptors. Applications of proteomics science: Genomics, proteomics,metabolomics, functionomics, nutrigenomics.	<b>12hrs</b>
<b>5</b>	a. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media,various types of cell culture, general procedure for cell cultures;isolation of cells, subculture, cryopreservation, characterization ofcells and their application. Principles and applications of cell viability assays, glucose uptakeassay, Calcium influx assaysPrinciples and applications of flow cytometry b. Biosimilars	<b>12hrs</b>

#### REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J.Licinio and M - L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Miller
6. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current protocols in molecular biology vol I to VI edited by Frederick M. Ausubel et al.



<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MLP105P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

At the end of the practical course of experiments, the student will be able to

C105.1	Demonstrate the skill to adopt standard operating procedure to handle modern analytical technique like spectroscopy, chromatography, electrophoresis, x-ray methods.
C105.2	Conduct experiments using modern analytical techniques for the analysis of dosage forms.
C105.3	Elucidate the chemical structure from the spectral data by applying the principles of spectroscopy.

## PRACTICALS

1. Study of auxo-chrome effect by UV-Visible spectrum
2. Assay of Metformin tablets by A (1%, 1 cm) method as per IP 2014
3. Assay of Ciprofloxacin injection using ferric chloride by Colorimetric method
4. Assay of Riboflavin tablets by Fluorimetry
5. Assay of FDC using simultaneous method by UV Spectrophotometer in drug dosage form
6. Identification of substance by IR and UV spectrum
7. Assay of caffeine by RP-HPLC method (Calibration curve method)
8. Determination of composition of volatile oil (lemon oil/ cinnamon oil) by GC (area normalization method)
9. Calculation of system suitability parameters for HPLC chromatograph
10. Determination of R<sub>f</sub>, R<sub>m</sub>, R<sub>x</sub> value for amino-acids /sugars/ analogue by PC/TLC
11. Isolation of  $\beta$ -carotene by preparative TLC method
12. Experiments on column packing and elution (Demo)
13. Workshop on Spectral interpretation (IR and <sup>1</sup>H NMR)
14. Problem based exercise /Revision (Woodward Fieser rule)

## References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein,
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman,

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Pharmacology Practical -1</b>
<b>Course Code</b>	<b>MLP106P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**At the end of the practical course of experiments, the student will be able to**

<b>C105.1</b>	Carry out handling of animals, different routes of drug administration, techniques of blood sampling, anaesthesia and euthanasia of experimental animals.
<b>C105.2</b>	Perform the dose curve of agonists and PA <sub>2</sub> value of antagonists by using suitable animal tissue preparations
<b>C105.3</b>	Perform the bioassays by using suitable animal tissue preparations

#### **PRACTICALS**

1. Handling of laboratory animals.
2. Various routes of drug administration.
3. Techniques of blood sampling
4. Anesthesia and euthanasia of experimental animals.
5. Isolation of various organs.
6. Cannulation of veins, arteries, trachea
7. To record the DRC of agonist using suitable isolated tissues preparation.
8. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
9. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
10. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
11. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
12. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
13. Estimation of PA<sub>2</sub> values of various antagonists using suitable isolated tissue preparations.

#### **References**

1. Fundamentals of experimental Pharmacology by M.N.Ghosh
2. Handbook of Experimental Pharmacology by S.K. Kulkarni.
3. Practical Manual of Experimental and Clinical Pharmacology by BikashMedhi (Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>ADVANCED PHARMACOLOGY – II</b>
<b>Course Code</b>	<b>MPL 201T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

#### **Course Outcomes:**

<b>C201.1</b>	<b>Explain the mechanism of drug actions at cellular and molecular level</b>
<b>C201.2</b>	<b>Discuss the Pathophysiology and pharmacotherapy of certain diseases</b>
<b>C201.3</b>	<b>Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases</b>
<b>C201.4</b>	<b>Demonstrate molecular biology techniques as applicable for pharmacology.</b>

#### **Objectives**

Upon completion of the course the student shall be able to

CO1. Explain the mechanism of drug actions at cellular and molecular level

CO2. Discuss the Pathophysiology and pharmacotherapy of certain diseases

CO3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

#### **THEORY**

60 hours

<b>1</b>	<b>Endocrine Pharmacology</b> Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones. Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation	<b>12hrs</b>
<b>2</b>	<b>Chemotherapy</b> Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as $\beta$ -lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.	<b>12 hrs</b>
<b>3</b>	<b>Chemotherapy</b> Drugs used in Protozoal Infections, Drugs used in the treatment of Helminthiasis, Chemotherapy of cancer, Immunopharmacology, Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants	<b>12hrs</b>
<b>4</b>	<b>GIT Pharmacology</b> Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases	<b>12hrs</b>

	like cardiovascular disease, diabetes, asthma and peptic ulcer	
<b>5</b>	Free radicals Pharmacology Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant. Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	<b>12hrs</b>

## REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cotran Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K. Srivastava published by APC Avichal Publishing Company.
11. K.D. Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>PHARMACOLOGICAL AND TOXICOLOGICAL SCREENINGMETHODS-II</b>
<b>Course Code</b>	<b>MPL 202T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

#### **Course Outcomes:**

<b>C202.1</b>	Explain the various types of toxicity studies.
<b>C202.2</b>	Appreciate the importance of ethical and regulatory requirements for toxicity studies.
<b>C202.3</b>	Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases
<b>C202.4</b>	Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Theory

60 hrs

<b>1</b>	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive), Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y. OECD principles of Good laboratory practice (GLP). History, concept and its importance in drug development	<b>12hrs</b>
<b>2</b>	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	<b>12 hrs</b>
<b>3</b>	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II), Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies), In vivo carcinogenicity studies	<b>12hrs</b>
<b>4</b>	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	<b>12hrs</b>
<b>5</b>	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation	<b>12hrs</b>

	kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	
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## REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glphandbook.pdf>).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>PRINCIPLES OF DRUG DISCOVERY</b>
<b>Course Code</b>	<b>MPL 203T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

#### **Course Outcomes:**

<b>C203.1</b>	Explain the various stages and targets of drug discovery.
<b>C203.2</b>	Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
<b>C203.3</b>	Explain various lead seeking method and lead optimization
<b>C203.4</b>	Appreciate the importance of the role of computer aided drug design in drug discovery

Theory

60hrs

<b>1</b>	An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.	<b>12hrs</b>
<b>2</b>	Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction	<b>12 hrs</b>
<b>3</b>	Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design,	<b>12hrs</b>

	Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,	
4	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.	12hrs
5	QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design	12hrs

#### REFERENCES

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markel In. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L. Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.



<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>PRINCIPLES OF DRUG DISCOVERY</b>
<b>Course Code</b>	<b>MPL 204T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

#### **Course Outcomes:**

<b>C204.1</b>	Explain the regulatory requirements for conducting clinical trial and clinical trial design
<b>C204.2</b>	Execute safety monitoring, reporting and close-out activities
<b>C204.3</b>	Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance
<b>C204.4</b>	Explain the principles of Pharmacovigilance

<b>1</b>	Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process	<b>12hrs</b>
<b>2</b>	Clinical Trials: Types and Design, Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional, Clinical Trial Study Team, Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	<b>12 hrs</b>
<b>3</b>	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT	<b>8 hrs</b>

	Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	
<b>4</b>	Basic aspects, terminologies and establishment of Pharmacovigilance. History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	<b>12hrs</b>
<b>5</b>	a) Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data. b) Pharmacoeconomics	<b>12hrs</b>

## REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996. 229
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Pharmacology Practical -II</b>
<b>Course Code</b>	<b>MPL 205P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours practical</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

This course is designed to impart knowledge and skills necessary to train the students to be on par to perform the screening of drugs using suitable animals and toxicity studies of drugs as per OECD guidelines.

#### **Course Outcomes:**

<b>C205.1</b>	Perform the screening of drugs by using suitable animals
<b>C205.2</b>	Perform the toxicity studies as per OECD guidelines.

#### **Practicals:**

1. Functional observation battery tests (modified Irwin test)
2. Evaluation of CNS stimulant, depressant activity
3. Evaluation of anxiogenic and anxiolytic activity
4. Anticonvulsant activity.
5. Evaluation of analgesic activity.
6. Evaluation of anti-inflammatory.
7. Evaluation local anesthetic activity
8. Evaluation of mydriatic and miotic activity.
7. Evaluation of diuretic activity.
8. Evaluation of antiulcer activity by pylorus ligation method.
9. Evaluation of antipsychotic activity
10. Evaluation of skeletal muscle relaxant activity
11. Evaluation of anti - Depressant activity
12. Evaluation of anti - Parkinsonism activity
13. Evaluation of anti - Alzheimer activity.
14. Evaluation of anti - Diarrhoeal activity.
15. Acute oral toxicity studies as per OECD guidelines.
16. Acute dermal toxicity studies
17. Method of calculation of ED50 and LD50

#### **REFERENCES**

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 2<sup>nd</sup> semester</b>
<b>Name of the course</b>	<b>Pharmacology Practical -III</b>
<b>Course Code</b>	<b>MPL 206P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

This course is designed to impart knowledge and skills necessary to train the students to be on par to perform the screening of drugs using suitable animals and toxicity studies of drugs as per OECD guidelines.

#### **Course Outcomes:**

<b>C205.1</b>	Perform the isolation and estimation of nucleic acids, proteins using biological samples
<b>C205.2</b>	Perform the various molecular techniques and various invitro methods using biological samples.

1. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
2. Isolation of RNA from yeast
3. Estimation of proteins by Bradford/Lowry's in biological samples.
4. Estimation of RNA/DNA by UV Spectroscopy
5. Gene amplification by PCR.
6. Protein quantification Western Blotting.
7. Enzyme based in-vitro assays (MPO, AChEs,  $\alpha$  amylase,  $\alpha$  glucosidase).
8. Cell viability assays (MTT/Trypan blue/SRB).
9. DNA fragmentation assay by agarose gel electrophoresis.
10. DNA damage study by Comet assay.
11. Apoptosis determination by fluorescent imaging studies.
12. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares.
13. Determination of cholesterol, triglycerides, LDL, HDL.
14. Determination of liver enzymes in order to evaluate Hepatoprotective drugs (ALT, AST, Serum bilirubin and alkaline phosphatase).
15. Evaluation of renal function by measuring blood urea nitrogen, creatinine clearance.

#### **References**

1. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
2. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
3. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

4. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Research Methodology and IPR</b>
<b>Course Code</b>	<b>MRM 301T</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

## **II YEAR I Semester**

### **Course description**

- To understand the research problem
- To know the literature studies, plagiarism, and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes:

At the end of this course, students will be able to

CO301T-1	Understand research problem formulation.
CO301T-2	Analyze research related information
CO301T-3	Follow research ethics
CO301T-4	Understand new ideas, concept, and creativity.
CO301T-5	Understanding about Intellectual Property Right to be promoted among students in general & engineering.

1	General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, approaches, analysis, Plagiarism, Research ethics	12h
2	Effective technical writing, how to write report, Paper Developing a Research Proposal. Citation of references in the manuscript. Format of research proposal.	12h
3	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (tudent's "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	12h
4	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment, and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia. Declaration of Helsinki: History, introduction, basic principles for all medical Research.	12h
5	Nature of Intellectual Property: Patents, Designs, Trade and Copyright.	12h

	<p>Process of Patenting and Development: technological research, innovation, patenting, development.</p> <p>International Scenario: International cooperation on Intellectual Property.</p> <p>Procedure for grants of patents, Patenting under PCT.</p> <p>Patent Rights: Scope of Patent Rights. Licensing and transfer of technology.</p> <p>Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies.</p>	
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### **TEXT BOOKS:**

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

### **REFERENCES:**

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step-by-Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
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7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Clinical Pharmacokinetics and Therapeutic Drug Monitoring (Elective)</b>
<b>Course Code</b>	<b>MPL 302 E1</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course description:** In current methods of treatment which involves individualization of drug therapy, the student should have sound knowledge in pharmacokinetics and the effects of changes in pharmacokinetic parameters on therapeutic efficacy of the drugs.

### Course Outcomes

On completion of this course, it is expected that students will be able to understand,

C302E1.1	Understand various pharmacokinetic parameters
C302E1.2	Influence of these parameters on efficacy of drugs
C302E1.3	Identify and resolve drug related problems

### Course Content

**60 Hours**

<b>Unit</b>	<b>Content</b>	<b>Hours</b>
1	Drug Absorption: Gastrointestinal, percutaneous, and rectal kinetics and factors affecting drug absorption. Absorption kinetics	12h
2	Drug Distribution: Plasma protein binding – factors affecting plasma protein binding – Tissue binding – transfer of drugs through biological barriers their therapeutic implication in drug action. Volume of distribution. Reaction of the body to foreign substances: Biotransformation of drugs, phase I and phase II metabolic reactions.	12h
3	Elimination of drugs: Concept of renal clearance and excretion of drugs – biological half – life, area under curve.	12h
4	Bioavailability of drug products: Bioavailability tests. Bioequivalence. Compartment models and relevant pharmacokinetic parameters.	12h
5	Therapeutic Drug Monitoring: a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, Age and weight, disease, interacting drugs). C. Indications for TDM. Protocol for TDM. d. Pharmacokinetic/Pharmacodynamic correlation in drug therapy. e. TDM of drugs used in the following disease conditions: cardiovascular disease, seizure disorders, psychiatric conditions and organ transplantations.	12h

## References

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2. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
3. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
4. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics; By Robert F Notari f. Biopharmaceutics; By Swarbrick
6. Biopharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
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8. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
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<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Clinical Pharmacy Practice (Elective)</b>
<b>Course Code</b>	<b>MPL 302 E2</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course description:** This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

**Course Outcomes:**

Upon completion of this course it is expected that students shall be able to:

<b>C302E2.1</b>	Understand the elements of pharmaceutical care and provide comprehensive patient care services
<b>C302E2.2</b>	Interpret the laboratory results to aid the clinical diagnosis of various disorders
<b>C302E2.3</b>	Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

**Course Content**

**60 Hours**

<b>Unit</b>	<b>Content</b>	<b>Hours</b>
<b>1</b>	Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical MPP, Pharmaceutical care Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)	12h
<b>2</b>	Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counseling, Drug utilization evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services.	12h
<b>3</b>	Patient Data Analysis: Patient Data & Practice Skills: Patient's case history – its structure and significances in drug therapy management, Common medical abbreviations, and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services. Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests.	12h
<b>4</b>	Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests	12h
<b>5</b>	Medicines & Poison Information Services: Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, establishing a drug information centre. Poison Information Service: Definition, need, organization and functions of poison information centre.	12h

## REFERENCES

1. A Textbook of Clinical MPP – Essential concepts and skills –Parthasarathi G, Karin NyfortHansen and MilapNahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Thomas J Johnson, Critical Care Pharmacotherapeutics
5. Collen D L, Sneha B S, Fundamental Skills for Patient Care in MPP
6. Patient Assessment in Pharmacy, by Yolanda M H
7. Relevant review articles from recent medical and pharmaceutical literature

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Clinical Pharmacy Practice (Elective)</b>
<b>Course Code</b>	<b>MPL 303 E3</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course description:**

The course is deals to formalize the students to communicate and get the research work published.

**Course Outcomes**

On completion of this course, it is expected that students will be able to understand,

C303E3.1	Analyze scientific writing concepts
C303E3.2	Understand the concept of publication
C303E3.3	Evaluate the journals and the work for publication

1	<b>Introduction skills:</b> Getting ideas, designing the research work, Types of papers, Structure of a typical paper, how to write an introduction, essentials of language and academic editing	12h
2	<b>Effective Literature Review:</b> Databases (Medline, Science direct, Springer, PubMed, Google Scholar, and others), Collection of the information, Inclusion, and sequencing of authors based on their roles, Preparation of title and abstract of manuscript, Discussion, and conclusion,	12h
3	<b>Skills in writing Methodology:</b> Purpose of the Methods section, Preparation of Experimental Design, Conventions regarding style, Designing and labeling tables, how to use Excel for graphs, how to use Pivot Tables in Excel	12h
4	<b>Results and discussion:</b> Purpose of the Results, how to write the results, Purpose of the discussion, Preparation of Experimental Design How to write the discussion and conclusion <b>References:</b> Referencing styles: Vancouver, others, Referencing software: End Note, Zotero etc. <b>Ethics:</b> Copyright, Plagiarism, Conflict of interest and disclosure. <b>English in writing skills:</b> Errors in grammar, punctuation.	12h
5	<b>Communication:</b> How to write an abstract, Graphical abstract/Image representation Selection of journal, Guide for SCOPUS/WOS/SCI Journals and Predatory Journals, Respond to the reviewer's comments	12h

**References**

1. Lebrun JL. Scientific writing: a reader and writer's guide. World Scientific; 2007 Apr 5.
2. Gitlin L, Kolanowski A, Lyons KJ. Successful grant writing: Strategies for health and human service professionals. Springer Publishing Company; 2020 May 26.
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4. Diskin S. The 21st Century Guide to Writing Articles in the Biomedical Sciences. World Scientific; 2018 Mar 9.
5. Joubert PH, Rogers SM. Strategic Scientific and Medical Writing. Berlin: Springer; 2015.
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# **PHARMACEUTICAL CHEMISTRY**

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MPC101T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description**

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

#### **Course Outcomes:**

C101.1	Discuss the principle of various modern analytical technique involved in the analysis of drugs using spectroscopy, chromatography, electrophoresis, x-ray methods.
C101.2	Apply the modern analytical techniques in the identification and quantification of drugs in dosage forms.
C101.3	Interpret the analytical data and spectral data to draw the conclusion of quality of pharmaceuticals.

#### **THEORY**

**60 hours**

<b>1</b>	a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectro-fluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	<b>10hrs</b>
<b>2</b>	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup> C NMR. Applications of NMR spectroscopy.	<b>10hrs</b>
<b>3</b>	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	<b>10hrs</b>
<b>4</b>	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: • Thin Layer chromatography	<b>10hrs</b>

	<ul style="list-style-type: none"> <li>• High Performance Thin Layer Chromatography</li> <li>• Ion exchange chromatography</li> <li>• Column chromatography</li> <li>• Gas chromatography</li> <li>• High Performance Liquid chromatography</li> <li>• Ultra-High Performance Liquid chromatography</li> <li>• Affinity chromatography</li> <li>• Gel Chromatography</li> </ul>	
5	<p>a. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:  a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing</p> <p>b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.</p>	10hrs
6	<p>a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.</p> <p>b. Thermal Techniques: Principle, thermal transitions, and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.</p>	10hrs

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.
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<b>Program</b>	<b>M. Pharm (Pharmaceutical Chemistry)</b>
<b>Year /Semester</b>	<b>First year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Advanced Organic Chemistry - I</b>
<b>Course Code</b>	<b>MPC102T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### Course description

Course Description: The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

#### Course Outcome

On completion of this course, it is expected that students will be able to understand-

CO 102.1	Understand the principles and applications of retrosynthesis
CO102.2	Describe mechanism & applications of various named reactions
CO102.3	Apply the concept of disconnection to develop synthetic routes for small target molecule.
CO102.4	Analyze various catalysts used in organic reactions
CO102.5	Illustrate the chemistry of heterocyclic compounds

#### THEORY

60 Hrs

1	<b>Basic Aspects of Organic Chemistry:</b> 1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications. 2. Types of reaction mechanisms and methods of determining them, 3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations. Addition reactions a) Nucleophilic and bimolecular reactions (SN1 and SN2) b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule) c) Rearrangement reaction	12h
2	<b>Study of mechanism and synthetic applications of following named Reactions:</b> Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction	12h
3	<b>Synthetic Reagents &amp; Applications:</b> Aluminium isopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Wittig reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP). <b>Protecting groups</b> a. Role of protection in organic synthesis b. Protection for the hydroxyl group, including 1,2- and 1,3-diols: ethers, esters,	12h

	carbonates, cyclic acetals&ketals c. Protection for the Carbonyl Group: Acetals and Ketals d. Protection for the Carboxyl Group: amides and hydrazides, esters e. Protection for the Amino Group and Amino acids: carbamates and amides	
4	<b>Heterocyclic Chemistry:</b> Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis. Synthesis of few representative drugs containing these heterocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorperazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.	12h
5	<b>Synthon approach and retrosynthesis applications</b> i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA) ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-, 1,4-, 1,5-, 1,6-difunctionalized compounds iii. Strategies for synthesis of three, four, five and six-membered ring.	12h

## REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Ltd, Dorling Kindersley (India) Pvt. Ltd.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandon and Gowell, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wiley India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thornes.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers



<b>Programme</b>	<b>M. Pharm (Pharmaceutical Chemistry)</b>
<b>Year /Semester</b>	<b>First year / 1st semester</b>
<b>Name of the course</b>	<b>Advanced Medicinal Chemistry</b>
<b>Course Code</b>	<b>MPC103T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

The subject is designed to impart the knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design..

#### **Course Outcome**

On completion of this course, it is expected that students will be able to understand

C103.2	Relate the role of medicinal chemistry in drug research
CO 103.2	Relate the role of medicinal chemistry in drug research
CO 103.3	Summarize the different techniques for drug discovery
CO 103.4	Analyze various strategies to design and develop new drug like molecules for biological targets and peptidomimetics

#### **THEORY**

60 Hrs

1	Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets.	12h
2	Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonistsvs antagonists, artificial enzymes.	12h
3	Prodrug Design and Analog design:	12h
4	a) Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.	12h
5	b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.	12h

## REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, VallabhPrakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

<b>Programme</b>	<b>M. Pharm (Pharmaceutical Chemistry)</b>
<b>Year /Semester</b>	<b>First year / 1st semester</b>
<b>Name of the course</b>	<b>Chemistry of Natural Products</b>
<b>Course Code</b>	<b>MPC104T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

### Course Outcome

On completion of this course, it is expected that students will be able to understand,

CO104.1	Differentiate types of natural compounds and their chemistry and medicinal importance
CO104.2	Identify the importance of natural compounds as lead molecules for new drug discovery
CO104.3	Understand the concept of rDNA technology tool for new drug discovery
CO104.4	Predict the general methods of structural elucidation of compounds of natural origin
CO104.5	Understand the techniques of isolation, purification and characterization of simple chemical constituents from natural source

### THEORY

60 Hrs

1	Study of Natural products as leads for new pharmaceuticals for the following class of drugs a) Drugs Affecting the Central Nervous System: Morphine Alkaloids b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol d) Neuromuscular Blocking Drugs: Curare alkaloids e) Anti-malarial drugs and Analogues f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and $\beta$ - Lactam antibiotics (Cephalosporins and Carbapenem)	12h
2	<b>a) Alkaloids</b> General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine. <b>b) Flavonoids</b> Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin. <b>c) Steroids</b> General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents	12h

	male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).	
3	<b>a) Terpenoids</b> Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di (retinol, Phytol, taxol) and tri terpenoids (Squalene, Ginsenoside), carotinoids ( $\beta$ carotene). <b>b) Vitamins</b> Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.	12h
4	<b>a). Recombinant DNA technology and drug discovery</b> rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation <b>b). Active constituent of certain crude drugs used in Indigenous system</b> Diabetic therapy – Gymnemasylvestre, Salacia reticulate, Pterocarpusmarsupium, Swertiachirata, Trigonellafoenumgracum; Liver dysfunction – Phyllanthusniruri; Antitumor – Curcuma longa Linn.	12h
5	<b>Structural Characterization of natural compounds</b> Structural characterization of natural compounds using IR, <sup>1</sup> HNMR, <sup>13</sup> CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.	12h

## REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – ScikelRuneckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry “A laboratory guide” – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmanstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, KrishanPrakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger’s Medicinal Chemistry.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>I year / 1<sup>st</sup> semester</b>
<b>Name of the course</b>	<b>Modern Pharmaceutical Analytical Techniques (MPAT)</b>
<b>Course Code</b>	<b>MIP105P</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>6 hours (Practical)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

At the end of the practical course of experiments, the student will be able to

C105.1	Demonstrate the skill to adopt standard operating procedure to handle modern analytical technique like spectroscopy, chromatography, electrophoresis, x-ray methods.
C105.2	Conduct experiments using modern analytical techniques for the analysis of dosage forms.
C105.3	Elucidate the chemical structure from the spectral data by applying the principles of spectroscopy.

### **PRACTICALS**

15. Study of auxo-chrome effect by UV-Visible spectrum
16. Assay of Metformin tablets by A (1%, 1 cm) method as per IP 2014
17. Assay of Ciprofloxacin injection using ferric chloride by Colorimetric method
18. Assay of Riboflavin tablets by Fluorimetry
19. Assay of FDC using simultaneous method by UV Spectrophotometer in drug dosage form
20. Identification of substance by IR and UV spectrum
21. Assay of caffeine by RP-HPLC method (Calibration curve method)
22. Determination of composition of volatile oil (lemon oil/ cinnamon oil) by GC (area normalization method)
23. Calculation of system suitability parameters for HPLC chromatograph
24. Determination of R<sub>f</sub>, R<sub>m</sub>, R<sub>x</sub> value for amino-acids /sugars/ analogue by PC/TLC
25. Isolation of  $\beta$ -carotene by preparative TLC method
26. Experiments on column packing and elution (Demo)
27. Workshop on Spectral interpretation (IR and <sup>1</sup>H NMR)
28. Problem based exercise /Revision (Woodward Fieser rule)

<b>Programme</b>	<b>M. Pharm (Pharmaceutical Chemistry)</b>
<b>Year /Semester</b>	<b>First year / 1st semester</b>
<b>Name of the course</b>	<b>Pharmaceutical Chemistry Practical</b>
<b>Course Code</b>	<b>MPC106P</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

This course also deals with various synthetic methods to develop new chemical entities and impart knowledge on isolation and characterization of phytoconstituents using various analytical methods.

#### **Course Outcomes**

C106.1	Apply various named reactions to synthesize small drug molecules.
C106.2	Demonstrate various degradation techniques to understand stability of crude drugs from plant origin

<b>Weeks</b>	<b>Duration</b>	<b>Description of Activity /Experiments</b>	<b>Type</b>
1	6h	Purification of organic solvents, column chromatography	Experiment
2	6h	Claisen-schmidt reaction.	Experiment
3	6h	Benzylic acid rearrangement.	Experiment
4	6h	Beckmann rearrangement.	Experiment
5	6h	Hoffmann rearrangement	Experiment
6	6h	Mannich reaction	Experiment
7	6h	Synthesis of medically important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)	Experiment
8	6h	Estimation of elements and functional groups in natural compounds	Experiment
9	6h	Estimation of elements and functional groups in organic compounds	Experiment
10	6h	Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.	Experiment
11	6h	Some typical degradation reactions to be carried on selected plant constituents	Experiment

## REFERENCES

1. Monographs: Indian Pharmacopoeia, British Pharmacopoeia, United States of Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia.
2. Martindale. The complete drug Reference. 34<sup>th</sup> and 35<sup>th</sup> editions.
3. Analytical profiles of drug substances. Edited by Klaus Florey. Published by Elsevier. Vol. 1 to Vol. 20.
4. Analytical profiles of drug substances. Edited by Harry G Brittain. Published by Elsevier. Vol. 21 to Vol. 30.
5. A Series of Analytical chemistry by open learning. Published by Wiley India.
6. Practical Organic Chemistry by Mann and Saunders.
7. Vogel's text book of Practical Organic Chemistry
8. Advanced Practical organic chemistry by N.K. Vishnoi.
9. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
10. Reaction and reaction mechanism by Ahluwaliah/Chatwal
11. Systematic Experiments in Chemistry by ArunSethi, New age Publication

<b>Programme</b>	<b>M. Pharm (Pharmaceutical Chemistry)</b>
<b>Year /Semester</b>	<b>First year / 2nd semester</b>
<b>Name of the course</b>	<b>Advanced Spectral Analysis</b>
<b>Course Code</b>	<b>MPC 201T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### Course description

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

#### Course outcomes

On completion of this course, it is expected that students will be able to understand,

C201.1	Interpret the NMR, Mass and IR spectra of various organic compounds
C201.2	Use Theoretical and practical skills of the hyphenated instruments
C201.3	Elucidate the structure of organic compounds

#### THEORY

60 Hrs

1	UV and IR spectroscopy: Woodward – Fieser rule for 1,3- butadienes, cyclic dienes and $\alpha$ , $\beta$ -carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.	12h
2	NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.	12h
3	Mass Spectroscopy: Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, McLafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.	12h
4	Chromatography: Principle, Instrumentation and Applications of the following:	12h
5	a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE- MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion- Exclusion Chromatography) k) Flash chromatography	12h

#### REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series



<b>Programme</b>	<b>M. Pharm (Pharmaceutical Chemistry)</b>
<b>Year /Semester</b>	<b>First year / 2nd semester</b>
<b>Name of the course</b>	<b>Advanced Organic Chemistry - II</b>
<b>Course Code</b>	<b>MPC 202T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### Course description

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

#### Course Outcomes

On completion of this course, it is expected that students will be able to understand,

C202.1	Enumerate the principles and applications of Green chemistry.
C202.2	Understand the concept of peptide chemistry
C202.3	Analyze the various catalysts used in organic reactions
C202.4	Relate the concept of stereochemistry and asymmetric synthesis.

#### THEORY

60 Hrs

1	<b>Green Chemistry:</b> a. Introduction, principles of green chemistry b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications Continuous flow reactors: Working principle, advantages and synthetic applications.	12h
2	<b>Chemistry of peptides</b> a. Coupling reactions in peptide synthesis b. Principles of solid phase peptide synthesis, t-BOC and Fmoc protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.	12h
3	<b>Photochemical Reactions:</b> Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. <b>Pericyclic reactions:</b> Mechanism, Types of pericyclic reactions such as cycloaddition, electrocyclic reaction and sigmatropic rearrangement reactions with examples.	12h
4	<b>Catalysis:</b>	12h

	<p>a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages</p> <p>b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.</p> <p>c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs</p> <p>d. Transition-metal and Organo-catalysis in organic synthesis:</p> <p>e. Metal-catalyzed reactions</p> <p>f. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.</p> <p>Phase transfer catalysis - theory and applications</p>	
5	<p><b>Stereochemistry &amp; Asymmetric Synthesis</b></p> <p>a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.</p>	12h

## REFERENCES

1. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.
2. “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston, NewYork.
3. “Organic Chemistry” Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wiley India
7. Principles of organic synthesis, R.C. Norman and J.M. Coxon, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, NarosaPublishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

<b>Programme</b>	<b>M. Pharm (Pharmaceutical Chemistry)</b>
<b>Year /Semester</b>	<b>First year / 2nd semester</b>
<b>Name of the course</b>	<b>Computer Aided Drug Design</b>
<b>Course Code</b>	<b>MPC 203T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

#### **Course outcomes**

On completion of this course, it is expected that students will be able to understand,

C203.1	Understand the role of CADD in drug discovery
C203.2	Differentiate CADD techniques and their applications

#### **THEORY**

60 Hrs

1	<b>Introduction to Computer Aided Drug Design (CADD)</b> History, different techniques and applications. Quantitative Structure Activity Relationships: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.	12h
2	<b>Quantitative Structure Activity Relationships:</b> Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages, Deriving 2D-QSAR equations, 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters	12h
3	<b>Molecular Modeling and Docking:</b> a. Molecular and Quantum Mechanics in drug design. b. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation. Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AChE&BchE).	12h
4	<b>Molecular Properties and Drug Design</b> a. Prediction and analysis of ADMET properties of new molecules and	12h

	its importance in drug design. b. De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design. Homology modeling and generation of 3D-structure of protein.	
5	<b>Pharmacophore Mapping and Virtual Screening</b> Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.  In Silico Drug Design and Virtual Screening Techniques. Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.	12h

## REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

<b>Programme</b>	<b>M. Pharm (Pharmaceutical Chemistry)</b>
<b>Year /Semester</b>	<b>First year / 2nd semester</b>
<b>Name of the course</b>	<b>Pharmaceutical Process Chemistry</b>
<b>Course Code</b>	<b>MPC 204T</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### Course description

The course is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase. It also describes the synthetic routes that are safe, cost-effective, environmentally friendly, and efficient.

#### Course Outcomes

On completion of this course, it is expected that students will be able to understand.

C204.1	Understand the strategies of scale up process of APIs and intermediates.
C204.2	List the various unit operations and various reactions in process chemistry
C204.3	Label the environment and safety management principles involved in the organic synthesis.

#### THEORY

60 Hrs

1	<b>Process chemistry</b> Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities	12h
2	<b>Unit operations</b> a. <b>Extraction:</b> Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction. b. <b>Filtration:</b> Theory of filtration, pressure and vacuum filtration, centrifugal filtration, c. <b>Distillation:</b> azeotropic and steam distillation d. <b>Evaporation:</b> Types of evaporators, factors affecting evaporation. <b>Crystallization:</b> Crystallization from aqueous, non- aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.	12h
3	<b>Unit Processes - I</b> a. <b>Nitration:</b> Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration. b. <b>Halogenation:</b> Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process. <b>Oxidation:</b> Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H <sub>2</sub> O <sub>2</sub> , sodium	12h

	hypochlorite, Oxygen gas, ozonolysis.	
4	<b>Unit Processes - II</b> a. <b>Reduction:</b> Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. b. <b>Fermentation:</b> Aerobic and anaerobic fermentation. Production of i. Antibiotics; Penicillin and Streptomycin, ii. Vitamins: B2 and B12 ii. Statins: Lovastatin, Simvastatin c. Reaction progress kinetic analysis i. Streamlining reaction steps, route selection, Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.	12h
5	<b>Industrial Safety</b> a. MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE) b. Fire hazards, types of fire & fire extinguishers Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001 (Environmental Management System), Effluents and its management	12h

#### REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever- Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids. Dekker Series Volume 95 Ed: H G Brittain
7. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
8. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
9. P.H.Groggins: Unit processes in organic synthesis (MGH)
10. F.A.Henglein: Chemical Technology (Pergamon)
11. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
12. Clausen, Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
13. Lowenheim & M.K. Moran: Industrial Chemicals
14. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
15. J.K. Stille: Industrial Organic Chemistry (PH)
16. Shreve: Chemical Process, McGrawhill.
17. B.K.Sharma: Industrial Chemistry, Goel Publishing House
18. ICH Guidelines
19. United States Food and Drug Administration official website [www.fda.gov](http://www.fda.gov)

<b>Programme</b>	<b>M. Pharm (Pharmaceutical Chemistry)</b>
<b>Year /Semester</b>	<b>First year / 2nd semester</b>
<b>Name of the course</b>	<b>Advanced spectroscopic techniques</b>
<b>Course Code</b>	<b>MPC 205P</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The course is designed to impart knowledge on usage various spectrophotometric techniques in determination of structure of various natural or synthetic compounds.

### Course outcomes

On completion of this course, it is expected that students will be able to understand.

C205.1	Apply different synthetic routes to develop new organic molecules.
C205.2	Interpret the structure of organic compounds using various spectral techniques.
C205.3	Utilize virtual screening techniques to develop lead molecules.

<b>Weeks</b>	<b>Duration</b>	<b>Description of Activity /Experiments</b>	<b>Type</b>
1	6h	Comparison of absorption spectra by UV and Wood ward – Fieser rule	PBL Approach
2	6h	Interpretation of organic compounds by FT-IR	PBL Approach
3	6h	Interpretation of Natural compounds by FT-IR	PBL Approach
4	6h	Interpretation of organic compounds by $^1\text{H}$ NMR	PBL Approach
5	6h	Interpretation of Natural compounds by $^1\text{H}$ NMR	PBL Approach
6	6h	Interpretation of organic compounds by $^{13}\text{C}$ NMR	PBL Approach
7	6h	Interpretation of Natural compounds by $^{13}\text{C}$ NMR	PBL Approach
8	6h	Interpretation of organic compounds by DEPT	PBL Approach
9	6h	Interpretation of Natural compounds by DEPT	PBL Approach
10	6h	Determination of purity by DSC in pharmaceuticals	Experiment
11	6h	Interpretation of compounds by LC MS Mass Spectra	PBL Approach
12	6h	Interpretation of compounds by GC MS Mass Spectra	PBL Approach
13	6h	Isolation of phyto compounds and figure print analysis by HPTLC	Experiment

## REFERENCES

1. Vogel A. L. Vogel's Textbook of Practical Organic Chemistry, 5th ed. Pearson Prentice Hall: Dorling. Kindersley (India) Pvt, Ltd; 2007.
2. Mann F. G. & Saunders B. C. Practical Organic Chemistry, 4th ed.: Pearson Publishers; 2007.
3. Indian pharmacopoeia 2007/2010.
4. Burger's Medicinal Chemistry, Vol I to IV.
5. Introduction to principles of drug design- Smith and Williams.
6. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
7. Martin YC. "Quantitative Drug Design" Dekker, New York.
8. Delgado JN, Remers WA eds "Wilson &Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
9. Foye WO "Principles of Medicinal chemistry 'Lea &Febiger.
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11. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
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13. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
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<b>Programme</b>	<b>M. Pharm (Pharmaceutical Chemistry)</b>
<b>Year /Semester</b>	<b>First year / 2nd semester</b>
<b>Name of the course</b>	<b>Advanced Techniques of Drug Design and Synthesis</b>
<b>Course Code</b>	<b>MPC 206P</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The course is designed to impart knowledge on advanced techniques of drug design by computer aided drug design and other virtual screening methods to develop new leads of various biological activity interests. It also emphasizes on advanced synthetic methods based on green chemistry approaches.

### Course outcomes

On completion of this course, it is expected that students will be able to understand,

CO 206.1	Understand various techniques of biopharmaceutical evaluation of dosage forms
C206.2	Apply advanced synthetic methods and analyze the advantages over conventional methods.
C206.3	List out the regulatory accepts of API development.

<b>Weeks</b>	<b>Duration</b>	<b>Description of Activity /Experiments</b>	<b>Type</b>
<b>1</b>	6h	Synthesis of organic compounds by adapting different approaches involving (3 experiments) a) Oxidation b) Reduction/hydrogenation c) Nitration	Experiment
2	6h	Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)	Experiment
3	6h	Assignments on regulatory requirements in API (2 experiments)	Experiment
4	6h	NaBH <sub>4</sub> reduction of vanillin to vanillyl alcohol	Experiment
5	6h	Preparation of umbelliferone by Pechhman reaction	Experiment
6	6h	Preparation of triphenyl imidazole	Experiment
7	6h	To perform the Microwave irradiated reactions of synthetic importance (Any two)	Experiment
8	6h	Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares	Experiment
9	6h	Calculation of ADMET properties of drug molecules and its analysis using softwaresPharmacophore modeling	Experiment

10	6h	2D-QSAR based experiments	Experiment
11	6h	3D-QSAR based experiments	Experiment
12	6h	Docking study based experiment	Experiment
13	6h	Virtual screening based experiment	Experiment
14	6h	Preparation and Characterization of silver and Chitosan Nano particles	Experiment

## REFERENCES

1. Vogel A. L. Vogel's Textbook of Practical Organic Chemistry, 5th ed. Pearson Prentice Hall:  
Dorling. Kindersley (India) Pvt, Ltd; 2007.
2. Mann F. G. & Saunders B. C. Practical Organic Chemistry, 4th ed.: Pearson Publishers; 2007.
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5. Introduction to principles of drug design- Smith and Williams.
6. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore.
7. Martin YC. "Quantitative Drug Design" Dekker, New York.

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Research Methodology and IPR</b>
<b>Course Code</b>	<b>MRM 301T</b>
<b>Credits</b>	<b>3</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

## **II YEAR I Semester**

### **Course description**

- To understand the research problem
- To know the literature studies, plagiarism, and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

### **Course Outcomes:**

At the end of this course, students will be able to

CO301T-1	Understand research problem formulation.
CO301T-2	Analyze research related information
CO301T-3	Follow research ethics
CO301T-4	Understand new ideas, concept, and creativity.
CO301T-5	Understanding about Intellectual Property Right to be promoted among students in general & engineering.

1	General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, approaches, analysis, Plagiarism, Research ethics	12h
2	Effective technical writing, how to write report, Paper Developing a Research Proposal. Citation of references in the manuscript. Format of research proposal.	12h
3	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (tudent's "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	12h
4	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment, and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia. Declaration of Helsinki: History, introduction, basic principles for all medical Research.	12h
5	Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT. Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies.	12h

**TEXT BOOKS:**

10. Stuart Melville and Wayne Goddard, “Research methodology: an introduction for science & engineering students”
11. Wayne Goddard and Stuart Melville, “Research Methodology: An Introduction”

**REFERENCES:**

8. Ranjit Kumar, 2nd Edition, “Research Methodology: A Step-by-Step Guide for beginners”
9. Halbert, “Resisting Intellectual Property”, Taylor & Francis Ltd ,2007.
10. Mayall, “Industrial Design”, McGraw Hill, 1992.
11. Niebel, “Product Design”, McGraw Hill, 1974.
12. Asimov, “Introduction to Design”, Prentice Hall, 1962.
13. Robert P. Merges, Peter S. Menell, Mark A. Lemley, “Intellectual Property in New Technological Age”, 2016.
14. T. Ramappa, “Intellectual Property Rights Under WTO”, S. Chand, 2008

<b>Program</b>	<b>M. Pharm</b>
<b>Year /Semester</b>	<b>II year / I semester</b>
<b>Name of the course</b>	<b>Biological screening methods (Elective)</b>
<b>Course Code</b>	<b>MIP 302 E1</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4 hours (Theory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course description

The students are going to study about various techniques for screening of drugs for various pharmacological activities and guidelines for handling animals and human and animal ethics for screening of drugs.

### Course Outcomes

On completion of this course, it is expected that students will be able to understand,

C302E1.1	Understand handling of animals, usage
C302E1.2	Screening of dosage forms in animals
C302E1.3	Understand about Pharmacological procedures

### Course Content

**60 Hours**

Unit	Content	Hours
1	Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.	12h
2	Bioassays: Basic principles of biological standardization: Methods used in the bio-assay of Rabbits Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.	12h
3	Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.	12h
4	Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.	12h
5	Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.	12h

### TEXT BOOKS:

16. Screening methods in Pharmacology, Vol.-1&2 by Robert.A. Turner and Peter Hebborn.
17. Drug discovery and evaluation by H.G. Vogel and W.H. Vogel, Springer-Verlag, Berlin Heidelberg
18. Handbook of experimental pharmacology by S.K. Kulkarni, VallabhPrakashan, Delhi
19. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
20. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

<b>Program</b>	<b>M. Pharmacy</b>
<b>Year /Semester</b>	<b>II year / 3<sup>rd</sup> semester</b>
<b>Name of the course</b>	<b>Quality by Design in Organic Synthesis</b>
<b>Course Code</b>	<b>MPC 302E2</b>
<b>Credits</b>	<b>4</b>
<b>Hours /week</b>	<b>4</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course description**

The objective of Quality by Design is a modern approach that formalizes new chemical entity or lead compound, automates manual testing and streamlines trouble shooting. It uses a systemic approach to ensure quality by developing a thorough understanding of the compatibility of finally synthesized molecules to all the reaction conditions and processes involved in organic synthesis / extraction of phyto constituents.

#### **Course Outcomes**

On completion of this course it is expected that students will be able to understand

C302E2.1	Understand the QbD concepts in pharmaceutical field
C302E2.2	Optimize new chemical entity or lead compounds by QbD approach
C302E2.3	Analyze the applications of QbD in lead discovery through different case studies.

<b>Unit</b>	<b>Course content</b>	
1	<b>Overview of QbD</b> Introduction, history of QbD, Regulatory aspects of QbD, Pharmaceutical quality by testing, Elements of QbD, benefits of QbD and current state of QbD.	12h
2	<b>Aspects of QbD on lead compound development:</b> Introduction, Quality Target Profile, Critical Quality Attributes (CQAs), Critical process parameters, risk assessment. Potential applications of QbD in organic synthesis.	12h
3	Effect of parameters on lead discovery – Catalyst, Temperature, pH etc. Introduction to Design of Experiment (DOE)	12h
4	Steps in performing DOE, diagnostic plots, ANOVA, contour plots (Design space), softwares used in DOE, control strategy.	12h
5	Case studies on QbD in lead development – Microwave assisted synthesis, organic synthesis, Phytochemistry etc.	12h

#### **REFERENCES:**

- Introduction to Quality by Design for Pharmaceuticals by Nilesh Desai and Manohar A. Potdar
- Quality by Design (QbD): A new concept for Development of quality Pharmaceuticals by Patil.A.S. and Pethe.
- Hand book of Analytical Quality by design- Sarwar beg, MdsaquibHasnain. 1<sup>st</sup> edition, Elsevier publication, 2021.
- International Conference on Harmonization (ICH) Q8(R2): Pharmaceutical Development (August 2009)
- International Conference on Harmonization (ICH) Q9: Quality Risk Management (November 2005).
- Ahuja, S. and Jespersen, N. Modern Instrumental Analysis, Elsevier, Amsterdam, 2006.
- Raman VVSN, Useni Reddy et al. Quality improvement with scientific approaches (QbD, AQbD and PAT) in generic drug substance development: Review. International journal of Research and Development in Pharmacy and Life sciences 2015; 4(6): 1-10.

## SCIENTIFIC WRITING (MIP303E2)

### Course description

The objective of scientific writing is to formalize the students to communicate and get the research work published

### Course Outcomes

On completion of this course, it is expected that students will be able to understand,

C303E2.1	Analyze scientific writing concepts
C303E2.2	Understand the concept of publication
C303E2.3	Evaluate the journals and the work for publication

1	<b>Introduction skills:</b> Getting ideas, designing the research work, Types of papers, Structure of a typical paper, how to write an introduction, essentials of language and academic editing	12h
2	<b>Effective Literature Review:</b> Databases (Medline, Science direct, Springer, PubMed, Google Scholar, and others), Collection of the information, Inclusion, and sequencing of authors based on their roles, Preparation of title and abstract of manuscript, Discussion, and conclusion,	12h
3	<b>Skills in writing Methodology:</b> Purpose of the Methods section, Preparation of Experimental Design, Conventions regarding style, Designing and labeling tables, how to use Excel for graphs, how to use Pivot Tables in Excel	12h
4	<b>Results and discussion:</b> Purpose of the Results, how to write the results, Purpose of the discussion, Preparation of Experimental Design How to write the discussion and conclusion References: Referencing styles: Vancouver, others, Referencing software: EndNote, Zotero etc. <b>Ethics:</b> Copyright, Plagiarism, Conflict of interest and disclosure. <b>English in writing skills:</b> Errors in grammar, punctuation.	12h
5	<b>Communication:</b> How to write an abstract, Graphical abstract/Image representation Selection of journal, Guide for SCOPUS/WOS/SCI Journals and Predatory Journals, Respond to the reviewer's comments	12h

### References

1. Lebrun JL. Scientific writing: a reader and writer's guide. World Scientific; 2007 Apr 5.
2. Gitlin L, Kolanowski A, Lyons KJ. Successful grant writing: Strategies for health and human service professionals. Springer Publishing Company; 2020 May 26.
3. Markovac J, Kleinman M, Englesbe M, editors. Medical and scientific publishing: author, editor, and reviewer perspectives. Academic Press; 2017 Nov 13.
4. Diskin S. The 21st Century Guide to Writing Articles in the Biomedical Sciences. World Scientific; 2018 Mar 9.
5. Joubert PH, Rogers SM. Strategic Scientific and Medical Writing. Berlin: Springer; 2015.
6. [https://cactus-editorial.teachable.com/p/bet\\_open](https://cactus-editorial.teachable.com/p/bet_open)

**Raghavendra Institute of Pharmaceutical Education and Research  
(RIPER)** (Conferred Autonomous status from the academic year 2021-22) Accorded  
under Sections 2 (f) and 12 (B) of UGC act 1956 and Accredited by National Board of  
Accreditation (NBA) and National Assessment & Accreditation Council (NAAC: A)  
Approved by PCI and AICTE, New Delhi

## **Academic Regulations, Program structure & Syllabus**

**Effective from ACY 2021-2022**

### **DOCTOR OF PHARMACY**



**(Applicable for the students admitted from 2021-2022)**

**: Awarding University:**

**Jawaharlal Nehru Technological University Anantapuramu (JNTUA)**



<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Human Anatomy and Physiology</b>
<b>Course Code</b>	<b>16PMD101</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

The Human anatomy and physiology course that provides an integrated presentation of human anatomy and physiology. Information about each system is presented to explain the processes involved in homeostasis so that students will develop an understanding of the working of the entire human body. Wherever appropriate, information about mechanisms of action of selected drugs is presented. This course also provides the laboratory skills related to various systems, even though no dissection is involved, students must wear proper attire in the gross anatomy laboratory (requirements will be outlined in the introductory lecture). During lab periods students will work alone or in small groups and follow the instructions for each lab that are provided in the Lab Notes and Guide.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Recognize the anatomical structures and explain the physiological functions of body systems.

CO 2: Use anatomical knowledge to predict physiological consequences, and use knowledge of function to predict the features of anatomical structures

CO 3: Synthesize ideas to make a connection between knowledge of anatomy and physiology and real-world situations, including healthy lifestyle decisions and homeostatic imbalances.

CO 4: Demonstrate laboratory procedures used to examine anatomical structures and evaluate physiological functions of each organ system.

**Theory Course: Contents**

S. No.	Topics
I (12 Hours)	Scope of anatomy and physiology, basic terminologies used in this subject Description of the body as such planes and terminologies. Structure of cell – its components and their functions.
II (12 Hours)	Elementary tissues of the human body: Epithelial tissue, Connective tissue. Muscular and Nervous tissue & their sub-types and characteristics
III (12 Hours)	Osseous system - structure, composition and functions of the Skeleton. (done in practical classes - 6hrs). Classification of joints, Types of movements of joints and disorders of joints.
IV (12 Hours)	Haemopoietic System, Composition and functions of blood Haemopoiesis and disorders of blood components (definition of disorder), Blood groups, Clotting factors and mechanism
V (12 Hours)	Lymph and lymphatic system, composition, formation and circulation. Spleen: structure and functions, Disorders of lymphatic system. Cardiovascular system 1: Anatomy and functions of heart, Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
VII (12 Hours)	Cardiovascular system 2: Electrocardiogram (ECG) Cardiac cycle and heart sounds, Blood pressure – its maintenance and regulation Definition of the following disorders, Hypertension, Hypotension, Arteriosclerosis,

	Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias
VIII (12 Hours)	Respiratory system, Anatomy of respiratory organs and functions, Mechanism / physiology of respiration and regulation of respiration, Transport of respiratory gases, Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation. Sense organs: Eye, Ear, Nose, Skin and tongue
IX (12 Hours)	Digestive system: Anatomy and physiology of GIT, Anatomy and functions of accessory glands of GIT, Digestion and absorption, Disorders of GIT (definitions only), Nervous system 1: Definition and classification of nervous system Anatomy, physiology and functional areas of cerebrum
X (12 Hours)	Nervous system 2: Anatomy and physiology of cerebellum, mid brain, Thalamus, hypothalamus and Basal Ganglia, Spinal cord: Structure & reflexes – mono-poly-planter Cranial nerves – names and functions, ANS – Anatomy & functions of sympathetic & parasympathetic N.S. Urinary system, Anatomy and physiology of urinary system, Formation of urine
XI (12 Hours)	Renin Angiotensin system – Juxta glomerular apparatus - acid base Balance Endocrine system: Pituitary gland, Adrenal gland, Thyroid and Parathyroid glands Pancreas and gonads. Skeletal muscle: Histology and Physiology of Muscle contraction, Physiological properties of skeletal muscle and their disorders (definitions)
XII (12 Hours)	Reproductive system: Male and female reproductive system Their hormones – Physiology of menstruation Spermatogenesis & Oogenesis, Sex determination (genetic basis) Pregnancy, maintenance and parturition, Contraceptive devices. Sports physiology: Muscles in exercise, Effect of

	athletic training on muscles and muscle Performance Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise
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#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Recommended Text books (Latest Editions):

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

#### Reference books (Latest Editions):

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA

2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje, Academic Publishers Kolkata

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Human Anatomy and Physiology (Lab)</b>
<b>Course Code</b>	<b>16PMD107</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

Focus on the correlation between the structure and function of the various body systems, and examine topics such as the nervous, endocrine, cardiovascular and reproductive systems. Become familiar with dissection and basic microscopic examination of tissues. Biology majors, premedical and pre-health students, and those looking for a career change or to refresh their biological knowledge can benefit greatly from this course.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Learn procedures that are standard practice in an anatomy laboratory.

CO2: Communicate clearly and in a way, that reflects knowledge and understanding of the human body and demonstrates the ability to adapt information to different audiences and applications.

CO 3: Approach and examine issues related to anatomy and physiology from an evidence-based perspective

CO 4: Learn how to study, interpret and care for anatomical specimens.

### Practical Course: Contents

Week	Topics
1	Study of microscope
2	Study of Muscular tissue.
3	Study of Connective tissue.
4	Study of Nervous tissue.
5	Study of Epithelial tissue.
6	Study of appliances used in haematological experiments
7	Determination of W.B.C. count of blood.
8	Determination of R.B.C. count of blood.
9	Determination of Erythrocyte Sedimentation Rate.
10	Determination of Haemoglobin content of Blood.
11	Determination of Bleeding time
12	Determination of clotting time
13	Determination of Blood Pressure.
14	Determination of Blood group.
15	Study of various systems with the help of charts, models & specimens Skeleton system part I-axial skeleton.
16	Skeleton system part II- appendicular skeleton.
17	Study of Cardiovascular system.
18	Study of Respiratory system.
19	Study of Digestive system.
20	Study of Urinary system.
21	Study of Nervous system.

22	Study of Special senses: Ear
23	Study of Sense organ: Eye
24	Study of sense organ: Nose and Tongue
25	Study of sense organ: Skin
26	Study of Male Reproductive system.
27	Study of Female Reproductive system.
28	Study of different family planning appliances.
29	To perform pregnancy diagnosis test.
30	Study of appliances used in experimental physiology.
31	To record simple muscle curve using gastrocnemius sciatic nerve preparation.
32	To record simple summation curve using gastrocnemius sciatic nerve preparation.
33	To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
34	To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.
35	To record simple fatigue curve using gastrocnemius sciatic nerve preparation.
36	REVISION/Assessment



**Assessment methods and weightage (Practical)**

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

**Recommended Text books (Latest Editions):**

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

**Reference books (Latest Editions):**

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2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

<b>Program</b>	<b>Pharm. D</b>
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<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Pharmaceutics</b>
<b>Course Code</b>	<b>16PMD102</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>2+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

The Pharmaceutics course includes an introduction to the history and development of pharmacy, Prescription terminology, systems of measurement and Pharmaceutical calculations which are essential in preparation of various dosage forms. This course will emphasize on advantages, disadvantages, formulations and evaluations of different types of dosage forms.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: List the salient features of different Pharmacopoeias.

CO 2: Explain various procedures involved in formulation and evaluation of different types of dosage forms

CO 3: Calculate different Pharmaceutical calculations involved in formulation.

### **Theory Course: Contents**

<b>S. No.</b>	<b>Topics</b>
I (12 Hours)	Introduction to dosage forms, Prescription: definition, parts and handling. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.

II (12 Hours)	Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
III (12 Hours)	Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
IV (12 Hours)	Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
V (12 Hours)	Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
VI (12 Hours)	Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.
VII (12 Hours)	Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
VIII (12 Hours)	Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
IX (12 Hours)	Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

X (12 Hours)	Surgical aids: Surgical dressings, absorbable gelatine sponge, sutures, ligatures and medicated bandages.
XI (12 Hours)	Incompatibilities: Introduction, classification of incompatibilities
XII (12 Hours)	Methods to overcome the incompatibilities.

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources:

1. Carter S.J. Cooper & Gunns Dispensing for Pharmaceutical students. 12<sup>th</sup> ed. New Delhi: CBS Publication; 2008.
2. Mehtha R.M. Dispensing Pharmacy. New Delhi: Vallabh Publication; 2006.
3. Rawlins EA. Text Book of Pharmaceutics. 8<sup>th</sup> ed. New Delhi: ELBS Publications; 2004.
4. Gaud R.S. Modern dispensing Pharmacy. 3<sup>rd</sup> ed. Maharashtra: career publication; 2009
5. M.E. Aulton, Pharmaceutics, The Science & Dosage Form Design, Churchill Livingstone, Edinburgh.
6. Indian pharmacopoeia.
7. British pharmacopoeia

8. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
9. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.
10. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.

Program	Pharm. D
Year	First year

<b>Name of the course</b>	<b>Pharmaceutics (Lab)</b>
<b>Course Code</b>	<b>16PMD108</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

The Pharmaceutics laboratory course is aimed to train the students on formulation of different types of dosage forms. This course also deals with Pharmaceutical calculations which are essential in compounding, dispensing and utilisation of dosage forms. This course also provides the skills to identify various incompatibilities in handling of Prescriptions.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Identify various incompatibilities in handling of Prescriptions

CO2: Calculate different Pharmaceutical calculations involved in formulation.

CO 3: Formulate different types of dosage forms.

### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Preparation of Simple syrup IP
2	Preparation of Orange Syrup BP.
3	Preparation of Syrup of Ephedrine Hcl NF
4	Preparation of Syrup Vasaka IP
5	Preparation of Syrup of Ferrous phosphate IP
6	Preparation of Aqueous Iodine solution IP

7	Preparation of Strong solution of Iodine IP
8	Preparation of Strong Ammonium acetate solution IP
9	Preparation of Solution of cresol with soap
10	Preparation of Strong solution of ferric chloride BPC
11	Preparation of Linctus – Simple linctus BPC
12	Preparation of Paediatric simple linctus BPC
13	Preparation of Turpentine Liniment IP
14	Preparation of Liniment of camphor IP
15	Preparation of Eutectic powder
16	Preparation of Explosive powder
17	Preparation of Dusting powder
18	Preparation of Piperazine citrate elixir IP
19	Preparation of Paracetamol elixir BPC
20	Preparation of Cascara elixir BPC
21	Preparation of Magnesium hydroxide mixture BP
22	Preparation of Calamine Lotion.
23	Preparation of Emulsions – Cod liver oil emulsion
24	Preparation of Liquid Paraffin & castor oil emulsion
25	Preparation of Boric Acid Suppositories
26	Preparation of Chloral Suppositories
27	Mixture with physical incompatibilities
28	Mixture with Chemical incompatibilities
29	Mixture with therapeutic incompatibilities
30	Problem based exercise

31	Problem based exercise
32	<b>Revision</b>

#### **Assessment methods and weightage (Practical)**

<b>Assessment type</b>	<b>Assessment tool</b>	<b>Distribution</b>
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

#### **Learning Resources/Recommended Texts/Reference books/web resources:**

1. Subrahmanyam C.V.S. Laboratory manual of Pharmaceutics. Delhi: vallabh publications; 2006.
2. Carter S.J. Cooper & Gunns Dispensing for Pharmaceutical students. 12<sup>th</sup> ed. New Delhi: CBS Publication; 2008.
3. Metha R.M. Dispensing Pharmacy. New Delhi: Vallabh Publication; 2006

<b>Program</b>	<b>Pharm. D</b>
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<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Medicinal Biochemistry</b>
<b>Course Code</b>	<b>16PMD103</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3 +1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

The Medicinal Biochemistry gives information about transport mechanisms across membrane. It deals with catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases. It also provides the knowledge about the metabolic process of bio molecules in health and illness (metabolic disorders), genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism. This course also provides the biochemical principles of organ function tests of kidney, liver and endocrine gland. This course also deals with the qualitative analysis and determination of bio molecules in the urine and serum.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Understand the transport mechanisms across the membrane, catalytic activity of enzymes diagnostic importance.

CO 2: Explain the metabolism of bio molecules and their metabolic disorders. Demonstrate the possible mechanism and the intermediate product involved in a chemical reaction.

CO 3: Estimate the constituents present in urine and serum

CO 4: Describe the diagnosis for kidney and liver diseases.

#### **Theory Course: Contents**

S. No.	Topics
I (12 Hours)	Introduction to biochemistry: Cell and its biochemical organization, transport process across the cell membranes.
	Energy rich compounds; ATP, Cyclic AMP and their biological significance.
II (12 Hours)	Enzymes: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity;
	Enzyme action; enzyme inhibition.
	Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases
III (12 Hours)	Carbohydrate metabolism: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt.
	Glycogenolysis, gluconeogenesis, glycogenesis.
	Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism
IV (12 Hours)	Lipid metabolism: Oxidation of fatty acids ( $\beta$ -oxidation); Ketogenesis.
	Ketolysis and biosynthesis of fatty acids.
	Metabolism of cholesterol and Hormonal regulation of lipid metabolism.
	Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).
V (12 Hours)	Biological oxidation: Coenzyme system involved in Biological oxidation.
	Electron transport chain (its mechanism in energy capture; regulation and inhibition);
	Uncouplers of ETC; Oxidative phosphorylation

VII (12 Hours)	Protein and amino acid metabolism: protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation).
	Urea cycle and its metabolic disorders, production of bile pigments, hyperbilirubinemia, porphyria, jaundice.
	Metabolic disorder of Amino acids
VIII (12 Hours)	Nucleic acid metabolism: Metabolism of purine and pyrimidine nucleotides;
	Protein synthesis; Genetic code.
	Inhibition of protein synthesis, mutations.
	DNA replication (semiconservative /onion peel models) and DNA repair mechanism
IX (12 Hours)	Introduction to clinical chemistry: Cell; composition; malfunction; Roll of the clinical chemistry laboratory.
X (12 Hours)	The kidney function tests: Role of kidney; Laboratory tests for normal function includes- a) Urine analysis (macroscopic and physical examination).
	Quantitative and semi quantitative tests.
	b) Test for NPN constituents. (Creatinine /urea clearance).
	Determination of blood and urine creatinine, urea and uric acid.
	c) Urine concentration test d) Urinary tract calculi (stones).
	The liver function tests. Laboratory tests for SGPT, SGOT, Bilirubin.
XI (12 Hours)	Lipid profile tests: Lipoproteins, composition, functions. Determination of serum lipids,
	Determination of total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

XII (12 Hours)	Immunochemical techniques for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.
XIII (12 Hours)	Electrolytes: Body water, compartments, water balance, and electrolyte distribution.
	Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

1. Satyanarayana U. Textbook of Biochemistry, 4<sup>th</sup> ed. New Delhi: ELSEVIER a Division of Reed Elsevier India Pvt Ltd; 2013.
2. Lehninger. Principles of Biochemistry, 5<sup>th</sup> ed. New York: M/s worth Publishers; 1978.
3. Robert K. Murray, Daryl K. Granner, Peter A. Mayes, Victor W. Rodwell. Harper's Biochemistry, 5th ed. Mc Graw Hill Medical; 2013.
4. Jain J. L., Sunjay Jain, Nitin Jain. Fundamentals of Biochemistry, 6<sup>th</sup> ed.: Chand Company & Company Ltd.
5. Powar C. B. & Chatwal G. R. Biochemistry, 5th ed.: Himalaya Publishing House; 1989.
6. Stryer L. Textbook of Biochemistry, 6<sup>th</sup> ed.: W.H.Freemann & Co Ltd; 2012.

7. Conn E. E. & Stump P. K. *Outline of Biochemistry*, 5th ed.: John Wiley and sons, New York; 2010.
8. Harper, Biochemistry Mc Graw Hill Medical, 28th Edition.
9. Textbook of Biochemistry by Deb.

<b>Program</b>	<b>Pharm. D</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Medicinal Biochemistry (Lab)</b>
<b>Course Code</b>	<b>16PMD109</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

The Medicinal Biochemistry laboratory course is aimed to train the students on experimental techniques for the identification of normal and abnormal constituents in urine. This course also deals with estimation of amount of constituents present in urine and serum. This course also provides information about normal values and significance of estimation of constituents of urine and serum.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Identify the normal and abnormal constituents of urine.

CO 2: Explain about the normal values of components present in urine and serum and significance of their estimation

CO 3: Demonstrate the skills in determining the amount of components present in urine and serum.

### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Qualitative analysis of normal constituents of urine

2	Qualitative analysis of abnormal constituents of urine. *
3	Quantitative estimation of urine sugar by Benedict's reagent method. **
4	Quantitative estimation of urine chlorides by Volhard's method
5	Quantitative estimation of urine creatinine by Jaffe's method. **
6	Quantitative estimation of urine calcium by precipitation method. **
7	Kidney function tests
8	Preparation of Folin Wu filtrate from blood. *
9	Identification tests for carbohydrates and proteins
10	Quantitative estimation of blood sugar Folin-Wu tube method
11	Estimation of SGOT in serum. **
12	Estimation of SGPT in serum. **
13	Estimation of Urea in Serum. **
14	Estimation of Proteins in Serum. **
15	Determination of serum bilirubin**
16	Determination of Glucose by means of Glucose oxidase. **
17	Enzymatic hydrolysis of Glycogen/Starch by Amylases. ** (pH & Temp.) **
18	Study of factors affecting Enzyme activity.
19	Determination of sodium in serum. **
20	Determination of potassium in serum
21	Determination of Ammonia in urine
22	Lipid profile tests
23	Demo on colorimeter

**NOTE: \* Mark indicates minor experiment. \*\* Mark indicates major experiment**

Note: Three Sessional examinations to be conducted periodically throughout the year.

### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

### Learning Resources/Recommended Texts/Reference books/web resources

1. David T. Plummer. Introduction to Practical Biochemistry, 3rd ed.: Tata Mc Graw-Hill Education Pvt Ltd; 1988.
2. Pattabhiraman. Practical Biochemistry, 4<sup>th</sup> ed.: All India Pub (New Delhi); 2004
3. Practical Biochemistry-David T. Plummer.
4. Practical Biochemistry-Pattabhiraman.
5. Introduction of Practical Biochemistry by David T. Plummer (3rd Edition)
6. Practical Biochemistry by Harold Varley
7. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.



<b>Program</b>	<b>Pharm. D</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Pharmaceutical Organic Chemistry</b>
<b>Course Code</b>	<b>16PMD104</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

Pharmaceutical organic chemistry mainly deals with the knowledge about IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds, Some important physical properties of organic compounds, Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds, Some named organic reactions with mechanisms; and Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate the knowledge of the inter-link of pharmaceutical sciences with pharmaceutical organic chemistry by learning.

CO 2: Describe IUPAC Common system of nomenclature, types of organic reactions, mechanisms and named reaction with mechanism.

CO 3: Apply the appropriate substrate, catalyst and reaction conditions in the design of chemical reaction.

CO 4: Analyze the fundamentals on behaviour of chemical compounds in design of beneficial, economic and safe reaction for a new chemical entity.

### Theory Course: Contents

S. No.	Topic
I (12 Hours)	<b>Structures and Physical properties:</b> a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non-ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs, b. Acids and bases, Lowry Bronsted and Lewis theories c. Isomerism
II (12 Hours)	<b>Nomenclature of organic compounds:</b> Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides and Cycloalkanes.  <b>Free radicals chain reactions of alkane:</b> Mechanism, relative reactivity and stability
III (12 Hours)	<b>Alicyclic compounds:</b> Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.  <b>Nucleophilic aliphatic substitution:</b> Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.
IV (12 Hours)	<b>Dehydro halogenation of alkyl halides:</b> 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence

	of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.
V (12 Hours)	<b>Electrophilic and free radicals addition:</b> Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals addition, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.
VI (12 Hours)	<b>Carbon-carbon double bond as substituents:</b> Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.
VII (12 Hours)	<b>Theory of resonance:</b> Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophilic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes,

	1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.
VIII (12 Hours)	<b>Electrophilic aromatic substitution:</b> Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, Friedel craft alkylation, Friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.
IX (12 Hours)	<b>Nucleophilic addition reaction:</b> Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.
X (12 Hours)	<b>Nucleophilic aromatic substitution:</b> Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
XI (12 Hours)	<b>Named Reactions:</b> Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition. Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines,

	diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.
XII (12 Hours)	<b>Oxidation reduction reaction.</b> <b>Study of the following official compounds-</b> preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources:

1. Morrison and Boyd. Organic Chemistry. New York University, Allyn and Bacon, Inc. Boston, London, Sydney, Toronto, ISBN 0-205-05838-8.
2. M. Atherden. Bentley and Driver's Textbook of Pharmaceutical Chemistry. Ed: 1. Oxford University Press: Delhi.
3. I. L. Finar. Organic Chemistry. Longman, Scientific & Technical, Co-published in USA with John Wiley & Sons, Inc. New York. ISBN 0-582-44257-5.

4. Arunbahl & B. S. Bahl. Advanced Organic Chemistry. Edition 2012, S. Chand & Company Pvt. Ltd: New Delhi; 2014 (ISBN: 81-219-3515-6).
5. D. Abraham (Ed), Burger Medicinal chemistry and Drug discovery, Vol. 1 & 2, 6<sup>th</sup> ed, John Wiley & Sons, New York 2003.
6. T.W.Solomons. Organic Chemistry, University of SouthFlorida, John Wiley & Sons, Inc. New York, Chichester, Brisbane, Toronto, Singapore.
7. Jerry March. Advanced organic chemistry. John Wiley & Sons: New York.
8. EL Eliel and SH Wilen. Stereochemistry of Organic Compounds. Wiley: New York; 1994.
9. Organic chemistry- Brown
10. Organic chemistry- Cram and Hammered, Pine Hendrickson
11. Organic Chemistry by P. L. Soni

<b>Program</b>	<b>Pharm. D</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Pharmaceutical Organic chemistry (Lab)</b>
<b>Course Code</b>	<b>16PMD110</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>4 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

The pharmaceutical organic chemistry laboratory course is aimed to train the students on experimental techniques through demonstration involving synthesis & purification of the various organic compounds. This course also deals with wet laboratory based experiments on identification of various chemical classes of organic compounds using basic principles of organic chemistry.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate the skills on determination of various physical properties of organic molecules.

CO 2: Differentiate various classes of organic compounds by experimental techniques.

CO 3: Perform chemical reaction and purification of organic compounds of pharmaceutical interest.

#### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
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1	Determination of the Melting point
2	Determination of the boiling point
3	Detection of extra elements by Lassaignes test – Test for Nitrogen, sulphur, and Halogen
4	Synthesis of meta-dinitro benzene (Nitration)
5	Synthesis of benzophenone oxime
6	Synthesis of picric acid
7	Synthesis of 1-phenylazo-2-naphthol (Diazotisation and coupling)
8	Synthesis of 9,10-anthraquinone (Oxidation)
9	Synthesis of phenyl benzoate (Benzoylation)
10	Detection of extra elements by Lassaigne's test
11	Qualitative organic analysis of Carbohydrates
12	Qualitative organic analysis of Carboxylic acids
13	Qualitative organic analysis of Salicylic acid
14	Qualitative organic analysis of Benzoic acid
15	Qualitative organic analysis of Cresol
16	Qualitative organic analysis of Resorcinol
17	Qualitative organic analysis of Aldehydes & ketones
18	Qualitative organic analysis of Amines
19	Qualitative organic analysis of Alcohols
20	Qualitative organic analysis of Anilides
21	Qualitative organic analysis of Ester
22	Stereo models

#### **Assessment methods and weightage (Practical)**



Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

**Learning Resources/Recommended Texts/Reference books/web resources:**

1. A.I. Vogel. Text Book of Practical Organic Chemistry. 5th Edition. Pearson Prentice Hall.
2. R.K. Bansal. Laboratory Manual of Organic Chemistry. 5th Edition, New Age International; 2007.
3. O.P. Agarwal. Advanced Practical Organic Chemistry. 3rd Edition, Goel Publication.
4. F.G. Mann & B.C. Saunders. Practical Organic Chemistry. 4th Edition, Pearson Prentice Hall.
5. Practical Organic Chemistry by Mann and Saunders.
6. Advanced Practical Organic Chemistry by N. K. Vishnoi.
7. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
8. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

<b>Program</b>	<b>Pharm. D</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Pharmaceutical Inorganic Chemistry</b>
<b>Course Code</b>	<b>16PMD105</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>2+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

Pharmaceutical Inorganic chemistry course mainly deals with fundamentals of analytical chemistry and also the study of various classes of inorganic pharmaceuticals regarding their content of specifications according to monographs mentioned in pharmacopoeia. This course also deals with basic knowledge of various medicinal gases & radio pharmaceuticals towards their pharmaceutical & Medicinal or clinical applications.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: State the concept, preparations, and properties of various classes of inorganic compounds and also regarding the applications in the various fields.

CO 2: Demonstrate the various concepts of end point detection and also importance of various medicinal gases, trace elements and radio pharmaceuticals in the pharmaceutical / medicinal / clinical purposes.

CO 3: Analyze the standardization & purity evaluation of various pharmaceutical inorganic compounds as per IP with possible principle behind assays and the limit tests.

### Theory Course: Contents

S. No.	Topics
I (12 Hours)	<b>Errors</b> Errors in quantitative analysis, classification of errors, concept of accuracy and precision, treatment of analytical results.
	<b>Volumetric analysis</b> Principle of volumetric analysis, different methods of analysis
	Different methods for expressing concentrations of solutions, primary and secondary standards.
II (12 Hours)	<b>Acid-base titrations</b> Acid- base concepts, relative strength of acids and bases, law of mass action.
	Common-ion effect, ionic product of water, Henderson-Hasselbalch equation & Buffer solutions
	Theory of indicators, neutralization curves, choice of indicators, mixed and universal indicators.
III (12 Hours)	<b>Redox titrations</b> Concepts of oxidation–reduction reactions, redox reactions, theory of redox titrations, redox indicators,
	Titration involving iodometry and iodimetry, ceric sulphate
	Titration involving potassium iodate, potassium bromate, potassium permanganate, titanous chloride.
IV (12 Hours)	<b>Non-aqueous titration</b> Theoretical basis, types of solvents, preparations and standardization of titrant solutions,

	Titration of weak acid, weak bases and indicators. Standardisation of perchloric acid, lithium and sodium methoxide, tetra butyl ammonium hydroxide.
	<b>Complexometric titrations</b> Introduction, principle, types of titrations, endpoint detection.
V (12 Hours)	<b>Precipitation titrations</b> Introduction, types of precipitation titrations, end point detection.
	<b>Gravimetry</b> Basic concepts, Precipitation techniques, co-precipitation
	Post-precipitation, various steps involved in gravimetric analysis, pharmaceutical applications.
VI (12 Hours)	<b>Limit tests</b> Definition, importance, general procedure for limit test for chlorides,
	Sulphates, iron, arsenic
	Lead and heavy metals.
VII (12 Hours)	<b>Medicinal Gases</b> Preparation and uses of the following Oxygen, Carbon dioxide, Helium, Nitrogen and Nitrous Oxide.
	<b>Acidifiers</b> Dilute hydrochloric acid, Sodium phosphate, Ammonium chloride.
	<b>Antacids</b> Classification, Qualities of an ideal antacid, side effects, advantages, combination therapy, acid neutralizing capacity, Sodium bicarbonate, Potassium citrate

VIII (12 Hours)	Aluminium hydroxide gel, Dried aluminium hydroxide gel, Magnesium hydroxide, Light and heavy magnesium trisilicate
	light and heavy magnesium carbonate, Calcium carbonate, Magaldrate and Bismuth carbonate.
	<b>Cathartics</b>  Magnesium hydroxide, Magnesium sulphate, Magnesium carbonate and Sodium phosphate.
IX (12 Hours)	<b>Electrolyte replenishers</b>  <i>Electrolytes used for replacement therapy:</i> Sodium chloride, Potassium chloride, Calcium chloride, Calcium gluconate.
	<i>Electrolytes used in the acid-base therapy:</i> Sodium acetate, Potassium acetate, Sodium bicarbonate, Potassium bicarbonate, Sodium citrate, Sodium lactate, Ammonium chloride.
	<i>Electrolyte combination therapy:</i> Compound sodium chloride solution, Sodium chloride injection and Oral rehydration salt.
X (12 Hours)	<b>Essential Trace elements</b>  Definition, Physiological role of Iron, Copper, Zinc, Chromium,
	Manganese, Molybdenum, Selenium, Sulphur and Iodine.
	<b>Antimicrobials</b>  Hydrogen Peroxide, Potassium Permanganate, Chlorinated Lime, Iodine, Boric Acid, Silver Nitrate, Selenium Sulphide.
XI (12 Hours)	<b>Pharmaceutical Aids:</b> Sodium bisulphite, sodium metabisulphite, bentonite, magnesium stearate, zinc stearate, aluminium sulphate, sodium carboxy methyl cellulose, purified water, water for injection and sterile water for injection.

	<b>Dental products</b> <i>Anti-caries Agents:</i> Role of Fluorides as anti-caries agents, Sodium fluoride.
	<i>Dentifrices:</i> Calcium carbonate, dibasic calcium phosphate, Zinc chloride.
XII (12 Hours)	<b>Miscellaneous compounds.</b>  <b>Sclerosing agents:</b> Hypertonic saline, Sodium tetra decyl sulphate.  <b>Expectorants:</b> Potassium citrate and Potassium iodide.
	<b>Sedative:</b> Potassium bromide.  <b>Antidotes:</b> Sodium nitrite, Sodium thiosulphate and Charcoal  <b>Respiratory stimulant:</b> Ammonium carbonate.
	<b>Radiopharmaceuticals.</b>  Introduction, measurement of radioactivity, clinical applications and dosage, hazards and precautions
	Revision

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

1. G.R. Chatwal. Pharmaceutical Chemistry – Inorganic. 5<sup>th</sup> edition. Himalaya Publishing House: Mumbai, India; 2014.

2. A.A. Napoleon. Pharmaceutical Titrimetric Analysis Theory and Practical. 2<sup>nd</sup> ed. Kalaimani Publishers & Distributors: Kanchipuram; 2013.
3. A.H. Beckett and J.B. Stenlake. Practical pharmaceutical chemistry. Part-I & II. The Athlone press: University of London; 1968.
4. P. Gundu Rao. Pharmaceutical and Medicinal Inorganic Chemistry. 1st edition. Vallabh Prakashan Delhi; 2008.
5. Indian pharmacopoeia. Govt. of India; Ministry of health; 1996, 2010 & 2014.
6. Gary L. Miessler, Paul J. Fischer and Donald A. Tarr. Inorganic chemistry. 5<sup>th</sup> edition. Pearson education New Delhi; 2014.
7. G.D. Tuli, R.D. Madan, S.K. Basu and Satya Prakash. Advanced Inorganic Chemistry. Volume 1. Published by S. Chand & Company Ltd; 2014.
8. William L. Jolly. Modern Inorganic Chemistry. 2<sup>nd</sup> edition. Mc Graw-Hill: New York; 1984.
9. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
10. M.L. Schrock, Inorganic Pharmaceutical Chemistry
11. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
12. Pharmaceutical Inorganic chemistry by Dr. B.G. Nagavi
13. Analytical chemistry principles by John H. Kennedy
14. I.P. 1985 and 1996, Govt. of India, Ministry of health
15. Bentley and Driver's Textbook of Pharmaceutical Chemistry

<b>Program</b>	<b>Pharm. D</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Pharmaceutical Inorganic Chemistry (Lab)</b>
<b>Course Code</b>	<b>16PMD111</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

The Pharmaceutical Inorganic Chemistry laboratory course is aimed to train the students on experimental techniques for the determination of impurities limits as per the pharmacopoeia. This course deals with standardization & assay methods for the various classes of drugs. This course deals with identification of various cations & anions of inorganic compounds by their chemical tests. This course also provides the laboratory skills related to preparation & purification of few inorganic medicinal compounds.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate the skills on limit tests, standardization and assay methods for the various inorganic pharmaceuticals.

CO 2: Differentiate various cations & anions by their chemical tests.

CO 3: Perform the preparations and purification of some inorganic compounds.



### Practical Course: Contents

Week	Topics
1	Introduction to analytical balance
2	Calibration of burette & Pipette
3	Limit test for Chlorides
4	Limit test for Sulphates
5	Limit test for Iron
6	Limit test for Arsenic
7	Modified limit test for chlorides and sulphates
8	Assay of Ammonium chloride (Acid-base titration)
9	Assay of Ferrous sulphate (Ceriometry)
10	Assay of Copper sulphate (Iodometry)
11	Assay of Calcium gluconate (Complexometry)
12	Assay of Hydrogen peroxide (Permanganometry)
13	Assay of Sodium benzoate (Non-aqueous titration)
14	Assay of Sodium chloride (Modified Volhard's method)
15	Assay of KI-KIO <sub>3</sub> titration
16	Gravimetric estimation of Barium as Barium sulphate
17	Assay of Sodium antimony gluconate/Antimony potassium tartarate
18	Estimation of mixture Sodium hydroxide and Sodium carbonate
19	Estimation of mixture Boric acid and Borax
20	Test for identity of cations & anions in Sodium bicarbonate, Barium sulphate, Ferrous sulphate and Potassium chloride.
21	Swelling power in Bentonite

22	Acid neutralizing capacity in Aluminium hydroxide gel
23	Preparation of Boric acid
24	Preparation of Potash alum
25	Conductometric titration – Demo
26	Revision

#### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

1. A.H.Beckett and J.B.Stenlake. Practical pharmaceutical chemistry. Part-I. The Athtone press: University of London; 1968.
2. Gary L. Miessler and Donald A. Tarr. Inorganic chemistry. 3<sup>rd</sup> edition, Pearson education: New Delhi.
3. P. Gundu Rao. Inorganic pharmaceutical chemistry. VallabhPrakashan; Delhi.
4. G.D.Tuli, Satya prakash, S.Chand. Advanced Inorganic Chemistry. 2006.
5. William L. Jolly Mc Graw-Hill. Modern inorganic chemistry. New York; 1984.
6. Indian Pharmacopoeia 1996, 2010, 2014.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Remedial Mathematics</b>
<b>Course Code</b>	<b>16PMD106</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

This is an introductory course in mathematics. This subject deal with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, Laplace transform.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Define Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;

CO 2: Solve the problems of different types by applying theory

CO 3: Appreciate the important applications of mathematics in pharmacy.

### **Theory Course: Contents**

<b>S. No.</b>	<b>Topics</b>
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I (12 Hours)	<b>Algebra:</b> Matrices Definition, types of matrices, Addition of matrices, Scalar multiple matrix, Multiplication of matrices, Properties of matrices.
II (12 Hours)	Transpose of a matrix, Adjoint and inverse of a Matrix, Determinants, Solving the simultaneous linear equations by Cramer's rule <b>Trigonometry:</b> Basic concepts, Trigonometric ratios.
III (12 Hours)	Standard results, Signs of the Trigonometric functions, Compound angles, Multiple angles, submultiple angles, Solution of triangles.
IV (12 Hours)	<b>Analytical Geometry:</b> Rectangular Cartesian Coordinate system, Distance between two points, Triangles, Quadrilaterals, Section formula.
V (12 Hours)	Centroid of a triangle, Circum Centre of triangle, Ortho Centre of Triangle, In centre of Triangle Locus, Equation of Locus.
VI (12 Hours)	Straight lines, Inclination of line, slope of a line, Equation of straight lines in different forms.
VII (12 Hours)	Point of intersection of two lines, Angle between two lines, Foot of perpendicular from given point to a line Image of point with respect to line, Angular bisector of lines
VIII (12 Hours)	<b>Differential Calculus:</b> Limit of a function, Differential calculus, Differentiation of a sum product, Quotient composite function, Parametric, exponential, trigonometric functions
IX (12 Hours)	Logarithmic functions. Successive differentiation, Leibnitz's theorems, Partial differentiation, Euler's theorem on homogeneous functions of two variables
X (12 Hours)	<b>Integral Calculus:</b> Definite integrals, integration by substitution, integration by parts, Properties of definite integrals.

XI (12 Hours)	<b>Differential Equations:</b> Definition, order, degree Variable separable, homogeneous, Linear, heterogeneous Linear, differential equation with constant coefficient, Simultaneous linear equations of second order
XII (12 Hours)	<b>Laplace transforms:</b> Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books:

1. Riyaz Ahmad Khan Abdul Wadood Khan. Pharmacy and Biotechnology Mathematics. India: I.K. International Publishing House Private Limited; 2008.
2. Prabhakar Gupta, Vijay K Gupta. Remedial Mathematics. 5<sup>th</sup> ed. Meerut: Pragati Publications; 2008.
3. P Seshagiri Rao. A Textbook of Remedial Mathematics. Hyderabad: PharmaMed Press; 2008.
4. S S Rangi. Mathematics: For Students of Pharmacy. 1<sup>st</sup> ed. Jalandhar city: P K Jain. S Vikas & CO; 2008.
5. N P Bali, P N Gupta. C P Gandhi. A Textbook of Pharmaceutical Mathematics. 2<sup>nd</sup> ed. Vol II. New Delhi: Laxmi Publications (P) Ltd; 2008.
6. Shyam Patkar, Ramakant Bhardwaj Sarvesh Agrawal. Comprehensive Remedial Mathematics for B.Pharmacy. Hyderabad: PharmaMed Press; 2009.
7. Riyaz Ahmad Khan. A Textbook of Remedial Mathematics. 1<sup>st</sup>ed. India: S Chand &

Company Ltd; 2009.

8. Indrani Pramod Kelkar, J Jagan Mohan. A Textbook of Remedial Mathematics. Hyderabad: Biotech Pharma Publications; 2010.
9. G K Ranganath. A textbook of Remedial Mathematics. Mumabai: Himalaya Publishing House Pvt. Ltd; 2010.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Remedial Biology</b>
<b>Course Code</b>	<b>16PMD106</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

This course gives a detail study about plant and animal origin. This subject has been introducing to the pharmacy course in order to make the student aware of various naturally occurring drugs and its General organization of plants and its inclusions. Plant kingdom nd its classification, Modifications of Stem, Roots, Leaves. Inflorescence & Pollination of Flower, Morphology of Fruits& Seeds, and this course also learn about Plant Physiology, Taxonomy of some important plants, Detail Study of Frog, Poisonous Animals, Study of Pisces &Reptiles, Aves. General Organizations of Mammals.

### **Course Learning Outcomes:**

Upon successful completion of course, the student should be able to

CO 1: State about Morphological features fruits, Seeds, Modification of Leaf, Stem, Roots

CO 2: List about General organization of plants and its inclusions.

CO 3: Recognize the Histological structures and explain the importance of Plants and Animals

CO 4: Graduates will be able to have imperative knowledge on management in poisonous

### Theory Course: Contents

S. No.	Topics
I (12 Hours)	Introduction of biology, General organization of plants and its inclusions
II (12 Hours)	Plant tissues, Plant kingdom and its classifications
III (12 Hours)	Morphology of plants, Morphology of Fruits and Seeds
IV (12 Hours)	Plant Physiology, Root, Stem, Leaf modifications
V (12 Hours)	Inflorescence and pollination of flowers
VI (12 Hours)	Taxonomy of Leguminosae, Umbelliferae, Solonaceae, Lilliacae, Zinzibereceae, Rubiaceae
VII (12 Hours)	Study of Fungi, Yeast, Penicillin, Bacteria
VIII (12 Hours)	Animal Cell Structure and Functions of each and every Organelles of Cell Animal Tissues and Structure, Function, Types of Animal Tissues
IX (12 Hours)	Study of Frog- Digestive System, Respiratory, Cardiovascular System of Frog
X (12 Hours)	Classifications and Phyla, Kingdoms, Characteristics of Pisces, Reptiles, Aves
XI (12 Hours)	General Organization of Mammals

XII (12 Hours)	Study of Poisonous Animals
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#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources:

1. Linda R Berg. A Textbook of Botany. Indian edition. New Delhi: Cengage Learning India Private Limited; 2009.
2. B.P. Pandey. College Botany. 5<sup>th</sup>ed. Vol 1. New Delhi: S. Chand and Company Limited; 2007.
3. B.P. Pandey. College Botany. 7<sup>th</sup>ed. Vol 2. New Delhi: S. Chand and Company Limited; 2007.
4. S B Gokhale, D S Bidarkar. A Textbook of Biology. 4<sup>th</sup> ed. Pune: Nirali Prakashan; 2006.
5. Elden D Enger, Frederick C Ross, David B Bailey. Concepts in Biology. 11<sup>th</sup> ed. New Delhi: Tata McGraw Hill Publication Company Limited; 2005.



6. P.K.G Nair, K.P Achar, S.G Prabhu. A Textbook of Remedial Biology. 2<sup>nd</sup> ed. Mumabi: Himalaya Publishing House Private Limited; 2010.
7. Peter J Russell, Stephen L Wolfe, Paul E Hertz, Lecie Starr, Beverly Mcmillan. Cell and Molecular Biology. Indian edition. New Delhi: Cengage Learning India Private Limited; 2004.
8. Punam K Singh Remedial Biology. 1<sup>st</sup>ed. New Delhi: S. Chand and Company Limited; 2012.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Remedial Biology (Lab)</b>
<b>Course Code</b>	<b>16PMD112</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>2 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

Focus on the biology experiments like study of cell wall constituents, inclusions, root, stem, leaf modifications and identification of fruits, seeds, animals.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Learn procedures that are standard practice in biology laboratory

CO 2: Dissect the different systems of the frog

#### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
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1	Introduction of Biological Experiments
2	Study of microscope
3	Study of cell wall constituents and cell inclusions
4	Study of monocot leaf
5	Study of dicot leaf
6	Study of monocot root
7	Study of dicot root
8	Study of monocot stem
9	Study of dicot stem
10	Study of Leaf Modification
11	Study of stem Modification
12	Study of root modification
13	Identification of fruits
14	Study of morphology of fruits
15	Identification of seeds
16	Study of morphology of seeds
17	T.S of Senna
18	T.S of Cassia or Cinnamon
19	T.S of Ephedra
20	T.S of Podophyllum
21	Preparation of permanent slides
22	Simple plant Physiological Experiments
23	Respiratory system of frog
24	Digestive system of frog

25	Cardiovascular system of frog
26	Anatomical features of different organs of frog using charts
27	Identification of Animal tissues
28	Identification of Poisonous animals
29	Computer based tutorials
30	REVISION/Assessment

#### **Assessment methods and weightage (Practical)**

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

#### **Learning Resources/Recommended Texts/Reference books/web resources:**

1. Linda R Berg. A Textbook of Botany. Indian edition. New Delhi: Cengage Learning India Private Limited; 2009.
2. B.P. Pandey. College Botany. 5<sup>th</sup>ed. Vol 1. New Delhi: S.Chand and Company Limited; 2007.
3. B.P. Pandey. College Botany. 7<sup>th</sup>ed. Vol 2. New Delhi: S.Chand and Company Limited; 2007.
4. S B Gokhale, D S Bidarkar. A Textbook of Biology. 4<sup>th</sup> ed. Pune: Nirali Prakashan; 2006.

5. Elden D Enger, Frederick C Ross, David B Bailey. Concepts in Biology. 11<sup>th</sup> ed. New Delhi: Tata McGraw Hill Publication Company Limited; 2005.
6. P.K.G Nair, K.P Achar, S.G Prabhu. A Textbook of Remedial Biology. 2<sup>nd</sup> ed. Mumbai: Himalaya Publishing House Private Limited; 2010.
7. Peter J Russell, Stephen L Wolfe, Paul E Hertz, Lecie Starr, Beverly Mcmillan. Cell and Molecular Biology. Indian edition. New Delhi: Cengage Learning India Private Limited; 2004.
8. Punam K Singh Remedial Biology. 1<sup>st</sup>ed. New Delhi: S. Chand and Company Limited; 2012.

<b>Program</b>	<b>Pharm. D</b>
<b>Year</b>	<b>Second year</b>
<b>Name of the course</b>	<b>Pathophysiology</b>
<b>Course Code</b>	<b>16PMD201</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

The pathophysiology course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions and understanding of basic pathophysiological mechanisms. The course covers the basics of cell biology, inflammation, mechanism of body defense, abnormal cell growth and focuses on the pathophysiology of common disease processes of human body system.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Define the basic terminology related to pathophysiology.

CO 2: Describe the etiology and pathogenesis of the selected disease states.

CO 3: Name the signs, symptoms and complications of the diseases.

CO 4: Define the basic approach to diagnosis and diagnostic procedures of human diseases.

CO 5: Correlate the Pathophysiology with prognosis, medical treatment of the diseases.

CO 6: Evaluate medical journals, health articles and other forms of data related to Pathophysiology.

### Theory Course: Contents

S. No.	Topics
I (12 Hours)	<u>Basic principles of cell injury and Adaptation:</u> Causes, Pathogenesis and morphology of cell injury, Abnormalities in lipoproteinemia glycogen infiltration, glycogen storage diseases
II (12 Hours)	<u>Inflammation:</u> Pathogenesis of acute inflammation, Chemical mediators in inflammation Types of chronic inflammation, Repairs of wounds in the skin, factors influencing healing of wounds
III (12 Hours)	<u>Diseases of Immunity –I:</u> Introduction to T and B cells, MHC proteins or transplantation antigens Immune tolerance-Hypersensitivity, Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs Autoimmunity - Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity

IV (12 Hours)	<u>Diseases of Immunity –II:</u> Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft. Acquired immune deficiency syndrome (AIDS) Amyloidosis.
V (12 Hours)	<u>Cancer- I:</u> differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors.
VI (12 Hours)	<u>Cancer- II:</u> etiology and pathogenesis of cancer <u>Types of shock, mechanisms, stages and management</u>
VII (12 Hours)	<u>Biological effects of radiation</u> <u>Environmental and nutritional diseases:</u> Air pollution and smoking- SO <sub>2</sub> , NO, NO <sub>2</sub> , and CO; Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
VIII (12 Hours)	<u>Pathophysiology of common diseases-I:</u> Parkinsonism, Schizophrenia, Depression and mania, Hypertension, Stroke (Ischaemic and haemorrhage), Angina, CCF, Atherosclerosis, Myocardial infarction.
IX (12 Hours)	<u>Pathophysiology of common diseases-II:</u> Diabetes Mellitus, Peptic ulcer and inflammatory bowel diseases, Cirrhosis and Alcoholic liver diseases, Acute and chronic renal failure, Asthma and chronic obstructive airway diseases.

X (12 Hours)	<u>Infectious diseases-I:</u> Sexually transmitted diseases (Syphilis, Gonorrhoea), Urinary tract infections, Pneumonia
XI (12 Hours)	<u>Infectious diseases-II:</u> Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis
XII (12 Hours)	Revision/ Assessment

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

1. Robbins. Basic Pathologic.8<sup>th</sup> ed. Elsevier; 2007.
2. Harsh Mohan. Text book of Pathology.6<sup>th</sup> ed. India: Jaypee Brothers medical publishers (P) Ltd; 2010.
3. Roger Walker, Cate Whittlesea. Clinical Pharmacy and Therapeutics.4<sup>th</sup> ed. Churchill Livingstone ;2007

4. Porth, Carol. Essentials of Pathophysiology: Concepts of Altered Health States. Philadelphia: Lippincott Williams & Wilkins, 2004.
5. Stephen J McPhee; Gary D Hammer, Pathophysiology of Disease: An Introduction to Clinical Medicine 8E (A & L LANGE SERIES), 8th Edition
6. McCance, Kathryn L., and Sue E. Huether. Pathophysiology: The Biologic Basis for Disease in Adults and Children. 8th ed. Mosby Elsevier, 2010.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Second Year</b>
<b>Name of the course</b>	<b>Pharmaceutical Microbiology</b>
<b>Course Code</b>	<b>16PMD202</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

The course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the



immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Graduates will be able to know the anatomy, identification, growth factors and sterilization of microorganisms

CO 2: Assess the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect.

CO 3: Propose the reasons for microbial culture sensitivity testing.

### **Theory Course: Contents**

<b>S. No</b>	<b>Topics</b>
I  (12	Introduction to science of Microbiology,  Definition, history and scope of Pharmaceutical microbiology, Study of
II  (12 Hours)	Different stages of development of Microbiology, Major divisions of microbial world.  Different methods of Classification of Microbes, Study of Bacteria, Fungi, Virus, Study of Rickettsiae, Spirochaetes.
III  (12 Hours)	Nutritional Requirements, Growth and cultivation of Bacteria, Virus  Study of different types of Media. Special Medias,  Maintenance of Lab cultures
IV  (12 Hours)	Introduction to Isolation and Identification of MO  Staining techniques, principles, classifications.  Study of Biochemical reactions carried by MO  Enumeration of Bacteria, Counting for Total and Viable technique

V (12 Hours)	Merits and Demerits of Sterilization, Sterilization of Pharmaceutical Products, Test for sterility, Validation.
VI (12 Hours)	Study of Disinfectants, Antiseptics, Fungicidal and Virucidal agents, Factors affecting and mechanism of action of Antimicrobial agents, Evaluation of bactericidal agents, bacteriostatic agents and preservatives in pharmaceutical preparations.
VII (12 Hours)	Introduction to Immunology, Immunity, Definition, classification, principles of Immunity. Study of classification, principles of Immunity. Phagocytosis, Acquired- Active and Passive immunity. Study of antigen, antibody, and Ag-Ab reactions. Bacterial exotoxins and endotoxins.
VIII (12 Hours)	Significance of toxoids, Immunization, Immunization programme Booster dose
IX	Diagnostic tests introduction, Schick's tests, western protein.
X (12 Hours)	Study of Mantoux peripheral smear test, Study of Malaria parasite. Microbial culture sensitivity testing, Principles, Microbiological assays of antibiotics.
XI (12 Hours)	Study of Infectious Diseases, Typhoid, TB, Malaria, Cholera, Study of Hepatitis, Meningitis, Syphilis, Gonorrhoea and HIV Revision
XII (12 Hours)	Revision

### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

### Learning Resources/Recommended Texts/Reference books/web resources:

1. Prescott. Microbiology, 8<sup>th</sup> ed. UK: McGraw Hill Education; 2013.
2. Sanjay Kumar Jain, Vandana Soni. Bentley's Textbook of Pharmaceutics, 1<sup>st</sup> ed. India: Elsevier India: 2012.
3. Pelczar Jr MJ, Chan ECS, Krieg NR. Microbiology, 5<sup>th</sup> ed. UK: Tata McGraw Hill; 2004.
4. AnanthaNarayan, JayramPanikar. Text Book of Microbiology, 7<sup>th</sup> ed. India: Orient Blackswan; 2005.
5. Dubey RC. A Textbook of Microbiology, 1<sup>st</sup> ed. India: S. Chand & Company Ltd; 2000.
6. Kishore Namdeorao Gujar, Suhasini Bhatnagar. Pharmaceutical Microbiology Theory, 1<sup>st</sup> ed. India: Himalaya Publishing House; 2010.
7. Eugene WN, Martha TN, C. Evans Roberts, Denise Jr. GA, Nancy N P. Student Study Guide to Accompany Microbiology: A Human Perspective, 3<sup>rd</sup> ed. UK: McGraw-Hill Higher Education; 2001.
8. Stephen P, Norman AH, Sean PG, Brendan FG. Hugo and Russell's Pharmaceutical Microbiology, 8<sup>th</sup> ed. UK: Wiley Publications; 2011.
9. Tortora GJ, Funke BR, Case CL. Microbiology: An Introduction. 12<sup>th</sup> ed. UK: Benjamin-Cummings Publishing Company; 2014.

10. Prescott SC, Gordon Dunn C. Industrial Microbiology, 1<sup>st</sup> ed. UK: Mc.Graww Hill; 1940.
11. Chandrakant RK. Pharmaceutical Microbiology Principles and Applications. 6<sup>th</sup> ed. India: Nirali Prakashan; 2008.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Second year</b>
<b>Name of the course</b>	<b>Pharmaceutical Microbiology (Lab)</b>
<b>Course Code</b>	<b>16PMD207</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:**

The course is designed to focus on identification, nutritional requirements of microorganisms. Since microbiology is an upcoming and fascinating branch of biological sciences, medical and pharmaceutical sciences, the approach of performing experiments will lead to success of learning the subject.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Learn procedure to cultivate and identification of the microorganisms in the laboratory.

CO 2: Propose the procedure for identification of diseases by performing the diagnostic tests.

### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Introduction, Basic rules and requirements for laboratory.
2	Study of Equipments and Glassware's used in Microbiology laboratory.
3	Preparation and Sterilization of culture media.
4	Sterilization of Glassware, talcum powder, mineral oil etc.,
5	Distribution of microorganisms in nature.
6	Study of motility characters of microorganisms.
7	Cultivation and preservation of Bacteria from different methods by aseptic technique.
8	Simple staining
9	Negative staining
10	Gram's staining
11	Acid fast staining
12	Isolation of pure culture of microorganisms by Streak plate method

13	Isolation of pure culture of microorganisms by pour plate and spread plate method
14	Test for antibiotic sensitivity by disc method
15	Determination of minimum inhibitory concentration of antibiotic (MIC).
16	Sterility testing of injectables as per IP
17	Biochemical identification of microorganisms by Fermentation.
18	Biochemical identification of microorganisms by 'IMVIC' tests.
19	Biochemical identification of microorganisms by Starch hydrolysis test.
20	Microbiological assay of Streptomycin.
21	Diagnostic test for Malaria.
22	Diagnostic test for Typhoid
23	Determination of phenol co-efficient of disinfectant
24	Microbiological assay of vitamin B12 by turbidometric method.
25	Revision/Assessment

#### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

**Learning Resources/Recommended Texts/Reference books/web resources:**

1. Cappuccino J G, Natalie Sherman. Microbiology- a Laboratory Manual, 7th ed. India: Pearson Education; 2005.
2. Dubey RC, Maheswari DK. Practical Microbiology, 2<sup>nd</sup> ed. India: S.Chand& Company Ltd; 2006.
3. Gaud RS, Gupta GD. Practical Microbiology, ISBN8185790310. India: Nirali Prakashan; 2008.
4. Kishore Namdeorao Gujar, Suhasini Bhatnagar. Pharmaceutical Microbiology Theory, 1st ed. India: Himalaya Publishing House; 2010.
5. EugeneWN, MarthaTN, C.Evans Roberts, Denise Jr.GA, NancyN P. Student Study Guide to Accompany Microbiology: A Human Perspective, 3rd ed. UK: McGraw-Hill Higher Education; 2001.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Second year</b>
<b>Name of the course</b>	<b>Pharmacognosy and Phytopharmaceuticals</b>
<b>Course Code</b>	<b>16PMD203</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:**

The pharmacognosy and phytopharmaceuticals course that provides an integrated presentation of pharmacognosy and phytopharmaceuticals. It gives detailed information about the introductory pharmacognosy. The course makes the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

**Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Record the basic principles of cultivation, collection and storage of crude drugs;

CO 2: List the source, active constituents and uses of various naturally occurring drugs

CO 3: Relate the applications of primary and secondary metabolites of the plant

CO 4: List the adulteration and its evaluation for the crude drugs

**Theory Course: Contents**

S. No.	Topics
I (12 Hours)	Introduction Definition, history and scope of Pharmacognosy
II (12 Hours)	Classification of crude drugs



III (12 Hours)	Cultivation, collection, processing and storage of crude drugs
IV (12 Hours)	Detailed method of cultivation of crude drugs. Factors influencing cultivation
V (12 Hours)	Introduction to parts of medicinal plants, study of morphology and microscopy of a medicinal plant. Microscopical and powder Microscopical study of crude drugs
VII (12 Hours)	Study of natural pesticides
VIII (12 Hours)	Introduction, classification, properties, chemical tests of carbohydrates. Biological source, chemical constituents, chemical test, uses of Agar, Acacia, Tragacanth, Honey, Ispagol, Starch, Guar gum.
IX (12 Hours)	Introduction, classification, properties, chemical tests of lipids. Biological source, chemical constituents, chemical test, uses of Castor oil, Chaulmoogra oil, Linseed oil, Cocoa butter, Kokum butter, Bees wax, Wool fat.
X (12 Hours)	Introduction, classification, properties, chemical tests of proteins and enzymes. Biological source, chemical constituents, chemical test, uses of Gelatin, Papain, Casein, Serratio Peptidase, Pepsin Study of plants fibers used in surgical dressings and related products
XI	Different methods of adulteration of crude drugs

(12 Hours)	
XII (12 Hours)	Different methods of evaluation of crude drugs

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources:

1. Evans WC, Trease. Pharmacognosy. 15<sup>th</sup> ed. Elsevier: Delhi; 2009.
2. Kokate CK, Purohit AP, Gokhale SB. Pharmacognosy. 44<sup>th</sup> ed. Nirali Prakashan: New Delhi; 2009.
3. James E Robbers, Varro E Tyler. Pharmacognosy and Pharmacobiotechnology. 9<sup>th</sup> ed. Williams & Wilkins: USA; 1988.
4. Wallies TE. Text book of Pharmacognosy. 5<sup>th</sup> ed. CBS Publishers & Distributors: Delhi; 1999.
5. Handa SS, Kapoor VK. Text book of Pharmacognosy. 1<sup>st</sup> ed. Vallabh Prakashan: Delhi; 2001.
6. Farooqui AA, Sreeramu BS. Cultivation and Utilization of Medicinal and Aromatic Crops. 1<sup>st</sup> ed. Universitites Press: Hyderabad; 2010.
7. Iyengar MA. Study of crude drugs. 12<sup>th</sup> ed. Manipal Press Limited: Manipal; 2004.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Second year</b>
<b>Name of the course</b>	<b>Pharmacognosy and Phytopharmaceuticals (Lab)</b>
<b>Course Code</b>	<b>16PMD208</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

Focus on the macroscopic, microscopic and powder microscopic study of various therapeutically important crude drugs. Become familiar with microscopic examination of crude drugs. The course also deals with the chemical evaluation of the crude drugs under fixed oils both qualitative and quantitative.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: demonstrate the basic macro, micro and powder microscopic nature of crude drugs.

CO 2: Illustrate the chemical evaluation of the crude drugs

CO 3: List the determinations of the fixed oils

#### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Introduction to Pharmacognosy laboratory and experiments
2	Study of cell wall constituents and cell inclusions

3	Macro, powder and microscopic study of Datura
4	Macro, powder and microscopic study of Senna
5	Macro, powder and microscopic study of cinnamon
6	Macro, powder and microscopic study of cinchona
7	Macro, powder and microscopic study of ephedra
8	Macro, powder and microscopic study of quassia
9	Macro, powder and microscopic study of clove
10	Macro, powder and microscopic study of fennel
11	Macro, powder and microscopic study of coriander
12	Macro, powder and microscopic study of isabgol
13	Macro, powder and microscopic study of nux vomica
14	Macro, powder and microscopic study of rauwolfia
15	Macro, powder and microscopic study of liquorice
16	Macro, powder and microscopic study of ginger
17	Macro, powder and microscopic study of Podophyllum
18	Chemical test for acacia
19	Chemical test for tragacanth
20	Chemical test for agar
21	Chemical test for starch
22	Chemical test for lipid drugs
23	Chemical test for gelatin
24	Determination of iodine value
25	Determination of saponification value

26	Determination of ester value
27	Determination of acid value
28	REVISION/Assessment

#### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources:

1. Kokate CK, Gokhale SB. Practical Pharmacognosy. 5<sup>th</sup> ed. Nirali Prakashan: Delhi; 2003.
2. Khandelwal KR, Vrunda Sethi. Practical Pharmacognosy. 25<sup>th</sup> ed. Nirali Prakashan: Delhi; 2015.
3. Evans WC, Trease. Pharmacognosy. 15<sup>th</sup> ed. Elsevier: Delhi; 2009.
4. Iyengar MA. Study of crude drugs. 12<sup>th</sup> ed. Manipal Press Limited: Manipal; 2004.
5. Biren N Shafi, Nayak BS. Experimental Pharmacognosy. 1<sup>st</sup> ed. S Vikas & Co: Pune; 2009.
6. Iyengar MA, Nayak SK. Anatomy of Crude drugs. 12<sup>th</sup> ed. Manipal Press Limited: Manipal; 2011.
7. James E Robbers, Varro E Tyler. Pharmacognosy and Pharmacobiotechnology. 9<sup>th</sup> ed. Williams & Wilkins: USA; 1988.
8. Wallies TE. Text book of Pharmacognosy. 5<sup>th</sup> ed. CBS Publishers & Distributors: Delhi; 1999.
9. Handa SS, Kapoor VK. Text book of Pharmacognosy. 1<sup>st</sup> ed. Vallabh Prakashan: Delhi; 2001.

<b>Program</b>	<b>Pharm. D</b>
<b>Year</b>	<b>Second year</b>
<b>Name of the course</b>	<b>Pharmacology – I</b>
<b>Course Code</b>	<b>16PMD204</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

The pharmacology I course is aimed to provide knowledge about the drugs with classification, pharmacokinetics & pharmacodynamics, route of administration, uses, dose, adverse effects, contra indications and drug interactions. This course deals with the study of general pharmacology, pharmacology of CNS, ANS, CVS, respiratory system and hormones.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Classify the drugs used in the treatment of various diseases.

CO 2: Describe the mechanism of actions, pharmacological actions, pharmacokinetics, route of administration, uses, dose, adverse effects, contra indications and drug interactions.

CO 3: Describe the mechanism of different types of receptors

CO 4: Apply the importance of pharmacology as a basis of therapeutics.

#### **Theory Course: Contents**

<b>S. No.</b>	<b>Topics</b>
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I  (12 Hours)	<b>1. General Pharmacology-I</b>  a) Introduction, definitions and scope of pharmacology  b) Routes of administration of drugs  c) Pharmacokinetics (absorption, distribution, metabolism and excretion)  Absorption: Mechanism of drug absorption, Factors modifying drug absorption Distribution: Physiological barriers, Volume of distribution  Metabolism: First pass effect, Enzyme inhibition, Enzyme induction  Excretion: Biological half-life, Clearance.  d) Pharmacodynamics
II  (12 Hours)	<b>2. General Pharmacology-II</b>  a) Factors modifying drug effects  b) Drug toxicity - Acute, sub- acute and chronic toxicity.  c) Pre-clinical evaluations  d) Drug interactions
III  (12 Hours)	<b>3. Pharmacology of drugs acting on ANS- I</b>  a) Adrenergic and anti adrenergic drugs  b) Cholinergic and anti cholinergic drugs
IV  (12 Hours)	<b>4. Pharmacology of drugs acting on ANS- II</b>  a) Neuromuscular blockers  b) Mydriatics and miotics  c) Drugs used in myasthenia gravis  d) Drugs used in Parkinsonism
V  (12 Hours)	<b>5. Pharmacology of drugs acting on cardiovascular system-I</b>  a) Antihypertensives  b) Anti-anginal drugs

	c) Drugs used for therapy of Congestive Heart Failure
VI (12 Hours)	<b>6. Pharmacology of drugs acting on cardiovascular system-II</b> a) Anti-arrhythmic drugs b) Drugs used for hyperlipidaemias
VII (12 Hours)	<b>7. Pharmacology of drugs acting on Central Nervous System- I</b> a) General anesthetics b) Sedatives and hypnotics c) Anticonvulsants d) Analgesic and anti-inflammatory agents
VIII (12 Hours)	<b>8. Pharmacology of drugs acting on Central Nervous System- II</b> a) <i>Psychotropic drugs</i> i) Anti-Psychotics ii) Antidepressants iii) Hallucinogens b) Alcohol and methyl alcohol c) CNS stimulants and cognition enhancers d) Pharmacology of local anesthetics
IX (12 Hours)	<b>9. Pharmacology of Drugs acting on Respiratory tract</b> a) Bronchodilators b) Mucolytics c) Expectorants d) Anti tussives e) Nasal Decongestants
X	<b>10. Pharmacology of Hormones and Hormone antagonists-I</b> a) Thyroid and Anti thyroid drugs



(12 Hours)	b) Insulin, Insulin analogues and oral hypoglycaemic agents
XI (12 Hours)	<b>11. Pharmacology of Hormones and Hormone antagonists- II</b> a) Sex hormones and oral contraceptives b) Oxytocin and other stimulants and relaxants
XII (12 Hours)	<b>12. Pharmacology of autacoids and their antagonists</b> a) Histamines and Anti histamines b) 5-Hydroxytryptamine and its antagonists. c) Lipid derived autacoids and platelet activating factor

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

**Learning Resources/Recommended Texts/Reference books/web resources:**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics

4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Leon Shargel, Andrew Yub.C. Applied Biopharmaceutics and pharmacokinetics. 7<sup>th</sup> ed.New York: Mcgrawhill; 2016.
9. Hardman J.G, Lee E. Limbard, Good Man & Gilmans. The Pharmacological basis of therapeutics. 11<sup>th</sup> ed.USA: Mc Grawhill; 2006.
10. Satoskar RS, Bhandarkar SD and Nirmala N.Rege. Pharmacology and Pharmacotherapeutics.19<sup>th</sup> ed. Mumbai: Popular prakashan.2005.
11. David E.Golan, Armen H.Tashjian and April W. Armstrong. Principles of pharmacology: the pathophysiological basis of drug therapy.2<sup>nd</sup> ed. Philadelphia: Lippincott Williams & Wilkins; 2008.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Second year</b>
<b>Name of the course</b>	<b>Community pharmacy</b>
<b>Course Code</b>	<b>16PMD205</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>2+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counseling, health screening services for improved patient care in the community set up.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Effectively use the pharmacy's prescription filling software to fill prescriptions, check for drug interactions, retrieve patient profiles and retrieve drug information.

CO 2: Demonstrate the proper usage of the commonly used blood glucose meters and train patients how to use them properly.

CO 3: Proper usage of OTC products and explain to patients how to use them properly.

CO 4: Collaborate with physicians and other health care providers to provide recommendations to drug therapy to enhance quality of care and the patients quality of life.

CO 5: The schedules of control substances, storage requirements and dispensing and inventory procedures.

### Theory Course: Contents

S. No.	Topics
I  (12 Hours)	Definition, scope, of community pharmacy  Roles and responsibilities of Community pharmacist
II  (12 Hours)	Community Pharmacy Management : Selection of site, Space layout, and design  Staff, Materials- coding, stocking and Legal requirements, Maintenance of various registers and Use of Computers: Business and health care soft wares
III  (12 Hours)	Prescriptions – parts of prescription, legality identification of medication related problems like drug interactions.  Essential Drugs concept and Rational Drug Therapy Role of community pharmacist
IV  (12 Hours)	Inventory control in community pharmacy: Definition, various methods of Inventory Control  ABC, VED, EOQ, Lead time, safety stock
V  (12 Hours)	Pharmaceutical care Definition and Principles of Pharmaceutical care  Patient counseling 1: Definition, outcomes, various stages

VII (12 Hours)	<p>Patient counseling II :</p> <p>barriers, Strategies to overcome barriers</p> <p>Patient information leaflets- content, design, &amp; layouts, advisory labels</p>
VIII (12 Hours)	<p>Patient medication adherence Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.</p> <p>OTC Medication- Definition, OTC medication list &amp; Counselling</p> <p>Code of ethics for community pharmacists</p>
IX (12 Hours)	<p>Health screening services Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function and Cholesterol testing</p> <p>Health Education 1: WHO Definition of health, and health promotion, care for children, pregnant &amp; breast feeding women, and geriatric patients. Commonly occurring Communicable Diseases, causative agents,</p>
X (12 Hours)	<p>Health Education 2: Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS</p>
XI (12 Hours)	<p>Health Education 3: Balance diet, and treatment &amp; prevention of deficiency disorders Family planning – role of pharmacist</p> <p>Responding to symptoms of minor ailments 1: Relevant pathophysiology, common drug therapy to, Pain,</p>
XII (12 Hours)	<p>Responding to symptoms of minor ailments 2: GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhoea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.</p>

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Adepu Ramesh. Community Pharmacy Practice. Hyderabad: Pharma Med Press; 2015.
2. G. Parthasarathi, Karin Nyfor-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice: Essential concepts and skills. 2<sup>nd</sup> ed. India: Universities Press (India) Private Limited; 2012.
3. Leon Shargel, Alan H Mutnick, Paul F Souney, Larry N S Wanson. Comprehensive Pharmacy Review. 7<sup>th</sup> ed. India: Wolters Kluwer (India) Private Limited. 2010.
4. Atmaram Pawar, R S Gaud. Modern Dispensing Pharmacy. 3<sup>rd</sup> ed. India: Career Publications; 2009.
5. Atmaram Pawar. Handbook for Community Pharmacists. 1<sup>st</sup> ed. India: Career Publications; 2007.
6. A J Winfield, R M E Richards, editors. Pharmaceutical Practice. 3<sup>rd</sup> ed. Churchill Livingstone; 2004.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Second Year</b>
<b>Name of the course</b>	<b>Pharmacotherapeutics – I</b>
<b>Course Code</b>	<b>16PMD206</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

This course is designed to impart knowledge and skills necessary for contribution to quality, rational use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualised therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);

CO 7: Summaries the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy;

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis; and

### Theory Course: Contents

S. No.	Topics
I (12 Hours)	<b>Introduction to rational drug use:</b> Definition, Role of pharmacist in rational drug use, Rational drug formulations, Essential drug concept – NLEM, NFI <b>Introduction to Pharmacotherapeutics</b> <b>Cardiovascular system:</b> Hypertension, Heart failure
II (12 Hours)	Ischemic heart diseases: Angina Pectoris, Myocardial infarction,
III (12 Hours)	Hyperlipidaemias, Electrophysiology of heart and Arrhythmias
IV (12 Hours)	<b>Respiratory system:</b> Introduction to Pulmonary function test, Asthma,



V (12 Hours)	Chronic obstructive airways disease, Drug induced pulmonary diseases
VII (12 Hours)	<b>Endocrine system:</b> Diabetes, Thyroid diseases,
VIII (12 Hours)	Oral contraceptives, Hormone replacement therapy, Osteoporosis
IX (12 Hours)	<b>General prescribing guidelines for</b> a. Pediatric patients
X (12 Hours)	Geriatric patients c. Pregnancy and breast feeding
XI (12 Hours)	<b>Ophthalmology:</b> Glaucoma,
XII (12 Hours)	Conjunctivitis- viral & bacterial

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
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Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

**Learning Resources/Recommended Texts/Reference books/web resources:**

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8<sup>th</sup> ed. lippincot Williams;2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach.9<sup>th</sup> ed. Mcgraw-hill education; 2012.
3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10<sup>th</sup> ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5<sup>th</sup> ed. Churchill livingstone;2011
5. Green,Russells,Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3<sup>rd</sup> ed. Pharmaceutical press: 2008.
6. Marie A, Terry L.S, Patrick M.M, Pharmacotherapy: Principles and Practice. 5th Edition. McGraw-Hill Education.
7. Christopher P.M, Robert L.T. Pharmacotherapy: Bedside Guide. McGraw-Hill Education.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Second Year</b>
<b>Name of the course</b>	<b>Pharmacotherapeutics - I (Lab)</b>
<b>Course Code</b>	<b>16PMD209</b>

<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>4 hours (Laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

This course is designed to impart knowledge and skills necessary for contribution to quality and rational use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualised therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);

CO 6: Collect subjective and objective evidence related to patient, medications, allergies/adverse reactions, and disease, by performing patient assessment from chart/electronic health records, laboratory tests, pharmacist records and patient/family interviews.

CO 7: Interpret evidence and patient data.

CO 8: Assess the healthcare status and identify the treatment needs of a targeted patient population.

CO 9: Prepare and deliver patient case presentation and document and communicate patient care activities clearly, concisely, and accurately using appropriate medical terminology.

### **Practical Course: Contents**

Unit	Topic
I	Introduction to the Healthcare System: Healthcare delivery system in the India and the role of the pharmacist within that system. The concepts, systems, and processes of healthcare.
II	Patient Assessment and the Pharmacist Role: Pharmaceutical Care as Professional Practice, Patient Care Process, Documentation (SOAP, FARM Notes).  Principles and Methods of the Basic Physical Examination and General Assessment and Vital Signs.
III	Pharmacist Assessment of Body Systems: Cardiovascular System, Respiratory System, Endocrine System.
IV	Case Presentation on Selected Diseases-Cardiovascular System: Hypertension, Hear Failure, Ischemic Heart Disease (Angina Pectoris, Myocardial Infarction), Dyslipidaemia, Cardiac Arrhythmias.
V	Case Presentation on Selected Diseases-Respiratory System: Asthma, Chronic Obstructive Pulmonary Disease, Drug Induced Pulmonary Disorders.
VI	Case Presentation on Selected Diseases-Endocrine System: Diabetes Mellitus, Thyroid Disorders, Hormone Replacement Therapy, Osteoporosis.
VII	Case Presentation on Selected Diseases-Ocular System: Glaucoma-Open Angle, Angle Closure Glaucoma, Bacterial and Viral Conjunctivitis.
VIII	Objective Structure Pharmacotherapy Evaluation (OSPE).

### **Assessment methods and weightage (Practical)**

Assessment type	Assessment tool	Distribution
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Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

### **Learning Resources/Recommended Texts/Reference books/web resources (Latest editions)**

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8<sup>th</sup> ed. lippincot Williams; 2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach.9<sup>th</sup> ed. Mcgraw-hill education; 2012.
3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10<sup>th</sup> ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5<sup>th</sup> ed. Churchill livingstone;2011
5. Green,Russells,Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3<sup>rd</sup> ed. Pharmaceutical press: 2008.
6. Rhonds Jones. Patient Assessment in Pharmacy Practice. Wolters Kluwer. 3rd Edition.
7. Sherif Hanafy M. Patient Assessment in Clinical Pharmacy: A Comprehensive guide. Springer.
8. Lynn S. Bickley. BATE's Guide to Physical Examination and History taking. Wolters Kluwer. 12th Edition.
9. Karen J. Tietze. Clinical Skills for Pharmacists: A patient focused approach. 3rd Edition. Elsevier.

10. Soraya D, Rebekha R. Pharmacy Case Studies. Pharmaceutical Press.
11. Pharmacotherapy casebook: A patient focused approach. 10th Edition. McGrawHill Education.
12. Michael DK, Kathryn RM, Marie ACB, Pharmacotherapy Principles & Practice Study Guide: A Case-Based Care Plan Approach.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Second Year</b>

<b>Name of the course</b>	<b>Dietary supplements and Nutraceuticals (Elective)</b>
<b>Course Code</b>	<b>16PMD210E1</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

This subject covers foundational topics that are important for understanding the need and requirements of dietary supplements among different groups in the population.

### **Course Learning Outcomes:**

At completion of this subject, it is expected that students will be able to explain

CO 1: Understand the need of supplements by the different group of people to maintain healthy life.

CO 2: Understand the outcome of deficiencies in dietary supplements.

CO 3: Appreciate the components in dietary supplements and the application.

CO 4: Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

### **Theory Course: Contents**

<b>S. No</b>	<b>Topics</b>
I (3 weeks)	a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.

II (3weeks)	Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
III (3 weeks)	Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Ginkgo, Flaxseeds
IV (3weeks)	<b>Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following</b> a. Carotenoids- $\alpha$ and $\beta$ -Carotene, Lycopene, Xanthophylls, leutin b. Sulfides: Diallyl sulfides, Allyl trisulfide. c. Polyphenolics: Resveratrol d. Flavonoids- Rutin , Naringin, Quercetin, Anthocyanidins, catechins, Flavones
V (3weeks)	<b>Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following</b> e. Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum f. Phyto estrogens : Isoflavones, daidzein, Geobustan, lignans g. Tocopherols h. Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.
VI (3 weeks)	Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
VII (3 weeks)	Dietary fibres and complex carbohydrates as functional food ingredients.



VIII (3 weeks)	Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals' involvement in other disorders. Free radicals' theory of ageing.
IX (3 weeks)	<b>Antioxidants:</b> Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, $\alpha$ - Lipoic acid, melatonin <b>Synthetic antioxidants:</b> Butylated hydroxy Toluene, Butylated hydroxy Anisole.
X (3 weeks)	Functional foods for chronic disease prevention
XI (3 weeks)	Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
XII (3 weeks)	Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods. Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors 2000 Functional foods Woodhead Publ.Co.London.
7. Goldberg, I. Functional Foods. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 Modern Nutrition in Health and Disease. Eighth edition. Lea and Febiger

<b>Program</b>	<b>Pharm D</b>
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<b>Year</b>	<b>Second Year</b>
<b>Name of the course</b>	<b>Social and Preventive Pharmacy (Elective)</b>
<b>Course Code</b>	<b>16PMD210E2</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

### **Course Learning Outcomes:**

At completion of this subject, it is expected that students will be able to

CO 1: Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.

CO 2: Have a critical way of thinking based on current healthcare development.

CO 3: Evaluate alternative ways of solving problems related to health and pharmaceutical issues

### **Theory Course: Contents**

<b>S. No</b>	<b>Topics</b>
I (3 weeks)	<b>Concept of health and disease:</b> Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

II (3weeks)	<b>Social and health education:</b> Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.
III (3 weeks)	<b>Sociology and health:</b> Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health
IV (3weeks)	<b>Hygiene and health:</b> personal hygiene and health care; avoidable habits
V (3weeks)	<b>Preventive medicine:</b> General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, and lymphatic filariasis
VI (3 weeks)	<b>Preventive medicine:</b> General principles of prevention and control of pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse
VII (3 weeks)	<b>National health programs, its objectives, functioning and outcome of the following:</b> HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program
VIII (3 weeks)	<b>National health programs, its objectives, functioning and outcome of the following:</b> National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme
IX (3 weeks)	National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National

	Malaria Prevention Program, National programme for the health care for the elderly, social health programme; role of WHO in Indian national program
X (3 weeks)	Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission,
XI (3 weeks)	Health promotion and education in school.
XII (3 weeks)	Revision

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications

4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

**Recommended Journals:**

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Second Year</b>
<b>Name of the course</b>	<b>Environmental Sciences (Elective)</b>
<b>Course Code</b>	<b>16PMD210E3</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

### **Course Learning Outcomes:**

CO 1: Create the awareness about environmental problems among learners.

CO 2: Impart basic knowledge about the environment, its allied problems and develop an attitude of concern for the environment.

CO 3: Motivate learner to participate in environment protection and environment improvement.

CO 4: Acquire skills to help the concerned individuals in identifying and solving environmental problems.

### **Theory Course: Contents**

<b>S. No</b>	<b>Topics</b>
I (3 weeks)	The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources: Natural resources and associated problems of the following-In context to INDIA.

	a) Forest resources: Types, distribution, Uses and deforestation and its consequences. Conservation of Forests.
II (3weeks)	b) Water resources: Types, distribution and conservation of water sources c) Mineral resources: Distribution and conservation d) Food resources: Sources of food, supply and security context
III (3 weeks)	e) Energy resources: overview on types. f) Land resources: overview on types, Distribution and conservation
IV (3weeks)	Ecosystems Concept of an ecosystem. Structure and function of an ecosystem.
V (3weeks)	<i>Introduction, types, characteristic features, structure and function of the ecosystems</i> Forest ecosystem
VI (3 weeks)	Grassland ecosystem; Desert ecosystem, Desertification causes and consequence. Aquatic Ecosystem: Fresh water and marine ecosystem.
VII (3 weeks)	Biodiversity: Levels of biodiversity and its conservation methods, Role of International organization like UNFCCC, IUCCD, IUCBD and etc. in Ecosystem.
VIII (3 weeks)	Environmental Pollution: Causes, consequences and overview on preventive measures in India for the following Air pollution, Water pollution, Soil pollution
IX (3 weeks)	Exercise 1
X (3 weeks)	Exercise 2
XI (3 weeks)	Exercise 3



XII (3 weeks)	Exercise 4
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Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

**Recommended Books (Latest edition):**

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India.
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd. Down of Earth, Centre for Science and Environment
8. Shankar IAS, Environment.2021, Shankar IAS Academy, Chennai.
9. Goh Cheng Leong, Certificate Physical and Human Geography, Oxford University Press

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third year</b>
<b>Name of the course</b>	<b>Pharmacology-II</b>
<b>Course Code</b>	<b>16PMD301</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on blood & blood forming agents, renal system, immune system. In addition, pharmacology of chemotherapeutic agents and dynamic cell, genome structure, function.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Classify the drugs used in the treatment of various diseases.

CO 2: Describe the mechanism of actions, pharmacological actions, pharmacokinetics, route of administration, uses, dose, adverse effects, contra indications and drug interactions.

CO 3: Apply the knowledge of gene study in the treatment of various diseases.

CO 4: Apply the importance of pharmacology as a basis of therapeutics.

### Theory Course: Contents

S. No.	Topics
I  (12 Hours)	<b>Pharmacology of Drugs acting on Blood and blood forming agents-I</b>  a) Coagulants & Anticoagulants  b) Thrombolytics and antiplatelet agents
II  (12 Hours)	<b>Pharmacology of Drugs acting on Blood and blood forming agents-II</b>  Haemopoietics and plasma expanders  <b>Pharmacology of drugs acting on Renal System</b>  a) Diuretics  b) Antidiuretics
III  (12 Hours)	<b>Chemotherapy-I</b>  a) Introduction, mechanism of antibiotic resistance  b) Sulfonamides and co-trimoxazole  c) Penicillins
IV  (12 Hours)	<b>Chemotherapy-II</b>  a) Cephalosporins, Tetracyclines and Chloramphenicol  b) Macrolides, Aminoglycosides, Polyene& Polypeptide antibiotic
V  (12 Hours)	<b>Chemotherapy-III</b>  a) Fluoroquinolones  b) Antifungal agents  c) Antiviral agents
VI  (12 Hours)	<b>Chemotherapy-IV</b>  a) Chemotherapy of tuberculosis and leprosy  b) Chemotherapy of cancer

VII (12 Hours)	<b>Chemotherapy-V</b>  Chemotherapy of Parasitic infections (Malaria, Helminthic infestations, Amoebiasis and Giardiasis)  <b>Immunopharmacology</b>  Pharmacology of immunosuppressants and immune stimulants
VIII (12 Hours)	<b>The dynamic cell: The structures and functions of the components of the cell</b>  a) Cell and macromolecules: Cellular classification, sub cellular organelles, large macromolecular assemblies  b) Chromosome structure: Pro and eukaryotic chromosome structures, genome complexity
X (12 Hours)	a) DNA replication: General, bacterial and eukaryotic DNA replication.  b) The cell cycle: Restriction point, cell cycle regulators and modifiers.  c) Cell signalling: Communication between cells and their environment, signal transduction pathways
X (12 Hours)	<b>The Gene: Genome structure and function:</b>  a) Gene structure: Organization and elucidation of genetic code.  b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
XII (12 Hours)	Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes.  Transcription factors that regulate transcription in pro and eukaryotes.  RNA processing: rRNA, tRNA and mRNA processing.

	Protein synthesis: Mechanisms of protein synthesis, translation control and post translation events.
XII  (12 Hours)	<p>Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.</p> <p>The gene sequencing, mapping and cloning of human disease genes.</p> <p>Introduction to gene therapy and targeting.</p> <p>Recombinant DNA technology: principles. Processes (gene transfer technology) and applications</p>

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

##### Recommended Text books:

- 1.Tripathi KD. Essentials of Medical Pharmacology. 7<sup>th</sup> ed. New Delhi: Jaypee Brothers; 2014.
- 2.Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Rang H.P, Dale M.M and Ritter J.M.Pharmacology. 8<sup>th</sup> ed .Edinburgh: Elsevier Churchill living stone; 2016.

4. David E.Golan, Armen H.Tashjian and April W. Armstrong. Principles of pharmacology: the pathophysiological basis of drug therapy.2<sup>nd</sup> ed. Philadelphia: Lippincott Williams & Wilkins; 2008.
5. Satoskar RS, Bhandarkar SD and Nirmala N.Rege. Pharmacology and Pharmacotherapeutics.19<sup>th</sup> ed. Mumbai: Popular prakashan.2005.
6. Sharma. H.L, Sharma K. K. Principles of pharmacology. 2<sup>nd</sup> ed. Hyderabad: Paras 2011.

**Reference books:.**

1. Hardman J.G, Lee E. Limbard, Good Man & Gilmans. The Pharmacological basis of therapeutics. 11<sup>th</sup> ed.USA: Mc Grawhill; 2006.
2. Leon Shargel, Andrew Yub.C. Applied Bio pharmaceutics and pharmacokinetics. 7<sup>th</sup> ed.New York: Mcgrawhill; 2016.
3. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
4. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
5. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third Year</b>
<b>Name of the course</b>	<b>Pharmacology-II (Lab)</b>
<b>Course Code</b>	<b>16PMD307</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

Deals with study of laboratory animals and their handling, Physiological salt solutions, laboratory appliances, anaesthetics, route of administration of drugs and Pharmacodynamic experiments on isolated tissues and intact animals.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate the Basic skills regarding Handling of Experimental animals, Routes of administration of drugs.

CO 2: Perform the *Invitro* experiments on isolated Tissues.

CO 3: Perform the bioassays of drugs by using suitable isolated tissues or organs

CO 4: Perform the Experiments on intact animals related to screening of drugs acting on CNS

CO 5: Correlate the preclinical studies with clinical studies.

### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).

2	Study of physiological salt solutions used in experimental pharmacology
3	Study of laboratory appliances used in experimental pharmacology.
4	Study of use of anesthetics in laboratory animals.
5	To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6	To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7	To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8	To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by matching method.
9	Study of agonistic and antagonistic effects of drugs using isolated ileum/rectus abdominis muscle preparation
10	To study the routes of administration of drugs in animals (Rats, Mice, Rabbits)
11	Analgesic property of drug using analgesiometer
12	Anti-inflammatory effect of drugs using rat-paw edema method.
13	Anticonvulsant activity of drugs using maximal electroshock and pentylenetetrazol methods
14	Antidepressant activity of drugs using swim test apparatus
15	Locomotor activity evaluation of drugs using actophotometer and rotarod
16	Cardiotonic activity of drugs using isolated frog heart.
17	Assignment
18	Demo on semi Autoanalyser



19	Demo on collection of blood samples
20	Demo on homogenizer
21	Class test
22	Demo on Histamine chamber
23	Demo on metabolic cage
24	Assignment

### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

### Learning Resources/Recommended Texts/Reference books/web resources:

#### Recommended Text books (Latest editions)

1. Ramesh k.Goyal, Natvar M.Patel, Prabhakar MC, Rajendra V.Bhatt and Anitha A.Mehta. Practicals in pharmacology.8<sup>th</sup> ed. Ahmendabad: B.S.Shah Prakashan ; 2009.
2. Kulakarni SK. Handbook of Experimental Pharmacology. 4<sup>th</sup> ed. New Delhi: vallabh Prakashan; 2012.
3. Ghosh MN. Fundamentals of Experimental pharmacology. 6<sup>th</sup> ed. Kolkata: Hilton& company; 2008.
4. Parmar NS, Shiv Prakash. Screening Methods in Pharmacology. New Delhi: Narosa Publishing House; 2011.

### **Reference books (Latest Editions)**

6. Hardman J.G, Lee E. Limbard, Good Man & Gilman. The Pharmacological basis of therapeutics. 11<sup>th</sup> ed. USA: Mc Grawhill; 2006.
7. Leon Shargel, Andrew Yub.C. Applied Bio pharmaceuticals and pharmacokinetics. 7<sup>th</sup> ed. New York: McGrawhill; 2016.
8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third year</b>
<b>Name of the course</b>	<b>Pharmaceutical Analysis</b>
<b>Course Code</b>	<b>16PMD302</b>
<b>Paper</b>	<b>theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

Pharmaceutical Analysis is mainly designed to impart a very good knowledge about different chromatographic methods, spectrophotometric methods with their instrumentations, applications towards the Pharmaceutical analysis of compounds or pharmaceuticals. It also describes the different guidelines ICH, quality control and validation parameters.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Define the fundamentals on conventional methods of drug analysis used in laboratories and also the basic principles of other analytical techniques used in analytical industry.

CO 2: Demonstrate the applications of various analytical methods to the drugs & pharmaceuticals as per the standards.

CO 3: Analyze various chromatographic techniques for the separation of mixtures.

CO 4: Apply the analytical data of various spectroscopic techniques for their identification, quantification and in structural illustration.

### Theory Course: Contents

S. No.	Topic
I (12 Hours)	<b>Quality Assurance:</b> a. Introduction, sources of quality variation, control of quality variation. b. Concept of statistical quality control. c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration. d. GLP, ISO 9000. e. Total quality management, quality review and documentation. f. ICH- international conference for harmonization-guidelines. g. Regulatory control.
II (12 Hours)	<b>Chromatography:</b> Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients. a. <b>Column Chromatography:</b> Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography. b. <b>TLC:</b> Introduction, principle, techniques, Rf value and applications.
III (12 Hours)	<b>PC:</b> Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.

	<p>d. <b>Ion-exchange chromatography:</b> Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.</p> <p>e. <b>HPLC:</b> Introduction, theory, instrumentation, and applications.</p> <p>f. <b>HPTLC:</b> Introduction, theory, instrumentation, and applications.</p>
IV (12 Hours)	<p><b>Gas Chromatography:</b> Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC &amp; GSC. Detectors-Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.</p> <p>h. <b>Electrophoresis:</b> Principles of separation, equipment for paper and gel electrophoresis, and application.</p> <p>i. <b>Gel filtration and affinity chromatography:</b> Introduction, technique, applications.</p>
V (12 Hours)	<p><b>Electrometric Methods:</b></p> <p>Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.</p> <p>a. <b>Potentiometry:</b> Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.</p> <p>b. <b>Conductometry:</b> Introduction, conductivity cell, conductometric titrations and applications.</p>
VI (12 Hours)	<p>c. <b>Polarography:</b> Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen</p>

	<p>on polarographic wave, Polarographic maxima and suppressors and applications.</p> <p>d. <b>Amperometric Titrations:</b> Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry.</p> <p>Pharma application</p>
VII (12 Hours)	<p><b>Spectroscopy:</b></p> <p>Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:</p> <p>a. <b>Absorption Spectroscopy:</b></p> <p>- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer- Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.</p> <p><b>Instrumentation</b> – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-</p> <p>Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.</p>
VIII (12 Hours)	<p><b>Infrared Spectroscopy:</b> Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectro-meter – sources of IR, Collimating systems, monochromators, sample cells, sample</p>

	handling in IR spectroscopy and detectors– Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.
IX (12 Hours)	<p><b>Fluorimetric Analysis:</b> Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.</p> <p><b>b. Flame Photometry:</b> Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.</p>
X (12 Hours)	<p>c. <b>Atomic Absorption Spectrometry:</b> Introduction, Theory, types of electrodes, instrumentation and applications.</p> <p>d. <b>Atomic Emission Spectroscopy:</b> Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.</p>
XI (12 Hours)	<p>e. <b>NMR &amp; ESR (introduction only):</b> Introduction, theoretical aspects and applications.</p> <p>f. <b>Mass Spectroscopy: (Introduction only)</b> – Fragmentation, types of ions produced mass spectrum and applications.</p> <p>g. <b>Polarimetry: (Introduction only)</b> – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.</p>
XII (12 Hours)	<p>h. <b>X-RAY Diffraction: (Introduction only)</b> – Theory, reciprocal lattice concept, diffraction patterns and applications.</p> <p>i. <b>Thermal Analysis:</b> Introduction, instrumentation, applications, and DSC and DTA.</p> <p>Revision</p>

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

### **Learning Resources/Recommended Texts/Reference books/web resources:**

#### **Reference books (Latest Editions):**

1. Higuchi. T and Hasen. E. B. Text Book of Pharm. Analysis. Inter Science Publishers: New York.
2. Jenkins. Quantitative Pharma. Analysis. The Blakiston division: New York.
3. Garrot. D. Quantitative Drug Analysis. Chapman & Hall Ltd: London.
4. James. E. Undergraduate Instrumental Analysis. CBS Publishers.
5. Willard and Merritt. Instrumental Analysis. East West Press Ltd: Delhi/Madras.
6. Skoog DA, James HF, Crouch SR. Principles of Instrumental Analysis. 6<sup>th</sup> ed. India: Cengage Learning; 2007. ISBN-13: 978-0495012016, ISBN-10: 0495012017.
7. Vogel AI. Text book of quantitative chemical analysis. 5<sup>th</sup> ed. Newyork: Longman Scientific & Technical; 1989. ISBN 0582446937
8. Connors KA. A textbook of Pharmaceutical Analysis. 3<sup>rd</sup> ed. India: Wiley India Pvt. Ltd; 1982. ISBN: 8LGYW9TY5P8.
9. Silverstein RM, Webster FX, Kiemle DJ, Bryce DL. Spectrometric identification of organic compounds. 8<sup>th</sup> ed. New Jersey: John Wiley & Sons; 2004. ISBN: 9780470914014.



10. Remington. The Science & Practice of Pharmacy. Vol-I & II. Mack Publishing Co. Pennsylvania.
11. Chatten. Text Book of Pharm. Chemistry. CBS Publications.
12. William Kemp. Spectroscopy. ELBS with Macmillan Press: Hampshire.
13. Monographs: Indian Pharmacopoeia, British Pharmacopoeia, United States of Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia.
14. Kemp W. Organic spectroscopy. 3<sup>rd</sup> ed. London: Palgrave Macmillan; 1991. ISBN-10: 033351954X, ISBN-13: 9780333519547.
15. Sharma BK. Instrumental chemical analysis, 28<sup>th</sup> ed. India: Goel publishing house; 2014. ISBN: 9788182830998.
16. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
17. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
18. Bentley and Driver's Textbook of Pharmaceutical Chemistry
19. John H. Kennedy, Analytical chemistry principles

**Recommended Books (Latest Editions):**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

## 10. Spectrophotometric identification of Organic Compounds by Silverstein

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third year</b>
<b>Name of the course</b>	<b>Pharmaceutical Analysis (Lab)</b>
<b>Course Code</b>	<b>16PMD308</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### Course Description:

The pharmaceutical analysis laboratory course is aimed to train the students on experimental techniques for the determination, separation, comparison and estimation of various pharmaceuticals by chromatographic, electrometric and spectroscopic methods. This course also provides the interpretation of various spectra and helps in the structural identification by their absorbance, functional groups, Resonance etc.

### Course Learning Outcomes:

Upon successful completion of this course, the student should be able to:

CO 1: Identify the compounds present in the samples by various analytical techniques like chromatography and spectroscopy.

CO 2: Analyze the various drugs by electrometric methods.

CO 3: Demonstration of various analytical techniques, spectra of drugs towards its applications in the analytical chemistry.

**Practical Course: Contents**

Week	Topics
1	Introduction to analysis
2	Pharmacopoeial considerations
3	Introduction & Calibration of analytical glass ware
4	Potentiometric titration of strong acid and strong base
5	Conductometric titration of mixture of acids and strong base
6	Introduction to chromatography
7	Preparation and activation of TLC plates
8	Identification of Paracetamol tablets by TLC
9	Identification of amino acids by ascending paper chromatographic technique
10	Identification of amino acids by Radial paper chromatographic technique
11	Determination of $p^{ka}$ of salicylic acid by pH meter
12	Demonstration of HPLC with Binary pump
13	Determination of maximum wavelength of given drug
14	Determination of Isobestic point
15	Effect of pH on UV spectrum for given compound
16	Interpretation of IR spectrum
17	Interpretation of HPLC chromatogram

18	Determination of quenching effect of quinine sulphate
19	Estimation of drug by Fluorimetry
20	Assay of Ciprofloxacin tablet by colorimetry using 0.5% FeCl <sub>3</sub>
21	Calibration of given analytical glass wares as per IP 2007
22	Flame photometry
23	Limit Test for sulphates in Calcium gluconate by Nephelo turbidimeter
24	Demonstration of GC
25	Revision

#### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources:

1. Vogel AI. Text book of quantitative chemical analysis. 5<sup>th</sup> ed. Newyork: Longman Scientific & Technical; 1989. ISBN 0582446937
2. A. H. Beckett and J. B. Stenlake. Practical pharmaceutical chemistry. Part-I & II. The Athtone press: University of London; 1968.
3. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations. 3rd ed. India: CBS Publishers; 2007. ISBN-10: 8123905602.

4. Silverstein RM, Webster FX, Kiemle DJ, Bryce DL. Spectrometric identification of organic compounds. 8th ed. New Jersey: John Wiley & Sons; 2004. ISBN: 9780470914014.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third year</b>
<b>Name of the course</b>	<b>Pharmacotherapeutics II</b>
<b>Course Code</b>	<b>16PMD303</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:**

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

**Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualised therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);

CO 6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO 7: Summaries the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy;

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis; and

CO 10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

### **Theory Course: Contents**

<b>S. No.</b>	<b>Topics</b>
I (12 Hours)	Musculoskeletal disorders: Rheumatoid arthritis, Osteoarthritis, Spondylitis
II (12 Hours)	Gout, Systemic Lupus Erythematosus Infectious diseases: Guidelines for rational use of antibiotics and surgical prophylaxis
III (12 Hours)	Respiratory tract infections, Tuberculosis, Meningitis , Malaria
IV (12 Hours)	Gastroenteritis, Fungal Infections, HIV & Opportunistic Infections
V (12 Hours)	Urinary tract infections, Syphilis Renal System: Acute Renal Failure, Renal Dialysis

VI (12 Hours)	Chronic Renal Failure, Drug induced renal disorders Endocarditis, Viral infections, Septicemia
VII (12 Hours)	Gonorrhea Dermatology: Scabies, Eczema, Impetigo, Psoriasis
VIII (12 Hours)	Oncology: Introduction and Basic principles of Cancer Therapy
IX (12 Hours)	General Introduction to cancer chemotherapeutic agents
X (12 Hours)	Chemotherapy of Breast Cancer, Pathophysiology of breast cancer Management of chemotherapy induced nausea and emesis
XI (12 Hours)	Types, pathophysiology and pharmacotherapy of Leukemia
XII (12 Hours)	Revision

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8<sup>th</sup> ed. lippincot Williams; 2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach.9<sup>th</sup> ed. McGraw-hill education; 2012.
3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10<sup>th</sup> ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5<sup>th</sup> ed. Churchill livingstone;2011
5. Green,Russells,Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3<sup>rd</sup> ed. Pharmaceutical press: 2008.
6. Rhonds Jones. Patient Assessment in Pharmacy Practice. Wolters Kluwer. 3rd Edition.
7. Sherif Hanafy M. Patient Assessment in Clinical Pharmacy: A Comprehensive guide. Springer.
8. Lynn S. Bickley. BATE's Guide to Physical Examination and History taking. Wolters Kluwer. 12th Edition.
9. Karen J. Tietze. Clinical Skills for Pharmacists: A patient focused approach. 3rd Edition. Elsevier.
10. Soraya D, Rebekha R. Pharmacy Case Studies. Pharmaceutical Press.
11. Pharmacotherapy casebook: A patient focused approach. 10th Edition. McGrawHill Education.
12. Michael DK, Kathryn RM, Marie ACB, Pharmacotherapy Principles & Practice Study Guide: A Case-Based Care Plan Approach.



<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third year</b>
<b>Name of the course</b>	<b>Pharmacotherapeutics II (Lab)</b>
<b>Course Code</b>	<b>16PMD309</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>4 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualised therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);

CO 6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO 7: Summaries the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis

### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>	
1	Introduction to soap Analysis, FARM notes	<b>Clinical skills</b>
2	Case presentation on GASTROENTRIRITS.	Assessing drug related problems
3	Case presentation on BREAST CANCER	Pharmaceutical care process
4	Case presentation on LRTI with GE with protein energy malnutrition	Medication therapy management
5	Case presentation on Malaria with thrombocytopenia	Monitoring plan
6	Case presentation on tuberculosis	Patient counseling
7	Case presentation on LRTI with sepsis with hypochromic microcytic anemia	ADR monitoring
8	Case presentation on Dengue with thrombocytopenia	Drug counseling
9	Case presentation on myocardial infraction	Clinical pharmacokinetics
10	Case presentation on Rheumatoid Arthritis	Medication review / medication history interview
11	Case presentation on post meningitis sequalor with seizures	Ward round participation
12	Case presentation on impetigo	Drug information
13	Case presentation on COPD with anasarka corpural	Medication adherence
14	Case presentation on Acute renal failure.	Pharmacotherapy work up [drug therapy assessment]

15	Case presentation on exacerbation of bronchiectasis	Medication safety assessment
16	Case presentation on liver cirrhosis	Rational drug use
17	Case presentation on UTI with anemia	Medication effective assessment
18	Case presentation on OP compound poisoning	Evidence based medicine
19	Case presentation on malaria with thrombocytopenia with clinical jaundice	Pediatric clinical practice
20	Case presentation on chronic kidney failure with electrolyte disturbance	Medical ward-clinical practice
21	Case presentation on COPD with gastroenteritis	Medication errors
22	Case presentation on Rational use of drugs	Geriatric/OB&GYN Clinical practice

#### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8<sup>th</sup> ed. lippincot Williams; 2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach.9<sup>th</sup> ed. Mcgraw-hill education; 2012.

3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10<sup>th</sup> ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5<sup>th</sup> ed. Churchill livingstone;2011
5. Green,Russells,Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3<sup>rd</sup> ed. Pharmaceutical press: 2008.
6. Rhonds Jones. Patient Assessment in Pharmacy Practice. Wolters Kluwer. 3rd Edition.
7. Sherif Hanafy M. Patient Assessment in Clinical Pharmacy: A Comprehensive guide. Springer.
8. Lynn S. Bickley. BATE's Guide to Physical Examination and History taking. Wolters Kluwer. 12th Edition.
9. Karen J. Tietze. Clinical Skills for Pharmacists: A patient focused approach. 3rd Edition. Elsevier.
10. Soraya D, Rebekha R. Pharmacy Case Studies. Pharmaceutical Press.
11. Pharmacotherapy casebook: A patient focused approach. 10th Edition. McGrawHill Education.
12. Michael DK, Kathryn RM, Marie ACB, Pharmacotherapy Principles & Practice Study Guide: A Case-Based Care Plan Approach.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third Year</b>
<b>Subject</b>	<b>Pharmaceutical Jurisprudence</b>
<b>Course Code</b>	<b>16PMD304</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3 + 1 hours (lectures)</b>
<b>Pre /co-requisite(s)</b>	<b>Nil</b>

### **Course Description:**

This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, Medicinal and Toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to -

CO1: Know the history and significance of pharmaceutical legislations in India and practice professional ethics, responsibilities.

CO2: Know the administrative bodies, authorities, officers, inspectors' roles and responsibilities.

CO3: Understand the procedures for import, manufacturing and sale of drugs, cosmetics, other substances along with schedules.

CO4: Know the constitution, functions of central, state councils, registration procedure and importance of education regulations.

CO5: Know the policy, procedures, and control of pricing drugs.

CO6: Other laws and amendments as prescribed by the Central and State Councils from time to time including International Laws.

### Theory Course: Contents

S.No	Topics
I  (3 weeks)	<b>Introduction:</b> Legislation, types and legal terminology.  <b>Pharmaceutical Legislations</b> – A brief review.
II  (3 weeks)	<b>Principle and Significance of professional ethics.</b> Critical study of the code of pharmaceutical ethics drafted by PCI.
III  (3 weeks)	<b>Drugs and Cosmetics Act, 1940, and its rules 1945:</b> Objectives, Legal definition, General study of schedules to the Act (First, Second schedule) and Rules (A, B, C, C1, D, D-I, D-II, D-III, E1, F, F-I, F-II, F-III, FF, G, H, H1, J, K, L1, M, M-I, M-II, M-III, N, O, P, P1, Q, R, R1, S, T, U, U1, V, W, X, Y) with recent amendments.  Administration of the Act and Rules – Drugs Technical Advisory Board (DTAB), Central drugs Laboratory (CDL), Drugs Consultative Committee (DCC), Government drug analysts, Licensing authorities, Controlling authorities, Drugs Inspectors.  Import, Sales, Labelling and packaging of Drugs and Cosmetics.  Offences and penalties.
IV  (3 weeks)	Provisions Relating to Indigenous Systems.  <b>Pharmacy Act, 1948:</b> Objectives, Legal Definitions, General Study, Constitution and Functions of Central Council, State and Joint state councils. Registration and Procedure, Educational Regulations (ER), Pharmacy Practice regulations. Offences and penalties.
V  (3 weeks)	<b>Medicinal and Toilet Preparation Act, 1955:</b> Objectives, Legal Definitions, Licensing, Bonded and Non-Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Levy and collection of duties. Offences and Penalties.
VI  (3 weeks)	<b>Narcotic Drugs and Psychotropic substances Act, 1985 and Rules:</b>  Objectives, Legal Definitions, General Study, Constitution and Functions of Narcotic & Psychotropic Consultative Committee, National Fund for Controlling the

	Drug Abuse, Prohibition, Control and regulations, and Schedules to the Act. Offences and Penalties.
VII (3 weeks)	Study of Salient Features of Drugs and magic remedies Act and its Rules. Schedules to the Act. Offences and Penalties.
VIII (3 weeks)	Study of Essential Commodities Act Relevant to drugs price control Order. Offences and Penalties.
IX (3 weeks)	<b>National Pharmaceutical Pricing Authority (NPPA):</b> National Pharmaceutical Pricing Policy (NPPP) Drug Price Control Order. Schedules to DPCO, Offences and Penalties.
X (3 weeks)	<b>Prevention Of Cruelty to animals Act, 1960:</b> Objectives, Definitions, Brief study on Institutional Animal Ethics Committee (IAEC), Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines for experimenting animals. Offences and Penalties.
XI (3 weeks)	<b>Intellectual property rights:</b> Patents & Design Act-1970 and brief study on Copyright, Trademarks, Trade Secrets, Geographical indications, Plant variety rights.  Brief study on <b>Medical Termination of Pregnancy Act 1971.</b>
XII (3 weeks)	<b>Right to Information Act 2005:</b> Objectives, Definitions, right to information and obligations of public authorities, procedure in filing RTI application and supply of information, information exempted from disclosure.  <b>Medical Device and Diagnostics:</b> Medical Device Rules, 2017.  Brief study of prescription and Non-prescription Products.

### Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.

3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

**Learning Resources/Recommended Texts/Reference books/web resources:**

1. Mithal, B M. Textbook of Forensic Pharmacy. 10th ed. Delhi: Vallabh Prakashan; 2006.
2. S P Agarwal, Rajesh Knanna. Pharmaceutical Jurisprudence and Ethics. 5th ed. Delhi: Birla Publications Pvt Ltd. 2009.
3. Binay Kumar JHA. Pharmaceutical Jurisprudence. Jalandhar city: S Vikas & CO.
4. Singh, KK, Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
5. Jain NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan; 1995.
6. Reports of the Pharmaceutical enquiry Committee.
7. I.D.M.A., Mumbai. DPCO 1995.
8. Various reports of Amendments.
9. Deshpande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
10. Eastern Book Company. The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.
11. B. S. Kuchekar. Forensic Pharmacy. Pune: NiraliPrakashan.
12. Vijay Malik, Law relating to Drugs and Cosmetics. 26<sup>th</sup> Edition, 2021. Eastern Book Company.
13. Drugs and Cosmetics Act, 1940 with Medical Devices Rules 2017. 2021 Edition. Eastern Book Company.
14. The Complete Drugs and Medical Laws Referencer by Surendra Malik, Sudeep Malik and Vijay Malik, 2016 Edition. Eastern Book Company.
15. INDIA CODE (<https://www.indiacode.nic.in/>)

(It is an official database of all Central enactments which are in force and their subordinate legislations made from time to time. It also contains Legislations enacted by the States and Union Territory Administrations along with their relevant subordinate legislations.)



<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third year</b>
<b>Name of the course</b>	<b>Medicinal chemistry</b>
<b>Course Code</b>	<b>16PMD305</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

The pharmaceutical Medicinal chemistry course will explore role of organic chemistry in the design and action of drugs, it is helpful for discussing principles of drug discovery, drug development, drug receptor interactions and structure activity relationships and it is helpful to understand the relationship between the biological, chemical physical properties of medicinal compounds.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Define the drug targets and molecular mechanism action.

CO2: Encourage the development of problem – solving skills and knowledge related to chemotherapy which is necessary to provide pharmaceutical care.

CO 3: Build a knowledge base of chemotherapy principles for various disease states.

CO 4: applied the knowledge in discussing principles of drug discovery, drug development, drug/receptor interactions and structure/activity relationships.

## Theory Course: Contents

S. No.	Topics
I (12 Hours)	<b>Drug metabolism:</b> Introduction, classification with suitable examples.
II (12 Hours)	<b>Modern concept of rational drug design:</b> A brief introduction to Quantitative Structure Activity Relationship (QSAR), Prodrug, Combinatorial chemistry, computer aided drug design (CADD) and concept of Antisense molecules.
III (12 Hours)	<p><b>Anti-infective agents</b></p> <p>a) <b>Local anti-infective agents:</b> P – Chloro m-xyleneol, Chlorocresol, Halozane*, Benzalkonium chloride*, Methylene blue, Methyl paraben*.</p> <p>b) <b>Antifungal agents</b> <b>Antifungal antibiotics:</b> Amphotericin-B, Nystatin, Natamycin, Griseofulvin. Synthetic Antifungal agents: Clotrimazole, Miconazole*, Ketoconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*. c) <b>Urinary tract anti-infectives</b> <b>Quinolones:</b> SAR of quinolones, Nalidixic SAR of quinolones, Nalidixic Acid, Norfloxacin, Ciprofloxacin*, Ofloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin <b>Miscellaneous:</b> Furazolidine, Nitrofurantoin*, Methanamine.</p>
IV (12 Hours)	<p>d) <b>Antitubercular agents</b> <b>Synthetic anti tubercular agents:</b> Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.* <b>Anti tubercular antibiotics:</b> Rifampicin, Rifabutin, Cycloserine, Streptomycin.</p> <p>e) <b>Anthelmintics:</b> Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.</p>
V (12 Hours)	<p>f) <b>Antiviral agents and Anti AIDS agents</b> Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Ribavirin, Saquinavir, Indinavir.</p> <p>g) <b>Antiprotozoal agents</b> Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol.</p>

	h) <b>Antiscabies and antipedicular agents:</b> Benzylbenzoate, Gammexane, Chlorophenothane(DDT)*.
VI (12 Hours)	<p><b>a) Antimalarials:</b> Life cycle of malarial parasite  <b>Quinolines:</b> SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.  <b>Biguanides and dihydro triazines:</b> Cycloguanil pamoate, Proguanil.  <b>Miscellaneous:</b> Pyrimethamine, Artesunate, Artemether, Atovaquone</p> <p><b>b) Sulphonamides and sulphones</b>  Chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.  <b>Folate reductase inhibitors:</b> Trimethoprim*, Cotrimoxazole.  <b>Sulfones:</b> Dapsone*.</p>
VII (12 Hours)	<p><b>Antibiotics :</b> Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.  <b><math>\beta</math>-Lactam antibiotics:</b> Penicillin, Cephalosporins, <math>\beta</math>- Lactamase inhibitors, Monobactams  <b>Aminoglycosides:</b> Streptomycin, Neomycin, Kanamycin  <b>Tetracyclines:</b> Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline  <b>Macrolide:</b> Erythromycin Clarithromycin, Azithromycin.  <b>Miscellaneous:</b> Chloramphenicol*, Clindamycin</p>
VIII (3 weeks)	<p><b>Antineoplastic agents</b>  <b>Alkylating agents:</b> Mecllorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiopeta  <b>Antimetabolites:</b> Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine  <b>Antibiotics:</b> Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin  <b>Plant products:</b> Etoposide, Vinblastin sulphate, Vincristin sulphate</p> <p>Miscellaneous: Cisplatin, Mitotane.</p>
IX (3 weeks)	<p><b>Cardiovascular agents</b>  <b>a) Antihypertensive agents:</b> Atenolol, Propranolol*, Timolol, Captopril, Enalapril, Methyldopa hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Minoxidil, Reserpine, Hydralazine hydrochloride.  <b>b) Antianginal agents and vasodilators</b>  <b>Vasodilators:</b> Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrate*, Dipyridamole.  <b>c) Calcium channel blockers:</b> Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine*, Amlodipine, Felodipine.  <b>d) Antiarrhythmic agents :</b> Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Mexiletine hydrochloride, Amiodarone.</p>

	e) <b>Antihyperlipidemic agents:</b> Clofibrate, Lovastatin, Cholesteramine and Cholestipol
X (3weeks)	<b>Diuretics</b> <b>Carbonic anhydrase inhibitors:</b> Acetazolamide*, Methazolamide, Dichlorphenamide. <b>Thiazides:</b> Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, <b>Loop diuretics:</b> Furosemide*, Bumetanide, Ethacrynic acid. <b>Potassium sparing Diuretics:</b> Spironolactone, Triamterene, Amiloride. <b>Osmotic Diuretics:</b> Mannitol
XI (3 weeks)	<b>Hypoglycemic agents :</b> Insulin and its preparations <b>Sulfonyl ureas:</b> Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. <b>Biguanides:</b> Metformin. <b>Thiazolidinediones:</b> Pioglitazone, Rosiglitazone. <b>Meglitinides:</b> Repaglinide, Nateglinide. <b>Glucosidase inhibitors:</b> Acarbose, Voglibose.
XII (3 weeks)	<b>Drugs acting on Endocrine system</b> Nomenclature, Stereochemistry and metabolism of steroids <b>Sex hormones:</b> Testosterone, Nandrolone, Progesterones, Oestrinol, Oestradiol, Oestrone, Diethyl stilbestrol*. <b>Drugs for erectile dysfunction:</b> Sildenafil, Tadalafil. <b>Oral contraceptives:</b> Mifepristone, Norgestrel, Levonorgestrol <b>Corticosteroids:</b> Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone <b>Thyroid and antithyroid drugs:</b> L-Thyroxine, L-Thyronine, Propylthiouracil*, Methimazole, Carbimazole.

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

**Learning Resources/Recommended Texts/Reference books/web resources:**

1. Surendra N Pandeya. A textbook of Medicinal chemistry: Synthesis and Biochemical Approach. 3<sup>rd</sup> ed. Vol.I. Varanasi: S G Publisher; 2004.
2. Surendra N Pandeya. A textbook of Medicinal chemistry: Synthesis and Biochemical Approach. 1<sup>st</sup> ed. Vol.II. Varanasi: S G Publisher; 2001.
3. Robert F Doerge, editor. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry. 8<sup>th</sup> ed. Philadelphia: J B Lppncott Company.
4. S S Kadam, K R Mahedik, K G Bothere. Principles of Medicinal Chemistry. 18<sup>th</sup> ed. Vol I. Pune: Nirali Prakashan; 2007.
5. S S Kadam, K R Mahedik, K G Bothere. Principles of Medicinal Chemistry. 18<sup>th</sup> ed. Vol II. Pune: Nirali Prakashan; 2007.
6. Ashutoshkar. Medicinal Chemistry. 3<sup>rd</sup> ed. New Delhi: New Age International (P)Limited, Publishers: 2005.
7. K Ilango, P Valentina. Textbook of Medicinal Chemistry. 1<sup>st</sup> ed. Vol I. Chennai: Keerthi Publishers; 2007.
8. K Ilango, P Valentina. Textbook of Medicinal Chemistry. 1<sup>st</sup> ed. Vol II. Chennai: Keerthi Publishers; 2007.
9. Harkishan Singh. V K Kapoor. Medicinal and Pharmaceutical Chemistry. 2<sup>nd</sup> ed. Delhi: Vallabh Prakashan. 2010.
10. William O. Foye. Textbook of Medicinal Chemistry, 5<sup>th</sup> ed: Lea Febiger, Philadelphia.
11. John M Beale, John H Block, editors. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry. 12<sup>th</sup> ed. India: Wolters Kluwer (India) Pvt Ltd. 2011.
12. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wileyinterscience Publication, New York, Toranto.

13. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
14. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
15. V Alagarwamy. Textbook of Medicinal Chemistry. 2<sup>nd</sup> ed. Vol I. India: Elsevier; 2014.
16. V Alagarwamy. Textbook of Medicinal Chemistry. 2<sup>nd</sup> ed. Vol II. India: Elsevier; 2014.
17. Remington. The science and Practice of Pharmacy. 22<sup>nd</sup> ed. Vol I. Pharmaceutical Press; 2013.
18. Remington. The science and Practice of Pharmacy. 22<sup>nd</sup> ed. Vol II. Pharmaceutical Press; 2013.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third year</b>
<b>Name of the course</b>	<b>Medicinal chemistry (Lab)</b>
<b>Course Code</b>	<b>16PMD310</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

The Medicinal chemistry laboratory course is aimed to train the students on experimental techniques for the determination and Synthesis of different biologically active compound libraries and evaluation of their biological activity using cytotoxicity assays. Analysis of structure activity relationships using the data generated. This course also provides the laboratory skills related to reaction design, chemical synthesis and purification process for few medicinal compounds.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate the skills on determination of various physical properties of organic molecules related to biological activity.

CO 2: Differentiate various classes of medicinal compounds by experimental design.

CO 3: Perform chemical reaction and purification of medicinal compounds of pharmaceutical interest.

### Practical Course: Contents

Week	Topics
01	Assays of important drugs from the course content.
02	Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
03	Monograph analysis of important drugs.
04	Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.
	<b>Revision</b>

### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

### Learning Resources/Recommended Texts/Reference books/web resources (Latest editions)

1. A.I. Vogel, Text Book of Practical Organic Chemistry. Pearson Prentice Hall.
2. F.G. Mann & B.C. Saunders, Practical Organic Chemistry. Pearson Publishers.
3. Indian Pharmacopoeia



<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third year</b>
<b>Name of the course</b>	<b>Pharmaceutical formulations</b>
<b>Course Code</b>	<b>16PMD306</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

The pharmaceutical formulations course is aimed to present fundamental in formulation of drug into dosage forms. It emphasizes on physical and chemical properties of drugs and additives and their role in creating high –quality and efficacious dosage forms. The course deals with formulation and evaluation of various pharmaceutical preparations. This course also provides the knowledge of novel drug delivery systems to identifying potential drug delivery routes.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Define various types of pharmaceutical dosage forms and Novel drug delivery system.

CO 2: Explain principles involved in formulation and preparation of various pharmaceutical preparations

CO 3: Apply the principles for preparation of dosage forms with highest standards.

CO 4: Evaluate of pharmaceutical dosage forms by various official tests.

### Theory Course: Contents

S. No	Topics
I (3 weeks)	<u>Tablets 1</u> : Tablet excipients, Formulation of different types of tablets, Granulation techniques, Tablet coating,
II (3 weeks)	<u>Tablets 2</u> : Type of coating, quality control tests for coated tablet and evaluation of tablets
III (3 weeks)	<u>Tablets 3</u> : quality control tests for coated tablet and evaluation of tablets <u>Capsules 1</u> : Raw material for shell, production of hard gelatin capsules, filling of hard gelatin capsules and finishing
IV (3 weeks)	<u>Capsules 2</u> : Production of soft gelatin capsules, Filling of soft gelatin capsules, Quality control tests for hard and soft gelatin capsules.
V (3 weeks)	<u>Ophthalmic Preparations 1</u> : Formulation and preparation of eye drops, eye ointment, eye lotion
VI (3 weeks)	<u>Ophthalmic Preparations 2</u> : Formulation and preparation of contact lens solutions, evaluation and packing of ophthalmic preparations. Parenterals 1: Introduction, formulation of large volume parenterals
VII (3 weeks)	<u>Parenterals 2</u> : Formulation of small volume Parenterals, sterilization. Containers used for Parenterals. (including official tests)
VIII (3 weeks)	<u>Semi-Solids 1</u> : Introduction and classification, anatomy of skin and factors affecting absorption, Formulation, preparation, packaging, labeling and storage of ointments
IX (3 weeks)	<u>Semi-Solids 2</u> : Formulation, preparation, packaging, labeling and storage of jellies, creams, pastes.

X (3 weeks)	Definition and concept of controlled and novel Drug delivery system 1- parenteral,transdermal
XI (3 weeks)	<u>Drug delivery system 2:</u> Buccal, rectal, nasal.
XII (3 weeks)	<u>Drug delivery system 3:</u> Implants,ocular. Revision

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

1. Lean Lachman, Herbert A Lieberman, Kenneth E Avis, editors. Pharmaceutical Dosage Forms. 2<sup>nd</sup> ed. Vol I, II, III. New York: Marcel Dekker. 2005.
2. M.E.Aulton Pharmaceutics. The science of dosage form design. – 2<sup>nd</sup> ed. Churchill-Livingstone, 2002.
3. B.M.Mithal. A text book of pharmaceutical formulations, 6<sup>th</sup> ed. New Delhi, Vallabh Prakashan, 2010.
4. N.K.Jain, Advances in control and Novel drug delivery. CBS Publishers.
5. USP/BP/IP

6. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
7. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Third year</b>
<b>Name of the course</b>	<b>Pharmaceutical formulation (Lab)</b>
<b>Course Code</b>	<b>16PMD311</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

The pharmaceutical formulations laboratory course is aimed to train the students to prepare different pharmaceutical dosage forms. This course also deals with evaluation of the prepared formulations by various official tests.

#### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate the skills in preparation of different pharmaceutical formulations by various methods.

CO2: Operate tablet compression machine, capsule filling machine, disintegration and dissolution test apparatus.

CO 3: Evaluate the pharmaceutical formulations by various official and unofficial tests.

#### **Practical Course: Contents**

Week	Topics
1	Introduction to laboratory safety techniques and the use of glass wares and chemicals.
2	Preparation of Paracetamol tablets by wet granulation method.
3	Preparation of Diclofenac tablets by direct compression method.
4	Preparation of soluble Acetylsalicylic acid tablets.
5	Preparation of Chewable tablets.
6	Quality control test for paracetamol tablets.
7	Quality control test for paracetamol tablets.
8	Quality control test for paracetamol tablets.
9	Quality control test for diclofenac tablets.
10	Quality control test for diclofenac tablets.
11	Quality control test for diclofenac tablets.
12	Quality control test for soluble acetylsalicylic acid tablets.
13	Quality control test for soluble acetylsalicylic acid tablets.
14	Quality control test for soluble acetylsalicylic acid tablets.
15	Quality control test for chewable tablets.
16	Quality control test for chewable tablets.
17	Quality control test for chewable tablets.
18	Filling of hard gelatin capsules.
19	Evaluation of hard gelatin capsules.
20	Evaluation of hard gelatin capsules.
21	Evaluation of hard gelatin capsules.
22	Parenterals- Ascorbic acid injection.

23	Calcium gluconate injection.
24	Sodium chloride intravenous infusion.
25	Dextrose and sodium chloride infusion.
26	Evaluation of Ascorbic acid injection.
27	Evaluation of Calcium gluconate injection.
28	Evaluation of Sodium chloride intravenous infusion.
29	Evaluation of Dextrose and Sodium chloride infusion.
30	Semi solids- Salicylic acid and benzoic acid ointment.
31	Diclofenac gel preparation.
32	Evaluation of Diclofenac gel.
33	Cold cream.
34	Vanishing cream.
35	Toothpaste.
36	Revision

#### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

**Learning Resources/Recommended Texts/Reference books/web resources:**

1. L.Lachman, H.A, Lieberman and J.L. Kanig, Theory and Practice of industrial pharmacy, Lea and Febieger, Philadelphia Latest Edn.
2. USP/BP/IP
3. M.E.Aulton Pharmaceutics. The science of dosage form design.- 2<sup>nd</sup> ed. Churchill-Livingstone,2002.
4. B.M.Mithal. A text book of pharmaceutical formulations, 6<sup>th</sup> ed. New Delhi, Vallabh Prakashan, 2010.
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
6. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fourth Year</b>
<b>Name of the course</b>	<b>Pharmacotherapeutics III</b>
<b>Course Code</b>	<b>16PMD401</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management

#### **Course Learning Outcomes:**

At completion of this subject it is expected that students will be able to explain

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualized therapeutic plans based on diagnosis;



CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (Including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse Effects);

CO 6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO 7: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy;

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis; and

CO 10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

### Theory Course: Contents

S. No	Topics
I (3 weeks)	<b>Gastrointestinal system:</b> Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease.
II (3weeks)	<b>Liver disorders</b> - Alcoholic liver disease, Viral hepatitis including jaundice
III (3 weeks)	<b>Hematological system:</b> Anaemias, Venous thromboembolism,
IV (3weeks)	<b>Nervous system:</b> Epilepsy, Parkinsonism.
V (3weeks)	<b>Nervous system:</b> Stroke, Alzheimer's disease.

VI (3 weeks)	<b>Psychiatry disorders :</b> Schizophrenia, Affective disorders,
VII (3 weeks)	<b>Psychiatry disorders:</b> Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
VIII (3 weeks)	Pain management including Pain pathways.
IX (3 weeks)	Neuralgias and headache.
X (3 weeks)	Evidence Based Medicine
XI (3 weeks)	Drug induced liver disorders
XII (3 weeks)	Drug induced blood disorders.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

**Learning Resources/Recommended Texts/Reference books/web resources**

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8<sup>th</sup> ed. lippincot Williams;2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach.9<sup>th</sup> ed. McGraw-hill education; 2012.
3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10<sup>th</sup> ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5<sup>th</sup> ed. Churchill livingstone;2011
5. Green,Russells,Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3<sup>rd</sup> ed. Pharmaceutical press;2008

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fourth year</b>
<b>Name of the course</b>	<b>Pharmacotherapeutics III (Lab)</b>
<b>Course Code</b>	<b>16PMD407</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management

**Course Learning Outcomes:** At completion of this subject it is expected that students will be able to understand –

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualized therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (Including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse Effects);

CO 6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO 7: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy;

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis; and

CO 10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Introduction to ward round participation and case collection.
2	Peptic Ulcer
3	Gastro- esophageal reflex disorder
4	Inflammatory bowel disorder
5	Hepatitis
6	Alcoholic Liver disorder
7	Drug induced liver disorder
8	Anemia
9	Venous thromboembolism

10	Drug induced hematological disorder
11	Epilepsy
12	Parkinsonism
13	Stroke
14	Alzheimer's disease
15	Schizophrenia
16	Affective disorder
17	Anxiety disorders
18	Sleep disorders
19	Obsessive Compulsive disorders
20	Pain management
21	Neuralgia
22	Head ache
23	Case studies on Multiple disorders
24	Case studies on Multiple disorders
25	Case studies on Multiple disorders
26	Case studies on Multiple disorders
27	Drug club I
28	Drug club II
29	Drug club III
30	Journal club I
31	Journal Club II
32	Journal club III
33	Evidence based medicine (Critical appraisal of RCT)

34	Evidence based medicine (Critical appraisal of Cohort study)
35	Evidence based medicine (Critical appraisal of Case control study)
36	REVISION/Assessment

#### **Assessment methods and weightage (Practical)**

<b>Assessment type</b>	<b>Assessment tool</b>	<b>Distribution</b>
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

#### **Learning Resources/Recommended Texts/Reference books/web resources (Latest editions)**

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8<sup>th</sup> ed. lippincot Williams; 2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach.9<sup>th</sup> ed. Mcgraw-hill education; 2012.
3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10<sup>th</sup> ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5<sup>th</sup> ed. Churchill livingstone;2011
5. Green,Russells,Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3<sup>rd</sup> ed. Pharmaceutical press: 2008.

6. Rhonds Jones. Patient Assessment in Pharmacy Practice. Wolters Kluwer. 3rd Edition.
7. Sherif Hanafy M. Patient Assessment in Clinical Pharmacy: A Comprehensive guide. Springer.
8. Lynn S. Bickley. BATE's Guide to Physical Examination and History taking. Wolters Kluwer. 12th Edition.
9. Karen J. Tietze. Clinical Skills for Pharmacists: A patient focused approach. 3rd Edition. Elsevier.
10. Soraya D, Rebekha R. Pharmacy Case Studies. Pharmaceutical Press.
11. Pharmacotherapy casebook: A patient focused approach. 10th Edition. McGrawHill Education.
12. Michael DK, Kathryn RM, Marie ACB, Pharmacotherapy Principles & Practice Study Guide: A Case-Based Care Plan Approach.



<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fourth Year</b>
<b>Name of the course</b>	<b>Hospital Pharmacy</b>
<b>Course Code</b>	<b>16PMD402</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>2+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

The Hospital Pharmacy course is aimed to present fundamentals in understanding hospital pharmacy set up, organization and functioning at hospital settings dedicated in providing primary, secondary and tertiary care for the patients, emphasizing on basic requirements, working and helping hands, committees, interdependencies of all the departments, inventory management, drugs distribution, unit dose and bulk dose preparation and storage, management of radiopharmaceuticals, and as a practicing pharmacist how one can play active role in continuing pharmacy and medical education.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Abide by the policies and procedures, as well as rules and regulations affecting general pharmacy operations including inventory management.

CO 2: Describe the role of the pharmacist on hospital committees that have pharmacist representation and its impact or application to patient care.

CO 3: Demonstrate good aseptic technique to compound sterile dosage forms and IV medications.

CO 4: Professionally communicate and document recommendations and interventions to various healthcare professionals.

### Theory Course: Contents

S. No.	Topics
I (3 weeks)	<ul style="list-style-type: none"><li>• <b>Hospital - its Organisation and functions</b></li><li>• <b>Hospital pharmacy-Organisation and management</b></li></ul> <p>a) Organizational Structure-Staff, Infrastructure &amp; work load statistics</p> <p>b) Management of materials and finance</p> <p>c) Roles &amp; responsibilities of hospital pharmacist</p>
II (3 weeks)	<ul style="list-style-type: none"><li>• <b>The Budget – Preparation and implementation</b></li><li>• <b>Hospital drug policy</b></li></ul> <p>a) Pharmacy and Therapeutic committee (PTC)</p> <p>b) Hospital formulary</p> <p>c) Hospital committees</p> <p>- Infection committee</p>
III (3 weeks)	<ul style="list-style-type: none"><li>• <b>Hospital drug policy</b></li></ul> <p>- Research and ethical committee</p> <p>d) Developing therapeutic guidelines</p> <p>e) Hospital pharmacy communication – Newsletter</p>
IV (3 weeks)	<ul style="list-style-type: none"><li>• <b>Hospital pharmacy services</b></li></ul>

	<p>a) Procurement &amp; warehousing of drugs and Pharmaceuticals</p> <p>b) Inventory control</p> <p>Definition, various methods of Inventory Control</p> <p>ABC, VED, EOQ, Lead time, safety stock</p>
<p>V</p> <p>(3 weeks)</p>	<ul style="list-style-type: none"> <li>• <b>Hospital pharmacy services</b></li> </ul> <p>c) Drug distribution in the hospital</p> <p>i) Individual prescription method</p> <p>ii) Floor stock method</p> <p>iii) Unit dose drug distribution method</p>
<p>VI</p> <p>(3 weeks)</p>	<ul style="list-style-type: none"> <li>• Investigational use of drugs- Description, principles involved, classification, control, identification, role of hospital pharmacist</li> </ul>
<p>VII</p> <p>(3 weeks)</p>	<ul style="list-style-type: none"> <li>• <b>Hospital pharmacy services</b></li> </ul> <p>d) Distribution of Narcotic and other controlled substances</p> <p>e) Central sterile supply services – Role of pharmacist</p>
<p>VIII</p> <p>(3 weeks)</p>	<ul style="list-style-type: none"> <li>• <b>Manufacture of Pharmaceutical preparations</b></li> </ul> <p>a) Sterile formulations – large and small volume parenterals</p> <p>b) Manufacture of Ointments, Liquids, and creams</p> <p>c) Total parenteral nutrition</p>
<p>IX</p> <p>(3 weeks)</p>	<p>Drug store management organization of drug store, type of material stocked and stocked condition, purchase procedure</p>
<p>X</p> <p>(3 weeks)</p>	<ul style="list-style-type: none"> <li>• <b>Continuing professional development programs</b></li> </ul> <p>Education and training</p>
<p>XI</p> <p>(3 weeks)</p>	<ul style="list-style-type: none"> <li>• <b>Radio Pharmaceuticals – Handling and packaging</b></li> <li>• <b>Professional Relations and practices of hospital pharmacist</b></li> </ul>

XII (3 weeks)	Revision / Assessment
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#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

1. Merchant & Qadrys. A textbook of hospital pharmacy. ed: 10<sup>th</sup>. B.S. Shah Prakashan.
2. William Hassan. E, Hospital Pharmacy. ed: 5<sup>th</sup> Philadelphia: Lea and Febiger; 1986.
3. Parthasarathi .G. Karin Nyfort-Hansen, Milap C Nahata. A textbook of clinical pharmacy practice: essential concept and skills: ed. 2<sup>nd</sup> : university press: 2012.
4. Prathibha Nand, Roop khar. K . A text book of Hospital and Clinical pharmacy. ed: 6<sup>th</sup> , birla: 2008.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fourth Year</b>
<b>Name of the course</b>	<b>Hospital Pharmacy (Lab)</b>
<b>Course Code</b>	<b>16PMD408</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

The Hospital pharmacy laboratory course is aimed to train the students on investigational techniques for the determination of inventory of drugs and pharmaceuticals. This course also deals with unit dose conversions and bulk infusion preparation and storage. This course also provides the skills related to identification, detection, assessment and reporting of adverse reactions clinically during the ward rounds participation.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate the skills on determination of inventory related to drugs and pharmaceuticals.

CO2: Differentiate various classes of drugs along with their procurement and storage conditions.

CO 3: Perform lab activities related to the unit dose and bulk dose preparations.

CO 4: Demonstrate skills related to the identification, assessing and reporting of adverse drug reactions.

### Practical Course: Contents

Week	Topics
1	Introduction to laboratory safety techniques and the use of glass wares and chemicals.
2	Preparation of sterile water for injection. (500 ml)
3	Preparation of 5% dextrose solution for injection. (500 ml)
4	Preparation of 0.9% Normal saline solution for injection. (500 ml)
5	Preparation of N Dextrose-Normal saline solution for injection. (500 ml)
6	Preparation of Compound Normal saline solution for injection. (500 ml)
7	Preparation of Compound Normal saline solution for injection and ampoule sealing technique. (5 ml)
8	Preparation of salicylic acid dusting powder. (10 gms)
9	Preparation of ORS. (10 gms)
10	Introduction to Adverse Drug Reactions and Drug – Drug Interactions.
11	Identification and causality assessment of Clinically identified Adverse Drug Reaction.
12	Identification and causality assessment of Clinically identified Adverse Drug Reaction.
13	Identification and reporting of Drug – Drug reaction.

14	Identification and reporting of Drug – Drug reaction.
15	Inventory management through ABC, VED, EOQ, Lead time and Buffer stock
16	Responding drug information query in hospital
17	<b>Revision</b>

#### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources:

1. Merchant & Qadrys. A textbook of hospital pharmacy. ed: 10<sup>th</sup>. B.S. Shah Prakashan.
2. William Hassan. E, Hospital Pharmacy. ed: 5<sup>th</sup> Philadelphia: Lea and Febiger; 1986.
3. Parthasarathi .G. Karin Nyfort-Hansen, Milap C Nahata. A textbook of clinical pharmacy practice: essential concept and skills: ed. 2<sup>nd</sup> : university press: 2012
4. Prathibha Nand, Roop khar. K . A text book of Hospital and Clinical pharmacy. ed: 6<sup>th</sup> , birla: 2008

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fourth Year</b>
<b>Name of the course</b>	<b>Clinical Pharmacy</b>
<b>Course Code</b>	<b>16PMD403</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

Clinical Pharmacy Practice demonstrate a professional attitude (a desire for life-long learning and ethical conduct) in all activities related to clinical pharmacy practice; confidently assume a progressive role on an interdisciplinary health care team; use appropriate interpersonal skills, work harmoniously with others and display compassion for patients.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Monitor drug therapy of patient through medication chart review and clinical review and counsel the patients.

CO 2: Detection, assessment, monitoring, reporting and documentation of ADR's.



CO 3: Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states and designing appropriate drug therapy regimen.

CO 4: Identify and resolve drug related problems.

CO 5: Apply their knowledge and practice clinical decision-making.

CO 6: Use a systematic approach in retrieve, analyze, interpret, formulate and provide of drug or medicine information.

### Theory Course: Contents

S. No	Topics
I (3 weeks)	Definitions, development and scope of clinical pharmacy Introduction to daily activities of a clinical pharmacist
II (3weeks)	Introduction to daily activities of a clinical pharmacist: Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions) b. Ward round participation c. Adverse drug reaction management
III (3 weeks)	Introduction to daily activities of a clinical pharmacist: Drug information and poisons information e. Medication history f. Patient counselling.
IV (3weeks)	Introduction to daily activities of a clinical pharmacist: Drug utilisation evaluation (DUE) and review (DUR) h. Quality assurance of clinical pharmacy services
V (3weeks)	<b>Patient data analysis</b> The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.

VI (3 weeks)	<b>Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results:</b> a. Haematological, Liver function, Renal function, thyroid function tests b. Tests associated with cardiac disorders.
VII (3 weeks)	<b>Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results:</b> Fluid and electrolyte balance d. Microbiological culture sensitivity tests e. Pulmonary Function Tests
VIII (3 weeks)	<b>Drug &amp; Poison information:</b> a. Introduction to drug information resources available b. Systematic approach in answering DI queries c. Critical evaluation of drug information and literature & Preparation of written and verbal reports e. Establishing a Drug Information Centre f. Poisons information- organization & information resources
IX (3 weeks)	<b>Pharmacovigilance</b> a. Scope, definition and aims of pharmacovigilance b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used] c. Reporting, evaluation, monitoring, preventing & management of ADRs d. Role of pharmacist in management of ADR.
X (3 weeks)	Communication skills, including patient counselling techniques, medication history interview, presentation of cases. Pharmaceutical care concepts
XI (3 weeks)	Critical evaluation of biomedical literature Medication error
XII (3 weeks)	Revision/Assessment

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

### **Learning Resources/Recommended Texts/Reference books/web resources (Latest editions)**

#### **Text Books (Theory)**

1. A textbook of Clinical Pharmacy Practice; Essential concepts and skills. Dr. G. Parthasarathi et al. Second Edition. Orient Orient Langram Pvt. Ltd 2012. ISBN-13: 978-8173717567.
2. Pathology and Therapeutics for Pharmacists: A basis for clinical pharmacy practice. Greene, Russell J; Harris, Norman D. Third Edition. Pharmaceutical Press 2008. ISBN 978-0-85369-690-2.
3. Applied Biopharmaceutics and Pharmacokinetics. Leon Shargel and Andrew Yu. Seventh Edition. McGraw Hill Medical 2016. ISBN-13: 978-9814670241.
4. Basic Skills in Interpreting Laboratory Data. Mary Lee. American Society of Health-System Pharmacists; Fifth Edition (1 May 2013). ISBN-13: 978-1585283439.
5. Clinical pharmacy and therapeutics. Eric T Herfindal; D R Gourley; Linda Lloyd Hart. Fifth Edition. Baltimore: Williams and Wilkins 1992. ISBN-13: 978-0683039665.

#### **References**

1. Whittlesea C, Hodson K. Clinical pharmacy and therapeutics. Sixth edition. Elsevier Ltd. 2019. ISBN: 978-0-7020-7011-2.

2. Applied Therapeutics: The Clinical Use of Drugs. Caroline S. Zeind, Michael G. Carvalho. Eleventh Edition. Lippincott Williams and Wilkins. ISBN-13: 978-1496318299.
3. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications. Malcolm Rowland and Thomas N. Tozer. Lippincott Williams and Wilkins; Fourth Edition (5 February 2010). ISBN-13: 978-0781750097.
4. Pharmaceutical Statistics Practical And Clinical Applications. Bolton Sanford. CRC Press Third Edition (28 February 1997). ISBN-13: 978-0824798123.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fourth Year</b>
<b>Name of the course</b>	<b>Clinical Pharmacy (Lab)</b>
<b>Course Code</b>	<b>16PMD409</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

Clinical Pharmacy Practice demonstrate a professional attitude (a desire for life-long learning and ethical conduct) in all activities related to clinical pharmacy practice; confidently assume a progressive role on an interdisciplinary health care team; use appropriate interpersonal skills, work harmoniously with others and display compassion for patients.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Monitor drug therapy of patient through medication chart review and clinical review and counsel the patients.

CO 2: Detection, assessment, monitoring, reporting and documentation of ADR's.

CO 3: Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states and designing appropriate drug therapy regimen.

CO 4: Identify and resolve drug related problems.

### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1 to 10	Answering Drug Information Query
11 & 12	PMHI (Patient Medication History Interview)
13 to 18	
19 to 28	Case Presentations
29 to 36	Patient Counseling

### **Assessment methods and weightage (Practical)**

<b>Assessment type</b>	<b>Assessment tool</b>	<b>Distribution</b>
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

### **Learning Resources/Recommended Texts/Reference books/web resources:**

1. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.

2. Scott LT. Basic skills in interpreting laboratory data. American Society of Health System Pharmacists Inc.
3. David H Lawson, R Michael E. Richards. Clinical Pharmacy and Hospital Drug Management – 1982. Champan and Hall.
4. Dr. H.P.Tipnis, Dr. Amrita Bajaj. Clinical Pharmacy – 1<sup>st</sup> ed. Career Publications.
5. Leon Shargel, Susanna Wu Pong, Andrew B C Yu. Applied Biopharmaceutics and Pharmacokinetics. 5<sup>th</sup> ed. McGrawHill Companies; 2005.
6. G. Parthasarathi, Karin Nyfor-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice: Essential concepts and skills. 2<sup>nd</sup> ed. India: Universities Press (India) Private Limited; 2012.
7. Mary Lee. Basic skills in interpreting laboratory data – 5<sup>th</sup> ed. American Society of Health System Pharmacist®.
8. Rowland M, Tozer TN. Clinical Pharmacokinetics: Concepts and Applications: Lippincott Williams & Wilkins; 1995.
9. Susan Foran. Australian drug information - Procedure manual – 1996. Society of Hospital Pharmacists of Australia.
10. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fourth year</b>
<b>Name of the course</b>	<b>Bio-Statistics and Research Methodology</b>
<b>Course Code</b>	<b>16PMD404</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>2+1 hrs (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:**

The Bio Statistics and Research methodology course that provides an integrated presentation of Statistical methods and Research Methodologies. Information about each method is presented to explain the processes involved in Research Methodology and Bio statistical methods so that students will develop an understanding of the usage of the methods in Hospital Pharmacy. Students are able to interpret testing of hypothesis and Statistical methods and Computer applications in epidemiology and Pharmacy.

**Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Define Research Methodology, Biostatistics, data graphics, Basics of Testing of hypothesis

CO 2: Recognize types of clinical studies, types of data distribution, and Data graphics Statistical and computer applications in Pharmacy.

CO 3: Formulate Students test, chi-square test, Analysis of variance (One-way and two-ways)

**Theory Course: Contents**

S. No	Topics
I (3 weeks)	<b>Research Methodology-I</b> Types of clinical study designs: Case studies, Observational studies, interventional studies.
II (3weeks)	<b>Research Methodology-II</b> Designing the methodology, Sample size determination and power of a study Determination of sample size for simple comparative experiments.
III (3 weeks)	<b>Research Methodology-III</b> determination of sample size to obtain a confidence interval of specified width, power of a study, report writing and presentation of data
IV (3weeks)	<b>Biostatistics-I</b> Introduction, Types of data distribution, Measures describing the central tendency distributions-average, median, mode.



V (3weeks)	<b>Biostatistics-II</b> Measurement of the spread of data-range, variation of mean, standard deviation variance, coefficient of variation, standard error of mean.
VI (3 weeks)	<b>Biostatistics-III</b> <b>Data graphics</b> Construction and labelling of graphs, histogram, pie charts, scatter plots, semilogarithmic plots <b>Basics of testing hypothesis</b> Null hypothesis, level of significance, power of test.
VII (3 weeks)	<b>Biostatistics-IV</b> P value, statistical estimation of confidence intervals Level of significance (Parametric data)-students t test (paired and unpaired), chi Square test, Analysis of Variance(One way and two way)
VIII (3 weeks)	<b>Biostatistics-V</b> Level of significance (Non-Parametric data)-Sign test, Wilcoxon's signed test (Wilcoxon) rank sum test, Mann Whitney U test, Kruskal-Wallis test(One way ANOVA)
IX (3 weeks)	<b>Biostatistics-VI</b> Linear regression and correlation-Introduction, Pearson's and Spearman's correlation and correlation coefficient. Introduction to statistical software: SPSS, Epi Info, SAS.
X (3 weeks)	<b>Biostatistics-VI</b> <b>Statistical methods in epidemiology</b> Incidence and prevalence, relative risk, attributable risk <b>Computer applications in Pharmacy-I</b>

	Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record
XI (3 weeks)	<b>Computer applications in Pharmacy-II</b> database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, Patient medication profiles, Inventory control, Management report & Statistics. Computer In Community Pharmacy
XII (3 weeks)	<b>Computer applications in Pharmacy-III</b> Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system Drug Information Retrieval & Storage : Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### **Learning Resources/Recommended Texts/Reference books/web resources:**

1. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3<sup>rd</sup> ed. publisher Marcel Dekker Inc. New York.

2. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich, 3<sup>rd</sup> ed. McGraw Hill Publications.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fourth Year</b>
<b>Name of the course</b>	<b>Biopharmaceutics &amp; Pharmacokinetics</b>
<b>Course Code</b>	<b>16PMD405</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:**

This course includes a study of the physicochemical, physiological, pathological and pharmaceutical factors affecting the absorption, distribution and elimination of drugs from the body. The course will also include detailed discussion of interpretation of plasma drug concentrations, protein binding and its effect on the disposition of drugs, non compartmental pharmacokinetics, nonlinear pharmacokinetics bioavailability, bioequivalence and principles

of therapeutic drug monitoring. The course will also include elementary compartmental modeling, mechanisms of renal clearance, and assessment of drug bioavailability.

**Course Learning Outcomes:** Upon successful completion of this course, the student should be able to:

CO 1: Underline the basic concepts of pharmacokinetics and biopharmaceutics.

CO 2: Explain the physiological, physicochemical and dosage form-related factors that affects drug absorption from different dosage forms.

CO 3: Describe the different pharmacokinetic models.

CO 4: Differentiate between compartmental and non-compartmental analysis.

CO 5: Estimate the basic pharmacokinetic parameters that describe drug absorption and disposition.

#### **Theory Course: Contents**

<b>S. No.</b>	<b>Topics</b>
<b>I</b> (3 weeks)	<b>Introduction to Biopharmaceutics</b> a. Absorption of drugs from gastrointestinal tract.
<b>II</b> (3weeks)	b. Drug Distribution. c. Drug Elimination
<b>III</b> (3 weeks)	<b>Introduction to Pharmacokinetics</b> a. Mathematical model b. Drug levels in blood. c. Pharmacokinetic model
<b>IV</b> (3weeks)	d. Compartment models e. Pharmacokinetic study.
<b>V</b> (3weeks)	<b>One compartment open model</b> a. Intravenous Injection (Bolus)

	b. Intravenous infusion.
VII (3weeks)	c. Extravascular administration
VIII (3weeks)	<b>Multicompartment models</b> a. Two compartment open model.
IX (3 weeks)	b. IV bolus and oral administration <b>Nonlinear Pharmacokinetics</b> a. Introduction b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters.
X (3weeks)	<b>Multiple – Dosage Regimens</b> a. Repetitive Intravenous injections – One Compartment Open Model b. Repetitive Extravascular dosing – One Compartment Open model
XI (3 weeks)	<b>Noncompartmental Pharmacokinetics</b> a. Statistical Moment Theory. b. MRT for various compartment models. c. Physiological Pharmacokinetic model.
XII (3 weeks)	<b>Bioavailability and Bioequivalence</b> a. Introduction. b. Bioavailability study protocol. c. Methods of Assessment of Bioavailability

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
	Midterm examination	20%

Continuous Assessment	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

**Learning Resources/Recommended Texts/Reference books/web resources:**

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall International edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: ByMilo Gibaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, ByMilo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Rowland M, Tozer TN. Clinical Pharmacokinetics: Concepts and Applications: Lippincott Williams & Wilkins; 1995.
9. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.
11. Remington's Pharmaceutical Sciences, ByMack Publishing Company, Pennsylvania

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fourth year</b>
<b>Name of the course</b>	<b>Biopharmaceutics &amp; Pharmacokinetics (Lab)</b>
<b>Course Code</b>	<b>16PMD410</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>3 hours (laboratory)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

#### **Course Description:**

The Biopharmaceutics and Pharmacokinetics laboratory course is designed to provide the students on laboratory skill for the demonstration of instrumentation based on principles of dissolution and solubility such as dissolution test apparatus, orbital shaker incubator etc. This course also deals with wet laboratory based experiments on dissolution enhancement,

comparative dissolution, protein binding and *in vitro* absorption studies etc. This course also provides the skills for interpretation of plasma and urine drug concentration data after various routes of administration to determine necessary pharmacokinetic parameters.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: Demonstrate the skills on instrumentation related to dissolution and solubility.

CO 2: Compare the dissolution profiles of different marketed dosage forms and prepared formulations.

CO 3: Estimate various pharmacokinetic parameters of drugs following various compartment models after different routes of administration.

### **Practical Course: Contents**

<b>Week</b>	<b>Topics</b>
1	Determination of solubility of the given drug by gravimetric and spectrophotometric method.
2	Determination of $pK_a$ of the given drug by half neutralization method.
3	Improvement of dissolution characteristics of slightly soluble drugs by solid dispersion technique.
4	Improvement of dissolution characteristics of slightly soluble drugs by solid dispersion technique.
5	Improvement of dissolution characteristics of slightly soluble drugs by solvent deposition technique.



6	Improvement of dissolution characteristics of slightly soluble drugs by solvent deposition technique.
7	Improvement of solubility dissolution characteristics of slightly soluble drugs by micellar solubilization technique.
8	Improvement of solubility dissolution characteristics of slightly soluble drugs by micellar solubilization technique.
9	Comparison of dissolution studies of two different marketed products of same drug.
10	Comparison of dissolution studies of two different marketed products of same drug.
11	Influence of polymorphism on solubility and dissolution of poorly soluble drug.
12	Influence of polymorphism on solubility and dissolution of poorly soluble drug.
13	Influence of complexation on solubility and dissolution of poorly soluble drug.
14	Influence of complexation on solubility and dissolution of poorly soluble drug.
15	Protein binding studies of a highly protein bound drug.
16	Protein binding studies of a highly protein bound drug.
17	Protein binding studies of a poorly protein bound drug.
18	Protein binding studies of a poorly protein bound drug.

19	Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
20	Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
21	Effect of contact time on the plasma protein binding of drugs.
22	Effect of contact time on the plasma protein binding of drugs.
23	Absorption studies in animal inverted intestine using various drugs.
24	Absorption studies in animal inverted intestine using various drugs.
25	Calculation of $K_a$ , $K_E$ , $t_{1/2}$ , $C_{max}$ , AUC, AUMC, MRT etc. from blood profile data.
26	Calculation of $K_a$ , $K_E$ , $t_{1/2}$ , $C_{max}$ , AUC, AUMC, MRT etc. from blood profile data.
27	Calculation of bioavailability from urinary excretion data for given drug.
28	Calculation of bioavailability from urinary excretion data for given drug.
29	Calculation of AUC and bioequivalence from the given data for the given drug.
30	Calculation of AUC and bioequivalence from the given data for the given drug.
31	Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
32	Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.

33	Determination of absorption rate constant by Wagnor-Nelson method.
34	Determination of various pharmacokinetic parameters of a drug that is following two compartment model after IV bolus administration.
35	REVISION/Assessment

#### Assessment methods and weightage (Practical)

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources:

1. Shargel L, Wu-Pong S, Yu AB. Applied biopharmaceutics & pharmacokinetics: McGraw-Hill; 2007.
2. Gibaldi M, Perrier D. Pharmacokinetics. Second ed: Marcel Dekker; 1975.
3. Wagner JG. Fundamentals of Clinical Pharmacokinetics: Drug Intelligence Publications; 1975.
4. Abdou HM. Dissolution, bioavailability & bioequivalence: Mack; 1989.
5. Gibaldi M, Gibaldi M. Biopharmaceutics and Clinical Pharmacokinetics: Laurier Books Limited; 2005.
6. Notari RE. Biopharmaceutics and pharmacokinetics: an introduction: M. Dekker; 1975.
7. Rowland M, Tozer TN. Clinical Pharmacokinetics: Concepts and Applications: Lippincott Williams & Wilkins; 1995.

8. <https://www.boomer.org/c/p1/>

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fourth year</b>
<b>Name of the course</b>	<b>Clinical Toxicology</b>
<b>Course Code</b>	<b>16PMD406</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>2+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:**

This course will establish the scientific principles underlying the toxic actions of various substances and will introduce the various challenges within the field of toxicology. The chemical nature of injurious substances, their uptake and metabolism by non-target organisms, and their mode of toxic action will be studied in addition to the methods used in safety evaluations and risk assessment.

**Course Learning Outcomes:**

Upon completion of this course, the student will:

CO 1: Discuss the epidemiologic and demographic parameters that characterize toxic exposures in the United States.

CO 2: Discuss the role of the pharmaco-therapist in the evaluation and management of poisoned patients

CO 3: Utilize historical information and clinical patient assessments in the evaluation of the poisoned patient.

CO 4: Formulate a treatment plan based on history, time course of the exposure, presenting symptomatology, toxidrome recognition, and assessment of toxic potential.

CO 5: Discuss current philosophies, and cite the risks associated with, the use of various methods of gastrointestinal decontamination for ingested toxins. Choose the appropriate modality for specific poisoned/overdosed patients.

CO 6: Initiate appropriate diagnostic laboratory analyses and recommend the appropriate laboratory and physical assessments to aid in monitoring the progress of the toxic or suspected toxic exposure, correctly interpreting the results of such interventions.

CO 7: Discuss the indications for use and the risks associated with the various methods utilized to enhance elimination in the poisoned patient. Select the appropriate therapy based on the exposure and symptoms.

CO 8: Develop a therapeutic management and monitoring plan when the use of a pharmacologic antidote is indicated for the poisoned/overdosed patient.

CO 9: Define economic and therapeutic outcomes in poisoned patients

**Theory Course: Contents**

S. No.	Topics
I (3 weeks)	Introduction to toxicology, concept of poison and poison types. General principles involved in the management of poisoning (Elimination Enhancement, and Gut Decontamination) Food poisoning
II (3 weeks)	Antidotes and the clinical applications Envenomation's – Mushrooms, Mycotoxins
III (3 weeks)	Gut Decontamination Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries
IV (3 weeks)	Elimination Enhancement Clinical symptoms and management of acute poisoning with the following agents: a) Radiation Poisoning
V (3 week)	b) Opiates overdose c) Anti depressants d) Paracetamol and salicylates e) NSAID's f) Barbiturates & Benzodiazepines

VII (3 weeks)	g) Pesticide poisoning: Organophosphorus compounds, carbamates, Organochlorines, pyrethroids h) Alcohol: ethanol, methanol
VIII (3 weeks)	i) Hydrocarbons: Petroleum product and PEG j) Caustics: inorganic acids and alkalies Heavy Metals: Arsenic, lead
IX (3weeks)	Mercury, iron and copper
X (3 weeks)	Toxicokinetics
XI (3 weeks)	Substance abuse: a) CNS stimulants – amphetamine b) Opioids c) Tobacco
XII (3 weeks)	a) Hallucinogens – LSD b) Cannabis group c) CNS depressants

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%

End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

**Learning Resources/Recommended Texts/Reference books/web resources:**

1. Matthew J Ellenhorn. Ellenhorns Medical Toxicology – Diagnosis and Treatment of Poisoning. 2<sup>nd</sup> ed. Williams and Willkins publication, London.
2. V VPillay. Handbook of Forensic Medicine and Toxicology. 13<sup>th</sup> ed. 2003 Paras Publication, Hyderabad.
3. Narayana reddy. Medical toxicology.13<sup>th</sup> edition.
4. A Text book of Modern Toxicology by Ernest Hodgson
5. Casarett and Doull's, Toxicology the Basic Science of Poisons.
6. Clinical Forensic Medicine: A Physician's Guide, Second Edition edited by Margaret M. Stark, 2005
7. Clinical Toxicology-Principles and Mechanisms BY FRANK A. BARILE
8. Encyclopedia of Toxicology, Four-Volume Set, 1-4 Philip Wexler, Bethesda, MD Bruce Anderson, Ann de Peyster

<b>Program</b>	<b>Pharm D (P.B)</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Pharmacotherapeutics I &amp; II</b>
<b>Course Code</b>	<b>16PMD411</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>



**Course Description:**

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management

**Course Learning Outcomes:**

At completion of this subject it is expected that students will be able to describe

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualized therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (Including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse Effects);

CO 6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO 7: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy;

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis; and

CO 10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

**Theory Course: Contents**

S. No.	Topics
I (3 weeks)	<b>Cardiovascular system:</b> Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction
II (3weeks)	Hyperlipidaemias, Electrophysiology of heart and Arrhythmia
III (3 weeks)	<b>Respiratory system:</b> Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
IV (3weeks)	<b>Endocrine system:</b> Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
V (3weeks)	<b>General prescribing guidelines for</b> a. Pediatric patients b. Geriatric patients. Pregnancy and breast feeding <b>Ophthalmology:</b> Glaucoma,
VI (3 weeks)	Conjunctivitis <b>Introduction to rational drug use</b> Definition, viral & bacterial (Eye Infections)
VII	Role of pharmacist Essential drug concept Rational drug formulations

(3 weeks)	<b>Dermatology:</b> Psoriasis, Scabies, Eczema, Impetigo
VIII (3 weeks)	<b>Infectious disease:</b> Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditic, Septicemia,
IX (3 weeks)	Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
X (3 weeks)	<b>Musculoskeletal disorders</b> Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
XI (3 weeks)	<b>Renal system</b> Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
XII (3 weeks)	<b>Oncology:</b> Basic principles of Cancer therapy, General introduction to cancer Chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis & REVISION.

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%

<b>TOTAL</b>	<b>100%</b>
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Note: Three Midterm examinations to be conducted periodically throughout the year.

#### **Learning Resources/Recommended Texts/Reference books/web resources**

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8<sup>th</sup> ed. lippincot Williams;2008.
2. Joseph DiPiro. Pharmacotherapy a pathophysiology approach.9<sup>th</sup> ed. McGraw-hill education; 2012.
3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10<sup>th</sup> ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5<sup>th</sup> ed. Churchill livingstone;2011
5. Green, Russells, Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3<sup>rd</sup> ed. Pharmaceutical press;2008.

<b>Program</b>	<b>Pharm D (P.B)</b>
<b>Year</b>	<b>First year</b>
<b>Name of the course</b>	<b>Pharmacotherapeutics I &amp; II (Lab)</b>
<b>Course Code</b>	<b>16PMD412</b>
<b>Paper</b>	<b>Practical</b>
<b>Hours /week</b>	<b>4 hours (laboratory)</b>

<b>Pre / co-requisite/s</b>	<b>Nil</b>
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### **Course Description:**

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to describe the pathophysiology of common diseases and their management.

### **Course Learning Outcomes:**

At completion of this subject it is expected that students will be able to understand –

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualized therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (Including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse Effects);

CO 6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO 7: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy;

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis; and

CO 10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

## Practical Course: Contents

Week	Topics
1	Introduction to ward round participation and case collection
2	Hypertension
3	CCF (congestive cardiac failure)
4	Activity I
5	Hypothyroidism
6	Acute renal failure
7	Activity II (Drug utilization review).
8	Asthma
9	Depression diseases
10	Activity III
11	Epilepsy
12	Parkinson's disease
13	Activity IV
14	Infectious diseases [any five].
15	Chronic renal failure
16	Gastroenteritis,
17	Activity V
18	Malaria
19	Fungal infections
20	Activity VI
21	Anxiety
22	Psoriasis

23	Activity VII
24	Spondylitis
25	Hyperthyroidism
26	Activity VIII
27	Septicemia.
28	Osteoarthritis
29	Glaucoma
30	Activity IX
31	Tuberculosis.
32	Activity X
33	Stroke
34	HIV
35	Angina Pectoris
36	Revision/Assessment

#### **Assessment methods and weightage (Practical)**

<b>Assessment type</b>	<b>Assessment tool</b>	<b>Distribution</b>
Continuous Assessment	Midterm examination	20%
	Lab work and record	5%
	Regular viva voce	5%
End Assessment	End Practical examination	70 %
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm practical examinations to be conducted periodically throughout the year.

#### **Learning Resources/Recommended Texts/Reference books/web resources:**

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8th ed. lippincot Williams; 2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach. 9<sup>th</sup> ed. Mcgraw-hill education; 2012.
3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10<sup>th</sup> ed. lippincot Williams; 2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5<sup>th</sup> ed. Churchill livingstone; 2011
5. Green, Russells, Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3<sup>rd</sup> ed. Pharmaceutical press: 2008.
6. Rhonds Jones. Patient Assessment in Pharmacy Practice. Wolters Kluwer. 3rd Edition.
7. Sherif Hanafy M. Patient Assessment in Clinical Pharmacy: A Comprehensive guide. Springer.
8. Lynn S. Bickley. BATE's Guide to Physical Examination and History taking. Wolters Kluwer. 12th Edition.
9. Karen J. Tietze. Clinical Skills for Pharmacists: A patient focused approach. 3rd Edition. Elsevier.
10. Soraya D, Rebekha R. Pharmacy Case Studies. Pharmaceutical Press.
11. Pharmacotherapy casebook: A patient focused approach. 10th Edition. McGrawHill Education.
12. Michael DK, Kathryn RM, Marie ACB, Pharmacotherapy Principles & Practice Study Guide: A Case-Based Care Plan Approach.



<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fifth Year</b>
<b>Name of the course</b>	<b>Clinical Research</b>
<b>Course Code</b>	<b>16PMD501</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:**

The Clinical research course is aimed to present fundamental of animal and human research through clinical trials, emphasizing on basic pharmacological and toxicological research, drug characterization, all the phases of clinical trials including informed consent process, post marketing surveillance under the lights of ICH GCP Guidelines for the better outcomes.

**Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO 1: These courses provide students with a theoretical and practical understanding of the issues involved in the design, conduct, analysis and interpretation of preclinical and clinical trials in living beings.

CO 2: Skills to examine information, for critical analyses and carry out research, and to communicate effectively.

CO 3: Develop the capacity to understand and analyze the application of ICH – GCP guidelines clinically.

**Theory Course: Contents**

S. No.	Topics
I (3 weeks)	<ul style="list-style-type: none"><li>• <b>Drug development process:</b></li></ul> Introduction Various Approaches to drug discovery 1. Pharmacological 2. Toxicological
II	<ul style="list-style-type: none"><li>• <b>Drug development process:</b></li></ul>

(3 weeks)	<p>Introduction</p> <p>Various Approaches to drug discovery</p> <ol style="list-style-type: none"> <li>1. Drug characterization</li> <li>2. Dosage form</li> <li>3. IND Application</li> </ol>
III (3 weeks)	<ul style="list-style-type: none"> <li>• <b>Clinical development of drug:</b></li> </ul> <ol style="list-style-type: none"> <li>1. Introduction to Clinical trials</li> <li>2. Various phases of clinical trial.</li> </ol>
IV (3 weeks)	<ul style="list-style-type: none"> <li>• <b>Clinical development of drug:</b></li> </ul> <ol style="list-style-type: none"> <li>1. Methods of post marketing surveillance</li> <li>2. Abbreviated New Drug Application submission.</li> </ol>
V (3 weeks)	<ul style="list-style-type: none"> <li>• <b>Clinical development of drug:</b></li> </ul> <ol style="list-style-type: none"> <li>1. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines</li> <li>2. Challenges in the implementation of guidelines</li> <li>3. Ethical guidelines in Clinical Research</li> </ol>
VII (3 weeks)	<ul style="list-style-type: none"> <li>• <b>Clinical development of drug:</b></li> </ul> <ol style="list-style-type: none"> <li>1. Composition, responsibilities, procedures of IRB / IEC</li> <li>2. Overview of regulatory environment in USA, Europe and India.</li> </ol>
VIII (3 weeks)	<ul style="list-style-type: none"> <li>• <b>Clinical development of drug:</b></li> </ul> <p>Role and responsibilities of clinical trial personnel as per ICH GCP</p> <ol style="list-style-type: none"> <li>a. Sponsor</li> <li>b. Investigators</li> <li>c. Clinical research associate</li> </ol>

	d. Auditors e. Contract research coordinators f. Regulatory authority
IX (3 weeks)	<ul style="list-style-type: none"> <li><b>Clinical development of drug:</b></li> </ul> 1. Essential document required in Clinical trials, Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment) 2. Informed consent Process
X (3 weeks)	<ul style="list-style-type: none"> <li><b>Clinical development of drug:</b></li> </ul> 1. Data management and its components
XI (3 weeks)	<ul style="list-style-type: none"> <li><b>Clinical development of drug:</b></li> </ul> 1. Safety monitoring in clinical trials.
XII (3 weeks)	Revision / Assessment

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

**Learning Resources/Recommended Texts/Reference books/web resources**

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
6. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
7. Goodman & Gilman: JG Hardman, LE Limbard, 10<sup>th</sup> Edn. McGraw Hill Publications, 2001.
8. David Machin, Simon Day, Sylvan Green, Brian S. Everitt, Stephen George. Textbook of Clinical Trials. Wiley. 2nd Edition

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fifth Year</b>
<b>Name of the course</b>	<b>Pharmacoepidemiology and Pharmacoeconomics</b>
<b>Course Code</b>	<b>16PMD502</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:**

This course is designed to improve knowledge regarding usage of pharmaco epidemiological methods to identify, assess, evaluate and manage drug induced risks. This course will enable the student about usage of Pharmacoeconomic principles in therapeutic decision making process.

**Course Learning Outcomes:** At completion of this subject it is expected that students will be able to understand

CO 1: Epidemic measures and outcome measures in drug use

CO 2: Application of Pharmacoepidemiology

CO 3: Designing of Pharmacoepidemiological methods

CO 4: Special application of Pharmacoepidemiological methods

CO 5: Sources of data to conduct Pharmacoepidemiological studies

CO 6: Usage Pharmacoeconomic tools in various conditions

CO 7: Application of Pharmacoeconomic principles in decision making

CO 8: Software's used in pharmacoeconomics and Pharmacoepidemiology

**Theory Course: Contents**

S. No.	Topics
I (3 weeks)	<b>Pharmacoepidemiology:</b> <b>Definition and scope:</b> Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.
II (3weeks)	<b>Measurement of outcomes in Pharmacoepidemiology</b> Outcome measure and drug use measures

III (3 weeks)	Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement
IV (3weeks)	<b>Concept of risk in pharmacoepidemiology</b> Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio
V (3weeks)	<b>Pharmacoepidemiological methods</b> Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies.
VI (3 weeks)	<b>Pharmacoepidemiological methods</b> Meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.
VII (3 weeks)	<b>Sources of data for Pharmacoepidemiological studies</b> Ad Hoc data sources and automated data systems
VIII (3 weeks)	<b>Selected special applications of pharmacoepidemiology</b> Studies of vaccine safety, hospital pharmacoepidemiology.
IX (3 weeks)	<b>Selected special applications of pharmacoepidemiology</b> Pharmacoepidemiology and risk management, drug induced birth defects.
X (3 weeks)	<b>Pharmacoeconomics:</b> <b>Definition, history, needs of pharmacoeconomic evaluations</b> Role in formulary management decisions

<p>XI (3 weeks)</p>	<p><b>Pharmacoeconomic evaluation</b></p> <p>Outcome assessment and types of evaluation</p> <p>Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility</p>
<p>XII (3 weeks)</p>	<p><b>Applications of Pharmacoeconomics</b></p> <p>Software and case studies</p>

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

1. Brian L Storm. Pharmacoeconomics. 3<sup>rd</sup> ed. England: John Wiley & Sons Ltd. 2000.
2. F Randy Vogenberg. Introduction to Applied Pharmacoeconomics. McGraw-Hill. 2011.
3. Essentials of Pharmacoeconomics by Karen Rascati
4. Pharmacoeconomics: <http://www.ispor.org/>
5. Pharmacoeconomics: <http://www.pharmacoeconomics.org/>



<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fifth Year</b>
<b>Name of the course</b>	<b>Clinical Pharmacokinetics &amp; Pharmacotherapeutic Drug Monitoring</b>
<b>Course Code</b>	<b>16PMD503</b>
<b>Paper</b>	<b>Theory</b>

<b>Hours /week</b>	<b>2+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

### **Course Description:**

Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring course is designed to provide the student with exposure to the application of pharmacokinetic and pharmacodynamic principles of a variety of drug classes to clinical situations. The course will provide a review of clinical pharmacokinetic principles and provide background for the student to develop an approach to therapeutic drug monitoring. Situations and clinical conditions that are likely to alter the concentration: time and/or concentration: effect relationship will be emphasized. The remainder of the course will deal more specifically with the most common drug classes where therapeutic drug monitoring is applied in clinical practice.

### **Course Learning Outcomes:**

Upon successful completion of this course, the student should be able to:

CO: 1 Define important concepts of clinical pharmacokinetic and pharmacodynamic.

CO: 2 Understand the effect of pharmacokinetics and pharmacodynamic parameters and the observed drug concentration and clinical response.

CO: 3 Recommend dose adjustments of drugs based on renal and hepatic functions.

CO: 4 Provide patient-specific initial dosage recommendations for therapeutically monitored drugs and dosage adjustment based on plasma concentration.

### **Theory Course: Contents**

<b>S. No</b>	<b>Topics</b>
I  (3 weeks)	<b>Introduction to Clinical pharmacokinetics.</b>

II (3weeks)	<b>Design of dosage regimens:</b> Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
III (3 weeks)	<b>Pharmacokinetics of Drug Interaction:</b> a. Pharmacokinetic drug interactions
IV (3weeks)	<b>Pharmacokinetics of Drug Interaction:</b> Inhibition and Induction of Drug metabolism c. Inhibition of Biliary Excretion.
V (3weeks)	<b>Therapeutic Drug monitoring:</b> a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs). c. Indications for TDM. Protocol for TDM.
VII (3 weeks)	<b>Therapeutic Drug monitoring:</b> d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy. e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations
VIII (3 weeks)	<b>Dosage adjustment in Renal and hepatic Disease:</b> a. Renal impairment b. Pharmacokinetic considerations, General approach for dosage adjustment in Renal disease.
IX (3 weeks)	<b>Dosage adjustment in Renal and hepatic Disease:</b> Measurement of Glomerular Filtration rate and creatinine clearance. e. Dosage adjustment for uremic patients. f. Extracorporeal removal of drugs. g. Effect of Hepatic disease on pharmacokinetics
X (3 weeks)	<b>Population Pharmacokinetics.</b> a. Introduction to Bayesian Theory. b. Adaptive method or Dosing with feedback. c. Analysis of Population Pharmacokinetic Data.

XI (3 weeks)	<b>Pharmacogenetics</b> a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes. b. Genetic Polymorphism in Drug Transport and Drug Targets.
XII (3 weeks)	<b>Pharmacogenetics:</b> Pharmacogenetics and Pharmacokinetics/ Pharmacodynamic considerations

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources:

1. Larry A. Bauer. Applied Clinical Pharmacokinetics. McGraw-Hill/Appleton & Lange. 2001.
2. Michael E. Winter. Basic Clinical Pharmacokinetics. 3<sup>rd</sup> edition. Applied Therapeutics. 1994
3. Joseph T. Dipiro, William J. Spruill, Robert A. Bloum, Jane M. Pruemer, American Cancer Society, (Joan Heimann editors). Concepts in Clinical Pharmacokinetics. 3<sup>rd</sup> edition. American Hospital Association. 2002.
4. Malcolm Rowland, Thomas N. Tozer, Randy Rowland (Editors). Clinical Pharmacokinetics: Concepts and Applications. 3<sup>rd</sup> edition. Lippincott Williams & Wilkins. 1995

5. William E. Evans, Jerome J. Schentag, William J. Jusko (Editors). Applied Pharmacokinetics: Principles of Therapeutic Drug Monitoring. 3<sup>rd</sup> edition. Applied Therapeutics. 1992

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fifth Year</b>
<b>Name of the course</b>	<b>Entrepreneurship Development (Elective)</b>
<b>Course Code</b>	<b>16PMD506E1</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>

<b>Pre / co-requisite/s</b>	<b>Nil</b>
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### **Course Description:**

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

### **Course Learning Outcomes:**

At completion of this subject, it is expected that students will be able to

CO 1: The Role of enterprise in national and global economy

CO 2: Dynamics of motivation and concepts of entrepreneurship

CO 3: Demands and challenges of Growth Strategies and Networking

### **Theory Course: Contents**

<b>S. No</b>	<b>Topics</b>
I (3 weeks)	Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits.
II (3weeks)	Government policies and schemes for enterprise development. Institutional support in enterprise development and management
III (3 weeks)	Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

IV (3weeks)	Launching And Organising An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower.
V (3weeks)	Costing and marketing management and quality control. Feedback, monitoring and evaluation.
VI (3 weeks)	Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification.
VII (3 weeks)	Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study
VIII (3 weeks)	Preparing Project Proposal To Start On New Enterprise Project work – Feasibility report; Planning, resource mobilisation and implementation
IX (3 weeks)	Exercise 1
X (3 weeks)	Exercise 2
XI (3 weeks)	Exercise 3
XII (3 weeks)	Exercise 4

### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

### REFERENCES

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fifth Year</b>
<b>Name of the course</b>	<b>Pharmacological Screening Methods (Elective)</b>
<b>Course Code</b>	<b>16PMD506E2</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>



**Course Description:**

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

**Course Learning Outcomes:**

At completion of this subject, it is expected that students will be able to

CO 1: Appraise the regulations and ethical requirement for the usage of experimental animals.

CO 2: Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals

CO 3: Describe the various newer screening methods involved in the drug discovery process

CO 4: Appreciate and correlate the preclinical data to humans

**Theory Course: Contents**

S. No	Topics
I (3 weeks)	Laboratory Animals Common laboratory animals: Description, handling and applications of different species and strains of animals.
II (3weeks)	Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals
III (3 weeks)	Good laboratory practice. Bioassay-Principle, scope and limitations and methods
IV (3weeks)	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

	General principles of preclinical screening. CNS Pharmacology: behavioural and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's and multiple sclerosis. Drugs acting on Autonomic Nervous System.
V (3weeks)	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti-allergic. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: anti-ulcer, anti -emetic, anti- diarrheal and laxatives.
VI (3 weeks)	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerosis agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods.
VII (3 weeks)	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Immunomodulators, Immunosuppressants and immunostimulants
VIII (3 weeks)	General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems.
IX (3 weeks)	Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

X (3 weeks)	Limitations of animal experimentation and alternate animal experiments.
XI (3 weeks)	Extrapolation of in vitro data to preclinical and preclinical to humans
XII (3 weeks)	Revision

#### Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### Learning Resources/Recommended Texts/Reference books/web resources

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta

10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3 rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2 nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author),  
Ajay Prakash (Author)

<b>Program</b>	<b>Pharm D</b>
<b>Year</b>	<b>Fifth Year</b>
<b>Name of the course</b>	<b>Scientific Writing (Elective)</b>
<b>Course Code</b>	<b>16PMD506E3</b>
<b>Paper</b>	<b>Theory</b>
<b>Hours /week</b>	<b>3+1 hours (lectures)</b>
<b>Pre / co-requisite/s</b>	<b>Nil</b>

**Course Description:**

The objective of scientific writing is to formalize the students to communicate and get the research work published

**Course Learning Outcomes:**

At completion of this subject, it is expected that students will be able to

CO 1: Analyze scientific writing concepts

CO 2: Understand the concept of publication

CO 3: Evaluate the journals and the work for publication

**Theory Course: Contents**

S. No	Topics
I (3 weeks)	<b>Introduction skills:</b> Getting ideas, designing the research work, Types of papers, Structure of a typical paper, how to write an introduction, essentials of language and academic editing
II (3weeks)	<b>Effective Literature Review:</b> Databases (Medline, Science direct, Springer, PubMed, Google Scholar, and others), Collection of the information, Inclusion, and sequencing of authors based on their roles, Preparation of title and abstract of manuscript, Discussion, and conclusion.
III (3 weeks)	<b>Skills in writing Methodology:</b> Purpose of the Methods section, Preparation of Experimental Design, Conventions regarding style, Designing and labelling tables, how to use Excel for graphs, how to use Pivot Tables in Excel

IV (3weeks)	<p><b>Results and discussion:</b> Purpose of the Results, how to write the results, Purpose of the discussion, Preparation of Experimental Design</p> <p>How to write the discussion and conclusion</p> <p><b>References:</b> Referencing styles: Vancouver, others, Referencing software: EndNote, Zotero etc.</p>
V (3weeks)	<p><b>Ethics:</b> Copyright, Plagiarism, Conflict of interest and disclosure.</p> <p><b>English in writing skills:</b> Errors in grammar, punctuation.</p>
VI (3 weeks)	<p><b>Communication:</b> How to write an abstract, Graphical abstract/Image representation Selection of journal, Guide for SCOPUS/WOS/SCI Journals and Predatory Journals, Respond to the reviewer's comments</p>
VII (3 weeks)	Guidelines for proposal writing towards national and international funding agencies
VIII (3 weeks)	Exercise 1
IX (3 weeks)	Exercise 2
X (3 weeks)	Exercise 3
XI (3 weeks)	Exercise 4
XII (3 weeks)	Exercise 5

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Midterm examination	20%
	Assignment	5%
	Student-teacher interaction (Seminar & Group Discussion)	5%
End Assessment	End theory examination	70%
<b>TOTAL</b>		<b>100%</b>

Note: Three Midterm examinations to be conducted periodically throughout the year.

#### **Learning Resources/Recommended Texts/Reference books/web resources:**

1. Sin and Syntax, Constance Hale, Successful Scientific Writing: A step-by-step guide for biomedical scientists, Matthews and Bowen
2. The Scientist's Guide to Writing: How to Write More Easily and Effectively throughout your Scientific Career.
3. Writing Science in Plain English. Greene, Anne E.
4. How to Write and Publish a Scientific Paper, 8th Edition

## **INTERNSHIP**

### **1) SPECIFIC OBJECTIVES:**

- i) To provide patient care in cooperation with patients, prescribers, and other members of an inter professional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical,

pharmaceutical, social or behavioural or administrative, and clinical sciences that may impact therapeutic outcomes.

- ii) To manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
- iii) To promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an inter professional team of health care providers.
- iv) To demonstrate skills in monitoring of the National Health Programme s and schemes, oriented to provide preventive and promotive health care services to the community.
- v) To develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.
- vi) To communicate effectively with patients and the community.

## **2) OTHER DETAILS:**

- i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.
- ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee, a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.



- iii) Every candidate shall be required, after passing the final Pharm. D. or Pharm. D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm. D. or Pharm. D. (Post Baccalaureate) as the case may be.

### **3. ASSESSMENT OF INTERNSHIP:**

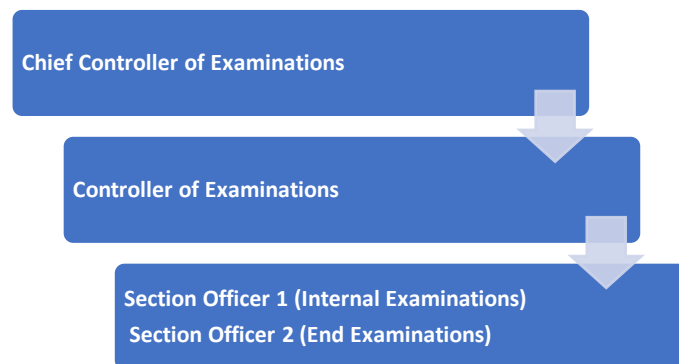
- i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practitioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.
- ii) Satisfactory completion of internship shall be determined on the basis of the following:
- (1) Proficiency of knowledge required for each case management      SCORE 0-5
  - (2) The competency in skills expected for providing Clinical  
Pharmacy Services      SCORE 0-5
  - (3) Responsibility, punctuality, work up of case, involvement  
in patient care      SCORE 0-5
  - (4) Ability to work in a team (Behaviour with other healthcare professionals  
including medical doctors, nursing staff and colleagues).      SCORE 0-5
  - (5) Initiative, participation in discussions, research aptitude.      SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

### **Examination Cell – Structure, Rules and Regulations**

#### **a) Organization structure**



#### **b) Infra-structure / Security / confidential zone**

- Single entry with complete partitions for various sections of examinations under CCTV surveillance
- Single door entry & exit
- Confidential room attached to Controller of examinations
- Separate strong room for Used and Un-used examination material
- Evaluation Hall with toilet facility / water facility etc.
- Repo-graphic area
- Office section

#### **C) Assurance of confidentiality**

- Free entry is restricted in the premises.
- Question paper selection and Question paper moderation will be done just 30 minutes before the examination commencement. During moderation, electronic gadgets

including mobiles and internet facility will not be entertained during question paper moderation.

- Question paper setting from Outside the University with minimum PG or preferably Ph.D. having five years of teaching experience in relevant subject. The obtained sets of question paper will be under the custody of controller of examinations.
- Question paper moderation will be done if required after consultation with the Chief controller of examination & after receiving inputs from of HOD's of concerned departments in CE chamber.
- All the experts involed in the moderation will be asked to be present in the chamber till the examination commences.
- Question papers will be carried in sealed covers by CE and will be handed over to Invigilators ten minutes before commencement examination.

**d) Eligibility criteria for experts in examination and evaluation.**

<b>End Examinations</b>	<b>B. Pharm</b>	<b>M.Pharm*</b>	<b>Pharm. D</b>
Theory Paper Evaluator	M. Pharm with 3 Years of Experience	Ph. D with 2 years of Experience	M. Pharm with 3 Years of Experience / Pharm. D with two years of Experience
Q. Paper Setter	M. Pharm with 10 Year of Experience / Ph. D with 2 years	Ph. D with 5 years of Experience	M. Pharm with 10 Years of Experience / Pharm. D with three years of

			Experience / Ph.D with 2 years
<b>Practical Examiner</b>  Internal	M. Pharm with 2 Years of Experience	M. Pharm with 5 Years of Experience	M. Pharm with 2 Years of Experience / Pharm. D with one year of Experience
<b>Practical Examiner</b>  External	M. Pharm with 3 Years of Experience	Ph. D with 2 years of Experience	M. Pharm with 3 Years of Experience / Pharm. D with two years of Experience
Project Evaluators	Ph. D with 2 years of Experience	Ph. D with 5 years of Experience / equivalent with industrial experience	M. Pharm with 10 Years of Experience / Pharm. D with three years of Experience / Ph. D with 2 years

**NOTE:**

\*Double Evaluation for M. Pharm, if there is a discrepancy of 15 % deviation between two evaluations, there will be third evaluation.

Challenge valuation will be adapted for end examinations results of all programs as per awarding university.

e) **Recommended assessment tools**

<b>B. Pharm</b>	<b>M.Pharm</b>	<b>Pharm. D</b>
Assignment	Assignment	Assignment
Seminar	Seminar	Seminar
Mid – Examination	Mid - Examination	Mid - Examination
End Examinations	End Examinations	End Examinations
Comprehensive exam (Quiz)	Journal club Participation	Presentations
MOOCs	PBL Assignment	Clerkship
Research Project / VIVA	Research Project / VIVA	Research Project / Internship
Participation	Participation	Participation

**Note:** Class tests & three Sessional examinations to be conducted periodically throughout the year.

**Annexure-I: Rubrics for Assignment / Seminar**

**Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)**

**Awarding University: JNT University, Anantapur (JNTUA)**

**Assignment - Evaluation / Marking Schemes (10 Marks) – Converted to 5 M**

<b>Parameter</b>	<b>Very good</b>	<b>Good</b>	<b>Satisfactory</b>	<b>Not satisfactory</b>
	<b>(2)</b>	<b>(1)</b>	<b>(0.5)</b>	<b>(0)</b>
<b>Relevance of content to Topic (2)</b>				

<b>Reliable resources used (2)</b>				
<b>Presentation of content (2)</b>				
<b>Similarity Index (2)</b>				
<b>Total</b>				
<b>Total (8)</b>				
<b>Submission Date</b>	<b>Before Due date (2)</b>		<b>After due date (1)</b>	

### **Annexure-II: Mid – Examination Rubrics**

**Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)**

**Awarding University: JNT University, Anantapur (JNTUA)**

**Subject Name:**

**Subject Code:**

**Date of Examination:**

**Total Marks: 30 M**

**Section-A**

- I. Short answer questions (All Compulsory)  $5 \times 2 = 10$  M**

**Section-B**

- II. Answer any TWO out of THREE questions  $2 \times 10 = 20$  M**

**Annexure-III: Mid – Examination Rubrics (Practical)**

**Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)**

**Awarding University: JNT University, Anantapur (JNTUA)**

Practical question paper pattern

**Course Name:**

**Date of Examination:**

**Course Code:**

**Total Marks: 20 M**

**I. Synopsis**

**5 M**

II. Experiment

12 M

III. Viva voce

3 M

**Annexure-IV: (Theory question paper rubrics) - End Examinations**

**Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)**

**Awarding University: JNT University, Anantapur (JNTUA)**



**Subject Name:**

**Subject Code:**

**Date of Examination:**

**Total Marks: 70 M**

**Section-A**

**I. Answer the following questions**

**$8 \times 2 = 16$  M**

**Section-B**

**II. Answer any SIX out of EIGHT questions**

**$6 \times 9 = 54$  M**

**Annexure-V: End examinations - Practical question paper rubrics**

**Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)**

**Awarding University: JNT University, Anantapur (JNTUA)**

**Subject Name:**  
**Date of Examination:**

**Subject Code:**  
**Total Marks: 70 M**

I. Synopsis	10 M
II. Major Experiment	25 M
III. Minor Experiment	20 M
IV. Viva voce	15 M

**Annexure – VI: Research Project / Presentation Rubrics**

**Project / Presentation - Marking Schemes (10 Marks)**

<b>Parameter</b>	<b>Very good (2)</b>	<b>Good (1)</b>	<b>Satisfactory (0.5)</b>	<b>Not satisfactory (0)</b>
<b>Skill in Experiment and presentation of data (2)</b>				
<b>Adequacy of literature (2)</b>				
<b>Performance / efficiency in Interpretation of data (2)</b>				
<b>Presentation of content / Result (2)</b>				
<b>VIVA (2)</b>				
<b>Total</b>				
<b>Total (10)</b>				

#### **Annexure – VII: Rubrics for Grading and Ranking**

Year Grade Point Average (GPA) and Cumulative Grade point average (CGPA) as per awarding university. Gold medal and ranking will be declared for those students who have passed all semesters in single attempt only.

#### **Annexure IX: Malpractices / Punishments**

As per the regulations and guidelines, of awarding university the malpractices and punishments will be changed from time to time.