Raghavendra Institute of Pharmaceutical Education and Research (RIPER)

(Conferred Autonomous status from the academic year 2016-17)

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)
Approved by PCI and AICTE, New Delhi

Academic regulations
Program structure
&
Syllabus

Effective from ACY 2016-2017

MASTER OF PHARMACY

(COMMON REGULATION TO ALL SPECIALIZATIONS)

(Applicable for the batch admitted from 2016 -2017)

: Awarding University:
Jawaharlal Nehru Technological University Anantapur (JNTUA)

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Academic regulations, Program structure & Syllabus

Master of Pharmacy

(Effective from ACY 2016-17)

Index

1. Academic Council Proceedings

Up on recommendation from Board of studies of this institution, regarding the approval of the document "Academic regulations, Program structure & Syllabus" for Master of Pharmacy Program at four specializations namely, Pharmaceutical analysis and quality assurance, Pharmaceutics, Pharmacology, and Pharmacy Practice, the academic council approved the same during the 2nd academic council meeting held on 09.07.2016 at Board room of Raghavendra Institute of Pharmaceutical Education and Research (RIPER), Anantapuramu, Andhra Pradesh, India.

S.NO	Category as per UGC	Name	Signature
1	The Principal (Chairman)	Dr. Y. Padmanabha Reddy	
2	Heads department	Dr. P. Ramalingam	
		Dr. S. Jaffar sadiq	
		Dr. B. Srinath	
3	Four teachers of College	Dr. K. Ramakrishna Reddy	
		Dr. M.V. Jyothi	
		Dr. K. Somasekhar Reddy	
		Mr. S. Nagarjuna	
4	Four experts from outside the college	Dr. S. Kannan, Physician, RDT Hospitals, Bathalapalli, Anantapur (dist))	
		Mr. K. Anand , Industrialist and President, chemist and druggist association. Anantapur District	
		Dr. Hari Hara Theja Drug Inspector, Drug control department, Govt. of Andhra Pradesh	10/5/16.
		Dr. M. Kiran Kumar (Pharmaceutical Scientists from Industry)	
5	Three Nominees of the University	Prof. A. Ananda Rao (Ex-officio member), JNTUA	
		Prof. K. Rama Naidu ((Ex-officio member), JNTUA	10.5.2016
		Pro. N. Devanna (Member) JNTUA	— ABSENT —
6	Faculty member (Member secretary)	Dr. C. Sowmya	

2. Program Outcome

The following program outcomes for Master of Pharmacy Program at various specializations have been structured based on outputs and opinion from various stakeholders who are relevant to this program.

M. Pharm (Pharmaceutical analysis and Quality assurance)

After completion of the program the graduate will be able to

1. Design and conduct analytical experiments for effective quality control and quality assurance system.
2. Utilize tools and skills to perform analytical research work using modern techniques.
3. Use knowledge and abilities to solve problem in pharmaceutical quality system.
4. Engage in innovative activities through creative thinking to envision better ways of accomplishing professional goals.
5. Exhibit behaviour and moral values that required for a pharmaceutical analyst at the satisfaction of corporate industry, other health care providers.
6. Demonstrate the ability to work in team by combining individual strength, team dynamics and emotional intelligence.
7. Compare different techniques/technologies to assess and evaluate dosage forms for better quality.
8. Relate scientific knowledge, exposure, risk assessment and policy in total quality management system.
9. Identify strategies for effective communication system to undertake multidisciplinary area at the interface of analytical method development.

Program: M. Pharm (Pharmaceutics)

After successful completion of the program the graduate will be able to

1. Apply the principles of drug delivery system in the development of eco-friendly, efficacious dosage forms.
2. Develop an ability to undertake multidisciplinary tasks in the pharmaceutical quality system.
3. Analyze, criticize, organize, improvise and manage documents, data and information related to pharmaceutical production process.
4. Imbibe ethical practices and moral values in personal and professional endeavours.
5. Execute team based research to implement innovative solutions in the area of formulation, quality assurance and technology transfer.
6. Apply problem-based learning approach and analytical thinking in academic and professional life.
7. Validate the knowledge and skills gained through education to gain recognition in Pharmaceutical society and related field.
8. Set-up pharmaceutical production unit to design and formulate pharmaceutical dosage form.

Program: M. Pharm (Pharmacology)

After successful completion of the program the graduate will be able to

1. Relate the acquired scientific informations and principles of pharmacokinetics and pharmacodynamics in drug discovery process.
2. Interpret data of pharmaceutical experiments in drug discovery as per the needs of pharmaceutical industries.
3. Translate the high-level of understanding of drug action into key stages in preclinical and clinical research studies.
4. Apply skills to do specialized research in the core and applied areas of pharmaceutical sciences.
5. Evaluate current drug informations in the delivery of pharmaceutical care and assure in regard to drug usage and their adverse effects
6. Demonstrate knowledge of professional and ethical responsibilities in clinical and non-clinical laboratory as required by regulatory bodies.
7. Develop an ability to visualize and work on multidisciplinary tasks in the area pharmaceutical and its allied field.
8. Appraise pharmacological model for investigation through logics and problem to solving ability.

Program: M. Pharm (Pharmacy Practice)

After successful completion of the program the graduate will be able to

1. Formulate effective inventory management and drug formulary at hospital pharmacy settings.
2. Use knowledge, attitude, skills and abilities to solve drug related problems in patients suffering from various ailments.
3. Adapt information technology to access and evaluate the drug informations for integrating the evidence from scientific studies into clinical practice.
4. Collaborate and Communicate on inter-professional teams to ensure that Pharmaceutical care is continuous and reliable.
5. Exhibit knowledge of pharmacist's role in health care systems to deliver patient care service at sectors like, hospital pharmacy settings, community pharmacy settings, ambulatory care and clinical practice.
6. Conduct clinical research along with team of health professional to add value to the evidence – based pharmaceutical car and needy health ailments.
7. Identify methods to design and conduct experiments and interpreting of results including cost – effectively, cost – benefit, cost – minimizing of medication use.
8. Set-up unbiased drug and poison information centre o provide drug information service to all the health care professionals with relevant evidence.
9. Possess ethical value and moral value in the delivery of health care delivery in multifaceted environment

3. Introduction to the Document

The guidelines published in this document are official guidelines by the Academic council and Board of studies (BoS) of Raghavendra Institute of Pharmaceutical Education and Research (RIPER) (An Autonomous institution) sponsored by Raghavendra Educational and Rural Development Society (RERDS) – Anantapuramu, Andhra Pradesh. The document is a fusion product based on

a. Recommendations and guidelines stipulated for syllabus structure by UGC, AICTE, PCI, New Delhi.

b. Academic regulations stipulated by Jawaharlal Nehru Technological University Anantapur (JNTUA), Ananthapuramu, Andhra Pradesh.

c. Experts opinion from the Academic Council approved Advisory boards members includes both academicians and researchers from reputed organizations at national and international levels.

d. Suggestions and inputs from members of academic council and Board of studies.

e. Recommendations based on stakeholders' feedback such as alumni, employers, faculty, students, parents and other experts from allied area.

This ***academic regulations, program structure & syllabus*** 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 and program structure 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.

Objectives:

The list of objectives for implementing academic regulations and program structure through these guidelines are listed below,

- to improve the academic regulations and program structure.
- to strengthen the Industry-Institute interaction.

  to comply with rules and regulations of regulatory bodies like 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.

4. Preamble

Title, application, and the authorities to interpret, clarify, modify and to amend a) The regulations stated herein below shall be called as a document of "**Academic regulations, Program structure & syllabus"** for Raghavendra Institute of Pharmaceutical Education and Research (RIPER) from the academic year 2016-17 and applicable till next revision.

b) These regulations shall be in force from the batch admitted from 2016 by the date of ratification by the Academic council and Board of studies (BoS) of the college after the conferment of autonomous status by UGC.

c) In the event of any doubt about the interpretation of these regulations, the matter shall be referred to Academic council and Board of studies (BoS) and their decision shall be final.

d) The Academic council and Board of studies (BoS) shall have the authority to modify, amend and repeal any of the provisions of these regulations from time to time.

Definitions

In this document, unless there is anything repugnant to the subject or context

i. "***College***" or **"institute**" means "Raghavendra Institute of Pharmaceutical Education & Research (RIPER) (An Autonomous Institution), Anantapuramu, Andhra Pradesh".

ii. "***Student***" means a candidate who has taken admission into Ph.D. / M. Pharm / B.Pharm / Pharm.D / D. Pharm Program of this Institute 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 of this institute which is constituted as per the guidelines of UGC.

iv. "***Board of Studies***" means Board of Studies of this institute which is 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 Institution.

vii. ***"Faculty member"*** means the teacher (Assistant/Associate/Professor) working on regular / adhoc / full time / part time basis in any of the Academic Departments of the Institution.

viii. *"**Program"*** means a candidate who has chosen to avail/award the degree /certificate of Ph.D. / M. Pharm /B. Pharm / Pharm.D and Diploma of this college as per the marks/ rank regulated by the awarding University/ State / central common entrance tests, India.

ix. *"**Course**" individual subjects described with content for instructions to the students in a semester/Year.*

x. ***"Specialization"*** means a candidate who has chosen into a specialty of the program such as "Pharmaceutical Analysis & Quality Assurance/ Pharmaceutics/Pharmacology/ Pharmacy Practice".

xi. *"**Assessment"*** means evaluation process for the outcome and grading in term of the marks.

xii. ***"Credit"*** means a weight to the time requirements of the academic course in the institute.

5. Academic regulation (common to all Post graduate Specializations)

As per the Academic council of Raghavendra Institute of Pharmaceutical Education and Research, (Autonomous Institution) and as directed by the University Grants Commission (UGC), the Jawaharlal Nehru Technological University Anantapuramu (JNTUA), shall confer the post graduate degree in Master of Pharmacy (M.Pharm) in all specializations with the fulfilment of the following requirements for the award of degree.

Eligibility

Admission to the program shall be made subject to the eligibility, qualifications, and specialization 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. The admission is based on GPAT/PGECET/PIOFN/management categories and is subjected reservation policy of the government from time to time.

Program details

Duration	2 years
Semesters	4 semesters (each semester will be not less than 20 week including examinations provided the academic calendar structured to fulfil 90 instruction days excluding examinations)
Mode	Full-time
Total credits	75
Maximum duration	Period equal to twice the prescribed duration (4 years)

Attendance Requirements:

i. A student shall be eligible to appear for end examinations if acquires a minimum of 75% of attendance in aggregate of all the courses (subjects).

ii. Condonation of shortage of attendance in aggregate up to 10 % (65% and above and below 75%) in each semester. Condonation may be fixed by examination / academic committee.

iii. A student will not be promoted to the next semester unless he satisfies the attendance requirement of 65 %, as applicable to all courses (subject). If any students fail to record 65 % in an individual Course, even he/she put 75% as aggregate, she/he should not be allowed for the particular course and rest of the courses may be allowed to register. He/she may register for the next semester/offered next.

iv. Shortage of aggregate attendance below 65% shall in NO case be condoned and will not be promoted. Students whose shortage of attendance is not condoned in any semester / I year are not eligible to take their end examination of that class and their registration shall stand cancelled and need to register as regular.

Distribution and Weightage of Marks:

i. The performance of a student in each semester shall be evaluated course-wise with a maximum of 100 marks for theory and 100 marks for practical Courses (subjects). In addition other assessments such as assignment, case study, Presentations, participation, Lab work, and Dissertation work shall be evaluated as prescribed.

ii. For theory paper the distribution shall be 30 marks for Continuous assessment (Class test, Mid-term exam, assignment/case study) and 70 marks for the End assessment (End-Examination).

iii. For Practical paper the distribution shall be 30 marks for Continuous assessment (Participation, Mid-term exam, Lab work and Record) and 70 marks for the End assessment (End-Examination).

iv. For theory paper, during the semester there shall be 2 class tests, which include both objective and descriptive questions for duration of 45 minutes. One class test should be conducted as pre-midterm and one should be as post mid-term test. Test may be conducted for 20 marks and the best score shall be converted to 10 marks for continuous assessment.

v. There will be only one mid-term theory and practical examination that has to be conducted for 30 marks. It has to be converted to 15 marks for continuous assessment. The mid-term examination shall be conducted once at middle of semester provided that the schedule should be indicated in the academic calendar, to avoid student absenteeism.

vi. For theory subject, there will be one or two assignments/case study (for 5 marks) in relevance to course outcome, and should be evaluated as per standard rubrics. Final score may be included in the continuous assessment as indicated in individual course syllabi.

vii. For practical Paper there shall be a continuous day to day evaluation based on lab work / record (10 marks), participation based on portfolio (5 marks) and there will be mid-term examination (15 marks) along with Mid-term theory examinations. The mid-term practical examinations should be conducted for 30 marks. It has to be converted to 15 for continuous assessment.

viii. In second year third semester, there shall be a problem based exercise to be given as assignment/case study (50 marks). There shall be not less than six activities. The activity has to be documented as problem based learning (PBL) based on course outcome and it should be relevant to the dissertation work.

ix. In addition, there shall be a seminar presentation in 1, 2, 3 semesters. For the seminars in 1st and 2nd semesters, the student shall collect the information on a specialized topic and prepare a technical report, showing his understanding over the topic, and submit to the internal departmental committee.

x. For the seminar in ^{3rd} Semester, there shall be presentation on research / review article. The presentation shall be as Journal club participation.

xi. All seminar reports shall be evaluated for 50 marks. There shall be no external examination for seminar; however, the candidate should secure 50% to be declared successful.

xii. There will be mini-project in first and second semester. The project shall be evaluated by IDC. There shall be no external examination for seminar; however, the candidate should secure 50% to be declared successful. An Industry visits / filed work report can also be considered as mini-project.

xiii. The dissertation work shall be allotted in beginning of 3rd semester and should be continued till the end of 4th semester.

xiv. During the Dissertation progress, there shall be three reviews on dissertation progress conducted by internal departmental committee (IDC). The research study of the work may be carried out at research laboratory of the college or at industry/hospital provided that area of research/work should justify the program outcome. However, the study protocol needs to be approved by IDC and RRC (Research Review Committee). In case of dissertation work from Industry/hospital, there shall be a co-supervisor from industry to supervise the work at industry/hospital.

xv. Continuous assessment marks awarded by the instructors are not final. They are subject to scrutiny and scaling by the chief controller of examinations, wherever felt desirable. In such conditions, the continuous assessment marks awarded by the Instructor will be referred to a Committee. The Committee will arrive at a scaling factor and the marks will be scaled as per the scaling factor. The recommendations of the Committee are final and binding. The laboratory records, Mid-term, test papers, assignments, presentations etc. shall be preserved in the respective departments as per the University norms and shall be produced to the Committees of the University/regulatory bodies as and when they ask for.

xvi. A candidate shall be deemed to have secured the minimum academic requirement in a course if he /she secures not less than 40% of marks in the end examinations (assessment) and the minimum aggregate of 50% of total marks of all courses (together end examinations and continuous assessment). The is no minimum requirement on continuous assessment marks.

xvii. In case, the student does not secure the minimum academic requirement in any course (i.e 40 % in end examination and 50 % aggregate of overall subject in the semester), he/she has to reappear for the End examination, either in supplementary or regular in that particular course, or repeat the course when next offered. However, the continues assessment marks remain same.

Note: In case any candidates continue assessment is low if only due to absenteeism to attend mid-term examination, he/she shall submit the application with appropriate reason to Principal. Then trueness of the application may be evaluated by the examination committee including controller of examination. In such cases, if committee feels to allow, a prescribed fee has be paid to the examination section, to undertake mid-term examination, scheduled by the Controller of examinations.

Evaluation of Dissertation work

i. Each student shall be required to submit a research / Industrial project work as bound dissertation book at the end of 4th semester as stipulated in the examination schedule.

ii. A candidate is permitted to register for the project (dissertation) work only, if she /he satisfy all the requirement of attendance and course participation in both continuous and end assessments.

iii. The work shall be allotted and initiated in penultimate semester and continued in final semester. The Supervisors are responsible for obtaining research approval /ethical clearance from appropriate committee of the institution as per regulatory requirement. Such ethical/research approval certificates shall be added as annexures in dissertation book.

iv. The project duration shall be not less than 36 weeks, if any extension the candidate need to apply to controller examinations with appropriate reason and prescribed fee.

v. During 36 weeks, there shall be three review meetings to monitor the status of the project work progress. The IDC shall approve all three reviews before final submission. The IDC shall also be evaluating the dissertation book for plagiarism, and 30 % shall be the maximum limit.

vi. Candidate shall be allowed to submit the dissertation book, only if she/he cleared all academic requirements (theory, practical, assignment/case study, seminar, projects etc.) of 1st, 2nd, 3rd semester as prescribed in the plan of study. If any candidate, fails to clear anyone or few courses of 1, 2, 3 semesters, she/he will not allowed for submission, and later, she/he can submit the dissertation immediately once the requirement has been fulfilled.

vii. Three copies of dissertation book certified in the prescribed format by RRC, Supervisor, HOD and Head of the institution shall be presented to examination cell/section. The Controller of examiner shall allot an external examiner from the proposed panel examiners by HOD.

viii. End dissertation evaluation shall be evaluated by a board of examiners consisting of external examiner, HOD and supervisor. The board shall jointly report candidate research/project work in the following scale.

Marks (200 M)	Grade	Impression	Results
180 and above	A	Very good	PASS
150 - 179	B	Good	PASS
100 - 149	C	Satisfactory	PASS
Below 100	D	Not satisfactory	FAIL

Teaching and learning methodologies, recommended

1	Black board teaching
2	Power point presentation
3	Interactive seminar /sessions
4	Problem based assignment activity/case study
5	Group discussions
6	Laboratory based experiments
8	Field/industry/hospital visits
9	Group research

6. Program Structure & Syllabus (Specialization wise)

Program Structure: M. Pharmacy - Pharmaceutical analysis and Quality assurance

Programme	Master of Pharmacy (M. Pharm)
Specialization	Pharmaceutical analysis and quality assurance
Approved by	Academic council
Effective from	Students admitted from AY 2016-17

Plan of study (Semester Wise):

M. Pharm: I-YEAR; SEM-1

Course code	Paper	Name of the course	Hrs /week	Credits
16MCP101	Theory	Modern methods of pharmaceutical analysis	4	4
16MCP102	Theory	Research methodology and intellectual property rights	4	4
16MPQ103	Theory	Spectral and chromatographic methods in drug analysis	4	4
16MPQ104	Theory	Quality assurance of pharmaceuticals	4	4
16MCP105	Practical	Modern methods of pharmaceutical analysis – Practical	6	4
16MPQ106	Practical	Spectral and chromatographic methods in drug analysis - Practical	6	4
16MPQ107	Research	Mini Project	4	2
16MPQ108	Seminar	Presentation	--	1

M. Pharm: I-YEAR; SEM-2

Course code	Paper	Name of the course	Hrs /week	Credits
16MPQ201	Theory	Quality control of pharmaceuticals	4	4
16MCP202	Theory	Regulatory aspects of pharmaceutical process	4	4
16MPQ203	Theory	Analytical method development and validation	4	4
16MPQ204	Theory	Advances in pharmaceutical analysis	4	4
16MPQ205	Practical	Quality control of pharmaceuticals – Practical	6	4
16MPQ206	Practical	Analytical method development and validation - Practical	6	4
16MPQ207	Research	Mini-project	4	2
16MPQ208	Seminar	Presentation	--	1

M. Pharm: II-YEAR; SEM-1

Course code	Paper	Name of the course	Hrs /week	Credits
16MPQ301	Assignment/Case study report	Assignment (Problem based Exercise)/ Case study report	6	3
16MPQ302	Seminar	Presentation (Journal club)	--	2
16MPQ303	Research	Dissertation (Continuation to semester 2)	--	--

M. Pharm: II-YEAR; SEM-2

Course code	Paper	Name of the course	Hrs /week	Credits
16MPQ401	Research	Dissertation / Defence VIVA	--	16

Programme	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 1st semester
Name of the course	Modern methods of pharmaceutical analysis
Course Code	16MCP101
Credits	4
Hours /week	4 hours (Lectures)
Pre / co-requisite/s	Nil

Course Description:

The modern methods of pharmaceutical analysis course aimed to provide knowledge and application on various analytical techniques in process and quality control of pharmaceuticals. It emphasizes on basic principle, instrumentation of various analytical instruments in analysis of drug substance/product. This course covers the use of various modern analytical methods such as spectroscopy, chromatography, electrochemical methods, thermal analysis, electrophoresis, x-ray analysis and scanning microscopy, in pharmaceutical process and research.

Course Learning Outcomes:

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

CO 1: Discuss the principle of various modern analytical techniques which are suitable for pharmaceutical process and development.

CO 2: Employ critical analysis on suitability of analytical technique in quantitative and qualitative analysis of drug substance in products and biological samples.

CO 3: Propose the appropriate analytical technique based on the type of drug substance or drug products or matrix sample of research interest.

CO 4: Evaluate the different analytical techniques for the selected application in Pharmaceutical manufacturing and quality control.

Theory: Course Contents

Unit	Topics
I (2 weeks)	UV-Visible Spectrophotometry: Principle and types of molecule interaction with different EMR, Concept of chromophore, electronic transition, λmax, molecular extinction coefficient and their significance. UV-Visible spectrophotometer instrumentation.
	UV spectrum characteristics, UV solvents, Beer law and its limit, Woodwards rule, quantification methods for single and multi-component dosage forms. Concept of optical rotatory dispersion and circular dichorism and its application

	in monograph analysis.
II (2 weeks)	Infra Red Spectroscopy: Molecular vibration and fundamental frequency, factors affecting fundamental frequency, Hook's law, FT-IR instrumentation, sample preparation techniques (including ATR and DRS).
	IR spectrum characteristics and it pharmaceutical application with reference to monograph. Raman Spectroscopy: Principle, Raman Spectrum and Application in pharmaceutical analysis with reference to Monograph.
III (2 weeks)	NMR Spectroscopy: Spin quantum number, Principle of NMR spectroscopy (flipping and relaxation process), processional frequency, chemical shift and factors affecting chemical shift, solvents, reference standard, and Interpretation of H^1 and C^{13} NMR spectra.
	Instrumentation for H^1 and C^{13} nuclei. Spin-spin coupling and its factors. Brief concept of NMDR, NOESY, INDOR and introduction to 2D NMR / COSY with example.
IV (2 weeks)	Mass Spectrometry: Basic principles, formation different ions like molecular ion, fragment ions, meta stable ions. Rules related to fragmentation patterns for structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks.
	Mass spectrum, its characteristics, Instrumentation of high resolution mass spectrometer and different ionization process. Different analysers in tandem spectrometry (Time of flight and quadruple analyser with reference to LC-MS/MS and GC-MS/MS)
V (2 weeks)	The stationary phase, mobile phase, procedure and application of the following • Paper chromatography • Thin layer chromatography
	The stationary phase, mobile phase, procedure and application of the following • Column chromatography • Ion exchange chromatography
VI (2 weeks)	Liquid chromatography: HPLC Vs Column chromatography, Instrumentation of isocratic and gradient system, detectors, vandeemter equation and column efficiency, chromatogram characteristics (retention time, resolution, etc.).
	Different quantification techniques in pharmaceutical analysis, internal standard method and simultaneous quantification technique. Concept of preparative HPLC, UPLC, RRLC, Micro HPLC.
VII (2 weeks)	Gas Chromatography: GSC Vs GLC, different column and career gas used and their characteristics, GC instrumentation, isothermal and gradient program, split and split less mode, different detectors, FID, ECD, TCD, NPDA.
	Critical comparison of selectivity and sensitivity for column, detector, career gas and Derivatisation technique. Pharmaceutical application of Gas chromatography

VIII (2 weeks)	The principle and application of the following • Electrophoresis (PAGE and Gel) • X-ray diffraction methods
	The principle and application of the following • Differential scanning calorimetry • SEM and TEM

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

1. Willard HH, Merritt LL, Dean JA and Settle FA. (2001). Instrumental Methods of Analysis, 7th ed., CBS Publishers and Distributors, Delhi, ISBN: 9788123909431.
2. Beckett AH, Stenlake JB.(1988). Practical Pharmaceutical Chemistry. Part-II, 4th ed., Published by Athlone Press of the University of London, London.
3. Skoog DA, James FH, Stanley RC. (2006). Principles of Instrumental Analysis, Cengage Learning; 6th edition, ISBN-10: 0495012017.
4. David G. Watson. (2012). Pharmaceutical Analysis. Churchill Livingstone; 3rd edition. ISBN-13: 978-0702046216.
5. Skoog DA, Donald M. (2003). West. Fundamentals of Analytical Chemistry. Brooks Cole; 8th edition. ISBN-13: 978-0030355233.
6. Kaur H. Instrumental methods of chemical analysis. Published by Pragati Prakashan, Meerut. ISBN No.: 978-81-8398-377-8.

Programme	M. Pharm (Pharmaceutical analysis & quality assurance)
Year /Semester	First year / 1st semester
Name of the course	Research methodology and intellectual property rights
Course Code	16MCP102
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:

Research methodology and Intellectual property rights course is aimed to develop research orientation among the students and to acquaint them with fundamentals of academic research and techniques in pharmaceutical sciences and regulatory context. It emphasizes the discussions on sampling techniques, research designs and techniques of analysis. The course allows student to examine and be practically exposed to the main components of a research framework i.e., problem definition, research design, data collection, ethical issues in research, report writing, and presentation. Course also emphasizes various intellectual property rights and regulatory affairs.

Course Learning Outcomes:

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

CO 1: Explain the basic framework of research process and various research designs and techniques.

CO 2: Demonstrate various sources of information for literature review and data related to research outcome.

CO 3: Propose the regulatory environment by implementing regulatory practices and intellectual property rights

CO 4: Evaluate the procedure and practice involved in the documentation of various regulatory processes related to NDA, ANDA, CTD, and SUPAC.

Theory:Course Contents

Unit	Topics
I (2 weeks)	Meaning, Objective and Motivation in Research: Types of Research.
	Research Approaches, Research Process, Validity and Reliability in Research
II (2 weeks)	Sampling Design: Steps in Sampling Design, Characteristics of a Good Sample Design, Random Samples and Random Sampling Design
	Types of Research Design, Basic Principles of Experimental Design
III	Standard deviation, Regression and Correlation coefficient: principles and

(2 weeks)	equations involved in calculation of SD. Positive and negative correlations and their significance. Slopes and Line equations
	Tests of significance: Testing hypotheses – Principles and applications of Z, t, F–ratio and chi-square tests in pharmaceutical and medical research
IV (2 weeks)	Interpretation of Data and Report Writing, Layout of a Research Paper, Techniques of Interpretation.
	Making Scientific Presentation at Conferences and Popular Lectures to Semi Technical Audience, Participating in Public Debates on Scientific Issues.
V (2 weeks)	History of IPR, WTO &WIPO
	Patents and Intellectual Property Rights (IPR): Definition, scope, objectives, sources of patent information, patent processing and application.
VI (2 weeks)	Patents, Copyrights, Trademarks, Salient features, international and regional agreements, trade secrets, non-disclosure agreement.
	Patent filling, patent search, and PCT
VII (2 weeks)	Related Quality Systems: Objectives and guidelines of USFDA, WHO and ICH. Introduction to ISO series.
	Documentation: Types related to pharmaceutical industry, protocols, harmonizing formulations, development for global filings, ANDA, NDA, CTD, dealing with post – approval changes – SUPAC, handling and maintenance including electronic documentation.
VIII (2 weeks)	Regulatory Affairs: Indian context – requirements and guidelines of GMP, understanding of Drugs and Cosmetics Act 1940 and Rules 1945 with reference to Schedule N ,U & Y.
	Revision

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Learning Resources/Recommended Texts/Reference books/web resources

1. Kothari CR. Research methodology: methods and techniques. 2nd ed., New age: India; 2013. ISBN-13: 978-8122436235
2. Narayana RP, Acharyulu GVRK. Research Methodology and Statistical Tools. 1st ed., Excel books: New Delhi; 2008.
3. Negi KS. Biostatistics. 2nd ed., AITBS: India; 2002.ISBN-13: 978-8174731777.
4. Irfan A. Fundamentals of Biostatistics. Ukaaz: India; 2004. ISBN 13: 9788190044103.
5. Nally JD. Good manufacturing practices for pharmaceuticals (Drugs and the Pharmaceutical Sciences). 6th ed., CRC press: USA; 2006.
6. Wiling SH. Good manufacturing practices for pharmaceuticals. Vol 78. Marcel Decker.
7. Das P, Das G. Protection of industrial property rights. Consulting engineering and patent atto: India; 1973.
8. Guarino RA. New Drug Approval Process (Drugs and the Pharmaceutical Sciences). Marcel Dekker Inc: USA; 1987. ISBN-13: 978-0824773823.
9. Chien YW. Novel drug delivery systems. 2nd ed., Marcel Dekker Inc: USA; 1992.

Programme	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 1st semester
Name of the course	Spectral and chromatographic methods in drug analysis
Course Code	16MPQ103
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:

The Spectral and chromatographic methods in drug analysis course is aimed to equip students with knowledge of spectral interpretation chromatographic methods in quality control of dosage forms. It provides concept, procedure and regulatory perspectives of Spectral and chromatographic methods. This course covers about the structure elucidation of various spectral techniques and different types of quantification procedures involved in UV, IR, NMR and chromatographic techniques like HPLC, GC. The course also covers the basic concepts of RRLC, UPLC and GC-HS.

Course Learning Outcomes:

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

CO 1: Enumerate the structure of the compound from spectral data from UV, IR, and NMR.

CO 2: Demonstrate the knowledge of calibration, qualification and validation for various aspects of pharmaceutical analytical, bio-analytical and quality assurance.

CO 3: Evaluate the research on different analytical techniques for the selected applications in pharmaceutical manufacturing and quality control.

Theory: Course Contents

Unit	Topics
I (2 weeks)	UV Spectroscopy: Woodward Fieser rules for calculation of λ- max, Effect of solvent and pH in UV absorption, Deviations of Beer's law.
	Multicomponent analysis of drugs by UV Spectroscopy: Quantitative applications includeSimultaneous equation method (Vierdott's method), Derivative Spectrophotometric method, Absorbance ratio method (Q-Absorbance method), Difference Spectroscopy, Geometric correction method, Orthogonal poly nominal method
II (2 weeks)	IR Spectroscopy: Vibrational energy in bond, types of vibrations, Hook's law, sample preparation, instrumentation – FT- IR
	ATR, Determination of functional group by IR spectra, Application of IR spectra in monograph analysis as per IP. Note on "mutual exclusion principle".

III (2 weeks)	^{1}H-NMR spectroscopy: Concept of flipping, relaxation, chemical shift in NMR, shielding andde-shielding, spin-spin coupling, J – value, Instrumentation, applications, Concept of ^{13}C-NMR Vs ^{1}H-NMR.
	Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY. NMR in Drug Purity.
IV (2 weeks)	Atomic absorption Spectroscopy: Emission spectra, Absorption spectra, line spectra, principle of absorption of UV light by elements, instrumentation, applications in pharmaceutical analysis. Focus on interference.
	Principles, instrumentation and applications of Plasma emission Spectroscopy
V (2 weeks)	Column chromatography: Adsorption and partition theory, adsorbents used, preparation, procedure and methods of detection and applications. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection.
	Thin layer chromatography: Principle, 1D and 2D techniques,preparation of plates, and detection techniques and applications. HPTLC: Basic concepts comparisons between HPLC & HPTLC Quantification using HPTLC.
VI (2 weeks)	Gas Chromatography: Principle, adsorption isotherm and its relation to tailing and fronting. Various parameters used in GC analysis. Derivatization techniques in quantitative Applications. Brief note on GC-MS. Concept of GC-HS.
	Size exclusion chromatography; Principles, instrumentation and applications. Supercritical fluid chromatography: Introduction, History of SFC, Basic Principles, Instrumentation, Applications with emphasis on chiral separations, Polymer separations.
VII (2 weeks)	Principles, types of ion exchange resins used, instrumentation and applications of ion exchange and affinity chromatography.
	Principles, instrumentation and applications of centrifugal partition chromatography
VIII (2 weeks)	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Quantification methods usedin HPLC. Brief note on HPLC Vs UPLC VS RRLC.
	Principles, instrumentation and applications of UPLC, RRLC: Principles of UPLC, modifications in UPLC compared to HPLC, advantages and applications.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

1. Beckett AH, Stenlake JB. (1988). Practical Pharmaceutical Chemistry. Part-II, 4th ed., Published by Athlone Press of the University of London, London.
2. Kemp W. (1991). Organic spectroscopy. 3rd ed., Published by Palgrave Macmillan, London.
3. Watson DG. (2012). Pharmaceutical Analysis.3rd ed., Published by Churchill Livingstone, Edinburgh.ISBN-13: 978-0702046216.
4. Willard HH, Merritt LL, Dean JA and Settle FA. (2001).Instrumental Methods of Analysis, 7thed., Published by CBS Publishers and Distributors, Delhi. ISBN: 9788123909431.
5. Skoog DA, James FH, Stanley RC. (2006).Principles of Instrumental Analysis, 6th ed., Published by Cengage Learning, United states of america.ISBN-10: 0495012017.
6. Herald G. (2013). NMR Spectroscopy: Basic Principles, concepts and application in Chemistry. 3rd ed., Published by John Wiley and Sons, United States of America. ISBN: 978-3-527-33000-3.

Program	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 1st semester
Name of the Course	Quality assurance of pharmaceuticals
Course Code	16MPQ104
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:

The Quality assurance of pharmaceuticals course aimed to provide knowledge about regulatory aspects of drugs in manufacturing process. It emphasizes on basic requirements for registration of drugs. This course covers the various practices followed in pharmaceutical industry, different documentation procedures, NDA, ANDA, SNDA, ICH, and DPCO.

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

CO 1: Relate the knowledge about registration of pharmaceuticals

CO 2: Prepare Batch Manufacturing record for any drug.

CO 3: Assess different documentation procedures in pharmaceutical industry.

Theory: Course Contents

Unit	Topics
I (2 weeks)	Concepts of Total Quality Management (TQM) and Good Manufacturing Practices (GMP)
	Organization and personnel – Responsibilities and Training.
II (2 weeks)	Good Laboratory Practices (GLP): Routine controls, Instruments: Selection, purchase specifications, maintenance, clean in place, sterilize in place;
	Protocols, Non-Clinical Testing, Controls on Animal House, Applications of Computers in Quality Control Laboratory.
III (2 weeks)	New Drug Development and Approval Process: Investigational New Drugs (IND) steps involved in the approval process. 21 CFR regulations in IND application process
	New Drug Applications (NDA), Supplemental New Drug Application (SNDA) steps involved in the approval process
IV (2 weeks)	ICH requirements for registration of Pharmaceuticals.
	WHO certification scheme on the quality of pharmaceutical products. Eligibility, requesting a certificate, issuing process.

V (2 weeks)	Documentation related to Product Development, Standard operating procedures, standard test procedures, cleaning methods.
	Quality control documents, batch release document, distribution records, complaints and recalls records, retention of records.
VI (2 weeks)	Warehousing: Good ware housing practices, premises, location, personal.
	Warehousing: Good ware housing practices Materials Management,
VII (2 weeks)	Finished product Release: WHO guidelines, SOP for release of finished product. Quality Review: Process in Quality review.
	Quality Audits: types of audits, principles of Auditing. Batch Release document
VIII (2 weeks)	Regulatory Affairs - Drugs and Cosmetic Act 1940 and rules 1945. DPCO.
	Intellectual Property right and patent laws. Trade mark, copy right. Filling patent, patent life.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Learning Resources/Recommended Texts/Reference books/web resources

1. Shah DH. QA Manual. 1st ed., Business Horizons: India; 2002. ISBN-10: 8190078828
2. Manohar AP. Pharmaceutical quality assurance. 2nd ed., Niraliprakashan: India; 2006.
3. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials, Vol 2., Good Manufacturing Practices and Inspection. World Health Organization; 2004. ISBN-13: 978-9241546195.
4. Shayne CG. Pharmaceutical manufacturing hand book: Regulations and quality. Wiley interscience: New Jersey; 2008. ISBN: 978-0-470-25959-7.
5. Official website: ICH guidelines (www.ich.org)
6. Official website: Food and drug administration (www.fda.gov).
7. Official website: Central Drugs Standard Control Organization (www.cdsco.nic.in)

Programme	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 1st semester
Name of the course	Modern methods of pharmaceutical analysis- Practical
Course Code	16MCP105
Credits	4
Hours /week	6 hours
Pre / co-requisite/s	NIL

Course Description:

The modern methods of pharmaceutical analysis laboratory course is designed to provide the skills for the demonstration of instrumentation procedure based up on principles of analytical techniques such as spectroscopy, chromatography etc. This course deals with wet laboratory based experiments on qualitative and quantitative analysis in pharmaceutical substances/products. This course also provides skills for interpretation of spectrum and analytical results.

Course Learning Outcomes:

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

CO 1: Demonstrate skills on instrumentation and quantitative analysis of analyte in drug products / matrix samples.

CO 2: Choose appropriate procedure and analytical instruments for qualitative and quantitative analysis of drug substance in pharmaceutical research.

CO 3: Solve problems related to spectral interpretation, analytical procedure and instrumentation skills.

Practical: Course Contents

Week	Topics
1	Study of auxochrome 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 normalisation method)
9	Calculation of system suitability parameters for HPLC chromatograph
10	Determination of R_f, R_m, R_x value for amino-acids /sugars/ analogue by PC/TLC
11	Isolation of β-carotene by preparative TLC method
12	Experiments on column packing and elution (Demo)
13	Workshop on Spectral interpretation (DSC and XRD)
14	Workshop on Spectral interpretation (IR and ^{1}H NMR)
15	Problem based exercise /Revision (Woodward Fieser rule)
16	**Revision**

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Indian pharmacopeia. (2014). Government of India, Ministry of health and family welfare. Vol 1, 2, 3. Ghaziabad: Published by Indian pharmacopeial commission.
2. 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).
3. The United states pharmacopoeia-National formulary. (USP 37-NF 32). Rockville: Published by the united states pharmacopoeial convention.
4. The European pharmacopoeia. (2008). 6th ed., Strasbourg: Published by the council of Europe.
5. 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.
6. Martindale- The extra pharmacopoeia. 35th ed., London: Published by the royal pharmaceutical society.
7. Analytical profiles of drug substances. Vol. 1 to Vol. 20. Edited by Klaus Florey. United States of America: Published by Academic Press, Inc. ISBN: 978-0-12-260820-9

8. Analytical profiles of drug substances. Vol. 21 to Vol. 30. Edited by Harry G Brittain. United States of America: Published by Academic Press, Inc.
9. A Series of Analytical chemistry by open learning. Edited by David J. Ando.India: Published by Wiley India.

Programme	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 1st semester
Name of the course	Spectral and chromatographic methods in drug analysis- Practical
Course Code	16MPQ106
Credits	4
Hours /week	6 hours
Pre / co-requisite/s	Nil

Course Description:

The spectral and chromatographic methods in drug analysis laboratory course are designed to equip skills and knowledge to students about different analytical instruments for testing of drug substance/product. This course trains the students on instrumentation skills, sample preparation and quantitative analysis of drugs in various matrixes using chromatography and spectroscopy principles as per monograph.

Course Learning Outcomes:

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

CO 1: Demonstrate the skills on instrumentation and quantitative analysis of analyze in drug products / matrix samples.

CO 2: Recommend appropriate procedure and analytical instruments for qualitative and quantitative analysis of drug substance in pharmaceutical research.

CO 3: Evaluate the problems related to spectral interpretation, analytical procedure and instrumentation skills.

Practical: Course Contents

Week	Topics
1	Optimization of volume of $Fecl_3$ Reagent for salicylic acid estimation (0.3% $Fecl_3$)
2	Assay of Acelofenac tablets using FC reagent by Colorimetry.
3	Estimation of salicylic acid in the degraded aspirin sample by colorimetry
4	Assay of Frusemide in injection dosage form by UV-Spectrophotometry
5	Assay of Tinidazole tablets by A(1%, 1cm) method by UV spectroscopy as per IP 2014
6	Simultaneous estimation of Paracetamol & Aceclofenac or Lopinavir & Ritonavir drugs by UV simultaneous equation method
7	Simultaneous estimation of FDC by UV Absorption ratio method.
8	Simultaneous estimation of FDC by UV derivative spectroscopy.

9	Preparation of sample for IR analysis(Pellet) & Interpretation of IR Spectrum
10	Assay of Quinine sulphate by flourimetry.
11	Study of chemical quenching effect of quinine sulphate by Flourimetry
12	Isolation of curcumin by column chromatography.
13	Flash chromatography: fraction mixtures (Demo for impurity separation)
14	Determination of % composition of OVI's in a mixture by Gas chromatography
15	Assay of Paracetamol drug by RP-HPLC by direct comparison method
16	Revision

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Indian pharmacopeia. (2014). Government of India, Ministry of health and family welfare. Vol 1, 2, 3. Ghaziabad: Published by Indian pharmacopeial commission.
2. 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).
3. The United states pharmacopoeia-National formulary. (USP 37-NF 32). Rockville: Published by the united states pharmacopoeial convention.
4. The European pharmacopoeia. (2008). 6th ed., Strasbourg: Published by the council of Europe.
5. 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.
6. Martindale- The extra pharmacopoeia. 35th ed., London: Published by the royal pharmaceutical society.
7. Analytical profiles of drug substances. Vol. 1 to Vol. 20. Edited by Klaus Florey. United States of America: Published by Academic Press, Inc. ISBN: 978-0-12-260820-9
8. Analytical profiles of drug substances. Vol. 21 to Vol. 30. Edited by Harry G Brittain. United States of America: Published by Academic Press, Inc.
9. A Series of Analytical chemistry by open learning. Edited by David J. Ando.India: Published by Wiley India.

Programme	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 2nd semester
Name of the course	Quality control of pharmaceuticals
Course Code	16MPQ201
Credits	4
Hours /week	4 hours (Lectures)
Pre / co-requisite/s	Nil

Course Description:

The Quality Control of Pharmaceuticals provides knowledge on evaluating the different types of dosage forms by various physical, chemical and microbial methods. The course compare the various principles and procedures involved in evaluation of the pharmaceutical dosage forms which include vitamins, sulphonamides, antibiotics, steroids, anti-histamines, adrenergic, anti-malarial, local anaesthetics, barbiturates, anti-diabetics, and diuretics. The course covers the quality control test for tablets, capsules, injectables, liquid orals, biological evaluation of various vaccines and vitamins, WHO guidelines, regulatory guidelines to cosmetic, cytotoxic and phototoxic agents.

Course Learning Outcomes:

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

CO 1: Compare the dosage form about its quality of the analysis from the respective monographs

CO 2: Design the proper analytical technique for analyze the quality of the dosage form

CO 3: Judge the dosage form based on quality control tests

Theory: Course Contents

Unit	Topics
I (2 Weeks)	Detailed study of the principles and procedures involved in various physicochemical methods of analysis of Pharmaceutical dosage forms belong to the following classes of drugs. • Sulphonamides • Antibiotic
	Detailed study of the principles and procedures involved in various physicochemical methods of analysis of Pharmaceutical dosage forms belong to the following classes of drugs. • Anti-histamines • Vitamins
II (2 Weeks)	A detailed study on the principles and procedures involved in the determination of the dosage forms of the following group of drugs • Adrenergic • Anti- malarial

	A detailed study on the principles and procedures involved in the determination of the dosage forms of the following group of drugs • Steroids • Analgesics and anti pyretic
III (2 Weeks)	Official methods of determination for the mentioned below pharmaceutical dosage forms of the following group of drugs • Local Anaesthetics • Barbiturates
	Official methods of determination for the mentioned below pharmaceutical dosage forms of the following group of drugs • Anti- diabetics • Diuretics
IV (2 Weeks)	Various in process Quality Control tests carried on the following of Dosage Forms • Tablets • Capsules
	Various in process Quality Control tests carried on the following of Dosage Forms • Injectables • Liquid Orals
V (2 Weeks)	A detailed study on the biological evaluation of the following dosage forms • Rabbis Vaccine • Polio vaccine
	A detailed study on the biological evaluation of the following dosage forms. • Oxytocin • Insulin
VI (2 Weeks)	Microbiological evaluation of the following dosage forms • Neomycin Sulphate • Streptomycin • C. Cyanocobalamin
	Regulatory guidelines to handle cosmetic, cytotoxic agents, photo toxic agents in quality control laboratory.
VII (2 Weeks)	Quality control of crude drugs: Proximate analysis including ash and extractive values, crude fibre content
	Quality control of crude drugs: UV and Florescence analysis of powdered drugs.
VIII (2 Weeks)	• Detection of common adulterants and insects infestation in whole and powdered drugs. • WHO guidelines for the quality control raw materials

	• Brief study of quality control of plant products and their High throughput Screening

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Learning Resources/Recommended Texts/Reference books/web resources

1. Indian pharmacopeia. (2014). Government of India, Ministry of health and family welfare. Vol 1, 2, 3. Ghaziabad: Published by Indian pharmacopeial commission.
2. 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).
3. The United states pharmacopoeia-National formulary. (USP 37-NF 32). Rockville: Published by the united states pharmacopoeial convention.
4. The European pharmacopoeia. (2008). 6th ed., Strasbourg: Published by the council of Europe.
5. 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.
6. Martindale- The extra pharmacopoeia. 35th ed., London: Published by the royal pharmaceutical society.
7. Lachman/ Liberman. The theory and practice of Industrial pharmacy. Roop K Khar, SP Vyas 3rd edition.
8. Hobart H. Willard. Instrumental methods of analysis, CBS publishers and Distributors New Delhi.
9. Sethi PD. Quantitative analysis of Drugs and Pharmaceutical formulations. 3rd edition,CBS Publishers, Delhi.
10. Higuchi T, Hanssen EB. Pharmaceutical analysis, (1961). Inter science publishers.
11. Kokate CK, Purohith AP, Ghokale SP. Text book of Pharmacognosy. Niraliprakashan publishers, India.

Programme	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 2nd semester
Name of the course	Regulatory aspects of pharmaceutical process
Course Code	16MCP202
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:

Regulatory aspects of Pharmaceutical process course are aimed to present the various aspects involved in pharmaceutical industry. It emphasizes on process validation, equipment validation and the regulatory affair procedures to be followed in the industry. The course also deals with in process controls in the manufacturing section and describes about the industrial hazards and safety measures to be followed. It also emphasize about the production and applications of radiopharmaceuticals.

Course Learning Outcomes:

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

CO 1: Discuss the aspects involved in technology transfer and commercialization

CO 2: Analyze the importance of process controls in the manufacturing process of dosage forms.

CO 3: Set up the stability protocol for various dosage forms.

CO4: Compare the different industrial hazards and methods to prevent the hazards.

Theory Course: Contents

Unit	Topics
I (2 weeks)	Validation: significance of validation, Validation life cycle, Validation master plan, process validations of pharmaceutical dosage forms
	Equipment validation with reference to GMP requirement for dry heat sterilizer, autoclave, membrane filtration
II (2 weeks)	Stability: Stability testing of pharmaceutical dosage forms as per ICH guidelines
III (2 weeks)	Quality control: In Process Quality control Tests involved in manufacturing process of APIs
IV (2 weeks)	Dissolution Testing: Introduction to Dissolution equipments, Calibration of dissolution apparatus,
	Dissolution procedure development and validation, Dissolution method development for generic drug products

V (2 weeks)	Technology Transfer/Commercialization: Importance of TOT, Challenges, TOT agencies in India.
	Commercialization –Practical aspects and problems, drug master file submissions and SOP's
VI (2 weeks)	Industrial hazards due to fire accidents, mechanical and electrical equipment, chemicals and pharmaceuticals. Monitoring and prevention. Industrial effluent testing and treatment.
	ICH Guidelines: Q7 & Q10
VII (2 weeks)	Regulatory requirements on animal and human studies for drug development requirements for new drug approval.
VIII (2 weeks)	Radiopharmaceuticals: Production control and safety precautions, applications, storage

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Learning Resources/Recommended Texts/Reference books/web resources

1. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: Tablets. 2nded., Vol I, II, III., MarceldekkerInc, New York. ISBN: 0-8247-8300-X.
2. Avis KE, Lieberman HA, Lachman L. Pharmaceutical dosage forms: Parental medications. 2nd ed., Vols 1-3., Marcel dekkerInc, New York; 1992-1993.
3. Turco S, King RE. Sterile dosage forms. 3rd ed., Lea &Febiger, Philadelphia; 1987.
4. Remington JP. The science and practice of pharmacy. 21st ed., Lippincott Williams &wilkins, USA; 2006. ISBN: 0-7817-4673-6.
5. Martin AN, Swarbrick J, Cammarata A. Physical pharmacy. 4th ed., Lea &Febiger, Philadelphia; 1993.
6. International and National Journals: Research and Review articles

Programme	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 2nd semester
Name of the course	Analytical method development and validation
Course Code	16MPQ203
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:

The Analytical method development and Validationmodern methods is aimed to equip students with knowledge of analytical method development, validation, qualification and calibration aspects of analytical techniques. It provides concept, procedure and regulatory perspectives of drug stability and quality measurements. This course covers about the qualification and validation of various components of pharmaceutical quality assurance system like water supply system, air handling system and sterilization units. This course also emphasize the advanced analytical techniques suitable for pharmacokinetic and bioequivalence studies.

Course Learning Outcomes:

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

CO 1: State the concept of analytical method development and validation parameters in relevance to chromatography and spectroscopy.

CO 2: Demonstrate the knowledge of calibration, qualification and validation for various aspects of pharmaceutical analytical, bio-analytical and quality assurance.

CO 3: Propose the quality assurance strategy as per regulatory requirement for pharmaceutical quality assurance system like water supply system, air handling system and sterilization units

CO 4: Conduct research on different analytical techniques for the selected application in Pharmaceutical manufacturing and quality control.

Theory: Course Contents

Unit	Topics
I (2 weeks)	Concept of Analytical Method development, validation, Revalidation, calibration, qualification.
	Outline on 21CFR part 11, SOP and STP, regulatory perspective of analytical method validation and method requirements.
II (2 weeks)	Development of analytical Methods and validation of the following techniques • UV-Visible spectrophotometer • Quantification techniques for single and multi-components

	Development of analytical Methods and validation using following techniques • IR Spectrophotometer • Flourimeter
III (2 weeks)	Development of analytical methods and validation using following techniques • HPLC • Quantification techniques for single and multi-components.
	Development of analytical Methods and validation of the following techniques • GC-MS • LC-MS (Biological analysis)
IV (2 weeks)	A detailed study impurities and related substance and their regulatory requirement as per ICH Q3
	A detailed study stability of drug substance and drug products and their regulatory requirement as per ICH Q1
V (2 weeks)	Validation of analytical methods, concept of various method parameters selection as per various regulatory bodies such as USP, ICH, FDA, etc.
	Detailed study of the following • Validation of analytical Procedures by ICH Q2 • Analyst Validation
VI (2 weeks)	Qualification and Validation of Air handling System.
	Qualification and qualification of different types Sterilization methods and unit.
VII (2 weeks)	Validation of Water supply system: Types of water, specification, validation of deionised, distilled, purified, demineralised and water for injections.
	Advancement in analytical method development
VIII (2 weeks)	Analytical quality by design, QTPP, ATP
	Design of experiments in method development

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

1. Beckett AH, Stenlake JB. Practical Pharmaceutical Chemistry (1988). Part-II, 4th Edition, Published by Athlone Press of the University of London, London
2. Kemp W. Organic spectroscopy. (1991). 3rd edition, Published by Palgrave Macmillan.
3. David G. Watson. Pharmaceutical Analysis, Churchill Livingstone, 3rd edition (2012), Edinburgh
4. Willard HH, Merritt LL, Dean JA and Settle FA, (2001), Instrumental Methods of Analysis, 7thed., CBS Publishers and Distributors, Delhi, ISBN: 9788123909431.
5. Skoog DA, James FH, Crouch SR. (2006). Principles of Instrumental Analysis, Cengage Learning; 6th edition, ISBN-10: 0495012017
6. Skoog DA, Donald M. West. Fundamentals of Analytical Chemistry. Brooks Cole; 8th edition (2003). ISBN-13: 978-0030355233
7. Herald G.NMR spectroscopy (Basic Principles, concepts and application in Chemistry), 3rd edition, Published by John Wiley and Sons. ISBN: 978-3-527-33000-3.

Programme	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 2nd semester
Name of the course	Advances in pharmaceutical analysis
Course Code	16MPQ204
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:

The advances in pharmaceutical analysis course is designed to equip the knowledge of current and recent trends related to quantitative and qualitative of pharmaceuticals application using various analytical procedure and instrumentation. This course covers the use of advanced techniques spectroscopy, chromatography, microscopy, in pharmaceutical process and research. It also covers the application of HPLC, UPLC, LC-NMR, Raman spectroscopy, RIA, ELISA in characterization of drug substances and life cycle of drug products.

Course Learning Outcomes:

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

CO 1: Enumerate the principle and procedure for qualitative and quantitative determination of various functional groups in drug substance, herbal and bio-molecules.

CO 2: Differentiate the use for various chemical reagents in quantitative and qualitative analysis of drug substance in products and biological samples.

CO 3: Propose the appropriate methods for sample preparation, stability and impurity profiling based different advances in instrumentation process.

CO 4: Evaluate the different analytical techniques for enantiomers separation, characterization of polymorphism, and particle size analysis.

Theory: Course Contents

Unit	Topics
I (2 weeks)	Principles and procedures involved in quantitative determination of the following functional groups • Hydroxy • Aldehyde • Ketone
	Principles and procedures involved in quantitative determination of the following functional groups • Amine • Methoxy

	• Ester
II (2 weeks)	Official and recent methods for the estimation of the following • Proteins • Carbohydrates • Fats
	Official and recent methods for the estimation of the following • Crude fibre • Moisture • Nitrogen
III (2 weeks)	Principles and procedures involved in the use of the following reagents in quantification of drugs with two examples • 3- Methyl 1-2- benzothiozolinehydrozone (MBTH) • Folin - Ciocalteau Reagent • Paradimethyl amino benzaldehyde.
	Principles and procedures involved in the use of the following reagents in quantification of drugs with two examples • 2-6- Dichloro quinine chlorimide • 2,3,5- Triphenyl tetrazolium salt • Ninhydrin Reagent
IV (2 weeks)	Pharmaceutical sample preparation, fundamental theories controlling preparation techniques, concept of pre-treatment, filtration, degassing, special precaution to be followed for heat sensitive and light sensitive drugs.
	Specific sample preparation techniques for • IR spectral analysis • HPLC analysis • Bio-analytical LC-MS
V (2 weeks)	Principle and application of following instrumental technique in stability and impurity profiling • LC-MS/MS • LC-NMR
	Principle and application of following instrumental technique in stability and impurity profiling • HPLC • UPLC
VI (2 weeks)	Radiometric analysis: radio activity, radioisotopes and Pharmaceutical Applications of radiopharmaceuticals
	Principle, Procedures and applications • Radio Immune Assay: • ELISA Test
VII	Chiral separation: concept of Chirality, Physicochemical differences of

(2 weeks)	enantiomers, Stability issues of enantiomers.
	Different analytical techniques for chiral separation. Instrumentation and application of HPLC in chiral separation. Current techniques used for separation and identification.
VIII (2 weeks)	Principle and Illustrated example of characterization of Pharmaceutical products by • Raman spectroscopy • Electron scanning microscopy
	Analytical technique used for Polymorphism studies and particle size analysis

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

1. David G. Watson. Pharmaceutical Analysis, Churchill Livingstone, 3rd edition (2012), Edinburgh
2. Willard HH, Merritt LL, Dean JA and Settle FA, (2001), Instrumental Methods of Analysis, 7thed., CBS Publishers and Distributors, Delhi. ISBN: 9788123909431.
3. Skoog DA, James FH, Crouch SR. (2006), Principles of Instrumental Analysis, Cengage Learning; 6th edition. ISBN-10: 0495012017
4. Watson DG. Pharmaceutical Analysis. Churchill Livingstone; 3rd edition (2012). ISBN-13: 978-0702046216
5. Skoog DA, West DM. Fundamentals of Analytical Chemistry. Brooks Cole; 8th edition (2003). ISBN-13: 978-0030355233
6. Herald G.NMR spectroscopy (Basic Principles, concepts and application in Chemistry), 3rd edition, Published by John Wiley and Sons. ISBN: 978-3-527-33000-3.
7. Beckett AH, Stenlake JB. Practical Pharmaceutical Chemistry (1988). Part-II, 4th Edition, Published by Athlone Press of the University of London, London
8. Kemp W. Organic spectroscopy (1991). 3rd edition, Published by Palgrave Macmillan.

Programme	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 2nd semester
Name of the course	Quality control of pharmaceuticals- Practical
Course Code	16MPQ205
Credits	3
Hours /week	6 hours (laboratory)
Pre / co-requisite/s	Nil

Course Description:

The Quality Control of Pharmaceuticals course describes the evaluating the dosage forms by both qualitative and quantitative manner. The course covers the UV, HPLC, dissolution studies, polarimetry and quality control evaluation of herbal formulations. The dosage forms have to be evaluated as per the official methods given in the IP/BP/USP/EP/JP which it helps to analyze quality of the dosage form.

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

CO 1: Relate the analysis of the dosage form with official monographs

CO 2: Formulate the instrumental technique for analysing the Quality of the drug

CO 3: Evaluate the result outcome of the drug analysis performed by self with marketed products

Practical Course: Contents

Week	Name of the experiments
1	Assay of Ascorbic Acid Tablets by redox titration
2	Assay of Paracetamol Tablets as Per IP,BP,USP, EP, JP
3	Identification of RS in API by HPLC (Paracetamol/Aspirin)
4	Preparation of SOP for dissolution apparatus
5	Dissolution study of uncoated tablet
6	Dissolution study of hard gelatine capsule
7	Quality control of herbal formulation
8	Assay of Dextrose Injection By Polarimetry
9	Monograph Analysis of Paracetamol Tablets-1
10	Monograph Analysis of Paracetamol Tablets-2
11	Determination of ash value(s) of given crude drug
12	Determination of LOD value crude powder.
13	Assay of Aceclofenac Tablet By RP-HPLC
14	Assay of Ibuprofen of Any One Drug By Internal Standard Method (RP-HPLC)
15	Assignment
16	Revision

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Indian pharmacopeia. (2014). Government of India, Ministry of health and family welfare. Vol 1, 2, 3. Ghaziabad: Published by Indian pharmacopeial commission.
2. 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).
3. The United states pharmacopoeia-National formulary. (USP 37-NF 32). Rockville: Published by the united states pharmacopoeial convention.
4. The European pharmacopoeia. (2008). 6th ed., Strasbourg: Published by the council of Europe.
5. 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.
6. Martindale- The extra pharmacopoeia. 35th ed., London: Published by the royal pharmaceutical society.
7. Analytical profiles of drug substances. Vol. 1 to Vol. 20. Edited by Klaus Florey. United States of America: Published by Academic Press, Inc. ISBN: 978-0-12-260820-9
8. Analytical profiles of drug substances. Vol. 21 to Vol. 30. Edited by Harry G Brittain. United States of America: Published by Academic Press, Inc.
9. A Series of Analytical chemistry by open learning. Edited by David J. Ando.India: Published by Wiley India.

Programme	M. Pharm (Pharmaceutical analysis and quality assurance)
Year /Semester	First year / 2nd semester
Name of the course	Analytical method development and validation- Practical
Course Code	16MPQ206
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:

The Analytical method development and Validation laboratory course is designed to equip skills and knowledge to students on analytical method development, validation, qualification and calibration aspects of analytical techniques. It equips the students on development of standard operating procedure and standard test procedure based on regulatory requirements. This course trains the students on instrumentation skills, sample preparation and quantitative analysis of drugs in various matrixes using chromatography and spectroscopy principles.

Course Learning Outcomes:

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

CO 1: Demonstrate the skills on instrumentation and quantitative analysis of analyze in drug products / matrix samples.

CO2: Recommend appropriate procedure and analytical instruments for qualitative and quantitative analysis of drug substance in pharmaceutical research.

CO 3: Solve problems related to spectral interpretation, analytical procedure and instrumentation skills.

Practical: Course Contents

Week	Topics
1	Preparation and documentation of Standard operating Procedure
2	Identification drug substance in dosage form by UV / IR finger print matching
3	Calibration of UV-Visible spectrophotometer
4	Calibration of HPLC instruments
5	Calibration of GC instruments
6	Determination of Beers limit for drug substance by UV-spectrophometry
7	Study the effect of flow rate on column elution characteristics for a drug substance

8	Assay of drug by HPLC (calibration curve method)
9	Assay of drug by HPLC (Internal standard method)
10	Determination of % Composition of volatile oil by GC (area normalisation method)
11	Experiment on specificity determination and % degradation by HPLC
12	Experiments on precision and accuracy by HPLC
13	Assay of phyto-constituents in extract by HPTLC
14	Workshop on calculation of SST parameters, RRF, Mass balance
15	Demo on sample preparation for LC-MS/MS (LL, PP, SPE) for biological matrixes
16	**Revision**

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Indian pharmacopeia. (2014). Government of India, Ministry of health and family welfare. Vol 1, 2, 3. Ghaziabad: Published by Indian pharmacopeial commission.
2. 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).
3. The United states pharmacopoeia-National formulary. (USP 37-NF 32). Rockville: Published by the united states pharmacopoeial convention.
4. The European pharmacopoeia. (2008). 6th ed., Strasbourg: Published by the council of Europe.
5. 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.
6. Martindale- The extra pharmacopoeia. 35th ed., London: Published by the royal pharmaceutical society.
7. Analytical profiles of drug substances. Vol. 1 to Vol. 20. Edited by Klaus Florey. United States of America: Published by Academic Press, Inc. ISBN: 978-0-12-260820-9

8. Analytical profiles of drug substances. Vol. 21 to Vol. 30. Edited by Harry G Brittain. United States of America: Published by Academic Press, Inc.
9. A Series of Analytical chemistry by open learning. Edited by David J. Ando. India: Published by Wiley India.
10. Douglas A. Skoog, Donald M. West. Fundamentals of Analytical Chemistry. Brooks Cole; 8th edition (2003). ISBN-13: 978-0030355233
11. Herald G.NMR spectroscopy (Basic Principles, concepts and application in Chemistry), 3rd edition, Published by John Wiley and Sons. ISBN: 978-3-527-33000-3.

M. Pharmacy – Pharmaceutics

Programme	Master of Pharmacy (M. Pharm)
Specialization	Pharmaceutics
Approved by	Academic council
Effective from	Students admitted from AY 2016-17

Plan of study (Semester Wise)

M. Pharm: I-YEAR; SEM-1

Course code	Paper	Name of the course	Hrs /week	Credits
16MCP101	Theory	Modern methods of Pharmaceutical Analysis	4	4
16MCP102	Theory	Research methodology and Intellectual property rights	4	4
16MPC103	Theory	Advanced Pharmaceutical and Formulation Technology	4	4
16MPC104	Theory	Physical Pharmaceutics	4	4
16MCP105	Practical	Modern methods of Pharmaceutical Analysis - Practical	6	4
16MPC106	Practical	Advanced Pharmaceutical and Formulation Technology and Physical Pharmaceutics Practical	6	4
16MPC107	Research	Mini Project	4	2
16MPC108	Seminar	Presentation	--	1

M. Pharm: I-YEAR; SEM-2

Course code	Paper	Name of the course	Hrs /week	Credits
16MCP201	Theory	Biopharmaceutics and Pharmacokinetics	4	4
16MCP202	Theory	Regulatory aspects of Pharmaceutical process	4	4
16MPC203	Theory	Controlled and Targeted Drug Delivery Systems	4	4
16MPC204	Theory	Advanced Drug Delivery Systems	4	4
16MPC205	Practical	Biopharmaceutics and Pharmacokinetics - Practical	6	4
16MPC206	Practical	Controlled and Targeted Drug Delivery Systems- Practical	6	4
16MPC207	Research	Mini-project	4	2
16MPC208	Seminar	Presentation	--	1

M. Pharm: II-YEAR; SEM-1

Course code	Paper	Name of the course	Hrs /week	Credits
16MPC301	Assignment	Assignment (Problem based Exercise)	6	3
16MPC302	Seminar	Presentation (Journal club)	--	2
16MPC303	Research	Dissertation (Continuation to semester 2)	--	--

M. Pharm: II-YEAR; SEM-2

Course code	Paper	Name of the course	Hrs /week	Credits
16MPC401	Research	Dissertation / Defence VIVA	--	16

For Modern Methods of Pharmaceutical Analysis (Theory & Practical): Course description, course learning outcomes, course contents and Assessment methods and weightage refer above specialization of Pharmaceutical Analysis and Quality Assurance

For Research methodology and Intellectual property rights (Theory): Course description, course learning outcomes, course contents and Assessment methods and weightage refer above specialization of Pharmaceutical Analysis and Quality Assurance

programme	M. Pharm (Pharmaceutics)
Year /Semester	First year / 1st semester
Name of the course	Advanced Pharmaceutical and Formulation Technology
Course Code	16MPC103
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:

Advanced Pharmaceutical and Formulation Technology course is aimed to provide students with an applicable understanding of formulated products, and how such products are designed and manufactured. It encompasses all the recent developments in pharmaceutical formulations, with respect to their designing, manufacturing and evaluations of solid dosage forms, parenteral dosage forms, liquids & dispersed systems. It emphasizes on the pre-formulation aspects of all dosage forms. It also describes the strategies of formulation for research and pilot scale and also the aspects of scale up and SUPAC guidelines. It also presents the novel optimization techniques used in the formulation of dosage forms like Response surface methodology, factorial designs etc. The course also aims to give the participants new ideas pertaining to development and improvement of formulated products. At completion of the course, the students will have gained an understanding of modern formulation technology and how a cross-disciplinary approach can be used to develop and improve commercial products. It prepares students for careers in the pharmaceutical industry.

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

CO 1: Demonstrate various pre-formulation and formulation aspects of dosage forms.

CO2: Examine formulation science and how to transfer into the practical situation of product development.

CO 3: Propose the suitable technology and equipments in formulation and preparation of dosage forms for R & D scale and pilot scale

CO 4: Choose the optimization techniques in systematic formulation of dosage forms.

Theory Course: Contents

Unit	Topics
I (2 weeks)	**Preformulation Studies in drug development**: Goals of preformulation, preformulation parameters, methodology, Solid state properties, Solubility and Partition coefficient, drug excipient compatibility.
	Excipients used in pharmaceutical dosage forms: Properties and selection criteria for various excipients like surfactants, diluents, coating materials, plasticizers, preservatives, flavours and colours. Regulatory perspectives:

	GRAS, IIG, New developments in excipient sciences, functional and coprocessed excipients, patented excipients.
II (2 weeks)	**Tablets:** Advanced techniques of granulation, manufacturing of tablets, New materials, process, equipments like high shear mixers, compression machines.
	Coating machines, coating techniques in tablet technology for product development, aqueous based film coating, solvent free coating. Computerization for in process quality control of tablets.
III (2 weeks)	**Powder and capsule dosage forms:** Advances in powder dosage forms - inhalations dosage forms.
	Formulations, production and evaluation of hard and soft gelatin capsules.
IV (2 weeks)	**Liquids and polydisperse systems**: Recent advances in formulation aspects and manufacturing of suspensions and dry syrups.
	Emulsions: Formulation aspects, stability evaluation, advances in emulsion technology-multiple, micro and nano emulsions.
V (2 weeks)	**Aerosols:** Advances in propellants, selection of containers and formulation aspects in aerosol formulation.
	Manufacturing and quality control, metered dose inhaler designs, dry powder inhalers
VI (2 weeks)	**Parenteral dosage forms:** Aseptic processing contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing.
	Characterization of aseptic process, media and incubation condition. Manufacturing of Parenterals and quality control.
VII (2 weeks)	**Scale up techniques and SUPAC:** Pilot plant production, strategies of scale-up
	Scale up of dosage forms, SUPAC guidelines
VIII (2 weeks)	**Systematic Optimization of Pharmaceutical Formulations:** Terminology, Pitfalls of traditional OVAT approach, Design of Experiments (DoE) using experimental designs.
	Response surface methodology, basics of factorial, composite and mixture designs with merits and limitations, applications of systematic optimization techniques.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Learning Resources/Recommended Texts/Reference books/web resources

1. Liberman, HA, Lachman L. Pharmaceutical dosage forms: Tablets Vol I, II & III. 2d Edi. New York: Marcel dekker;1990.
2. Liberman, HA, Rieger, Banker. Pharmaceutical dosage forms: Disperse systems Vol I, II & III. 2d Edi. New York: Marcel dekker;1998.
3. Avis, Lachman L, Liberman HA. Pharmaceutical dosage forms: Pareneteral medication Vol I & II. 2d Edi. New York: Marcel dekker;1993
4. Roop K Khar, Vyas SP, Farhan J Ahmed, Gaurav K Jain. Lachman & Liberman's The Theory and Practice of Industrial Pharmacy. 4th Edi. New Delhi: CBS Publishers; 2013.
5. Turco S. Sterile dosage forms- Their preparation and Clinical Application. 1st Edi. New Delhi: Wolters Kluwer; 1994.
6. Remintons-The science and Practice of Pharmacy. 22d Edi. London: Pharmaceutical Press; 2013.
7. Patrick J-Sinko. Martin's Physical Pharmacy and Pharmaceutical Sciences. 5th Edi. New Delhi: Wolters Kluwer; 2006.

8.Singh B. and Ahuja A. Response Surface Optimization of Drug Delivery Systems. In: Jain NK, editor. Progress in Controlled and Novel Drug Delivery Systems. 1st Edi.CBS Publishers: New Delhi;2004.

Programme	M. Pharm (Pharmaceutics)
Year /Semester	First year / 1st semester
Name of the course	Physical Pharmaceutics
Course Code	16MPC104
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:

This course aims at introducing the student to the different physical aspects related to drugs in different forms such as solid, liquid, gas, or disperse systems, fundamentals of physical pharmacy, adsorption, surfactants, solubility, cosolvent effect on solubility, dissolution, pH and buffering, concept of complexation, reaction kinetics, drug stability. This course also involves an analysis and application of basic physico-chemical principles and methodology as they relate to drug dosage form design, preparation, and evaluation. It also considers the relationship of these principles to selected therapeutic problems.

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

CO 1: Define the physicochemical properties of drug molecules, pH, and solubility.

CO 2: Explain the role of surfactants, interfacial phenomenon, dissolution and diffusion.

CO 3: Interpret the effect of cosolvents, surfactants, complexation and solid state manipulation on solubility of non electrolytes.

CO 4: Analyze the chemical stability tests of various drug products.

Theory: Course Contents

Unit	Topics
I (2 weeks)	Theory of Solubulization and Solubulization Techniques: Solubility and solubulization of non electrolytes, solubulization by the use of surfactants.
	Cosolvents, complexation, drug derivation and solid state manipulation.
II (2 weeks)	Theories of Dispersion: Solid- liquid dispersion; adsorption.
	Wetting, crystal growth mechanisms and prevention of crystal growth.
III (2 weeks)	Emulsions: Formulation and stability of emulsions with special emphasis on electrical double layer theory
	HLB theory and dielectric properties of emulsions.
IV (2 weeks)	Solid State Properties: Crystal properties and polymorphism, techniques for study of crystal properties.
	Solid state stability, flow properties of powder, segregation and its importance.

V (2 weeks)	Theories of compaction and compression: Compression, consolidation strength of granules, compression and consolidation under high loads, effects of friction, distribution of forces in compaction.
	Force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, strength of tablet, crushing strength, friability, lamination.
VI (2 weeks)	Polymer Science: Polymer structure, classification and properties of polymers, thermodynamics of polymer solution, phase separation.
	Polymer in solid state, Applications of polymers in pharmaceutical formulations.
VII (2 weeks)	Diffusion and Dissolution: Diffusion, steady state diffusion procedures and apparatus. Diffusion principles in biological system, thermodynamics of diffusion. Dissolution: Basic theories of dissolution and models.
	Sink conditions in dissolution and its importance, Dissolution testing for novel drug delivery systems.
VIII (2 weeks)	Kinetics and Drug stability: Stability calculations, rate equation, kinetics of decomposition, strategy of stability testing, methods of stabilization.
	Methods of accelerated stability testing in dosage forms. Freeze-thaw methods, centrifugal methods, temperature and humidity control.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

1. Martin AN, Sinko PJ, Singh Y. Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences: Lippincott Williams & Wilkins; 2011.
2. Attwood D, Florence AT. Physical Pharmacy: Pharmaceutical Press; 2008.
3. Carstensen JT. Theory of Pharmaceutical Systems: General principles: Academic Press; 1972.
4. Lieberman HA, Lachman L. Pharmaceutical dosage forms: tablets: M. Dekker; 1981.
5. Lieberman HA, Rieger MM, Banker GS. Pharmaceutical Dosage Forms-- Disperse Systems: M. Dekker; 1998.
6. Qiu Y, Chen Y, Zhang GGZ, Liu L, Porter W. Developing Solid Oral Dosage Forms: Pharmaceutical Theory & Practice: Elsevier Science; 2009.
7. http://healthprofessions.jbpub.com/physicalpharm/Login.aspx?ref=/physicalpharm/default.aspx

Programme	M. Pharm (Pharmaceutics)
Year /Semester	First year / 1st semester
Name of the course	Advanced Pharmaceutical and Formulation Technology and Physical Pharmaceutics Practical
Course Code	16MPC106
Credits	4
Hours /week	6 hours (laboratory)
Pre / co-requisite/s	Nil

Course Description:

Advanced Pharmaceutical and Formulation Technology Physical Pharmaceutics Practical course is aimed to train the students on skills of designing a formula for development of dosage forms and preparation of the same using various equipments. This course also deals with development of dosage forms adopting optimization statistics and characterization of the same as well as about drug and excipient interactions.

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

CO 1: Analyze drug and excipient interactions

CO 2: Experiment the advanced techniques adopted in the preparation of dosage forms.

CO3: Evaluate various prepared dosage forms for standards.

Practical Course : Contents

Week	Topics
1	Assay of Paracetamol Tablets IP
2	Intrinsic dissolution rate of Paracetamol
3	Effect of excipients on Ibuprofen tablets
4	Preparation and evaluation of Effervescent tablets.
5	Effect of compression force on tablet hardness and disintegration time.
6	Effect of disintegrants on hardness, disintegration time and dissolution of drug from dosage form
7	Comparison of drug release from tablets prepared by wet granulation and direct compression
8	Effect of pH of dissolution medium on release rate profile of a drug
9	Determination of CMC of surfactant (surface tension method)
10	Determination of Log P value
11	Diffusion study of drug through polymeric membranes

12	Formulation and Evaluation of Amoxycillin Trihydrate Dry Syrup
13	Determination of shelf life of a drug using accelerated stability studies by Temperature degradation studies
14	Good manufacturing Practices in Tablet preparation (Documentation)
15	Validation of dissolution apparatus
16	Workshop on Design of Experiments (Demo)
17	Interpretation of differential scanning calorimeter and FT-IR Spectra for Study of Drug- excipient compatibility. (Workshop)

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Liberman, HA, Lachman L. Pharmaceutical dosage forms: Tablets Vol I, II & III. 2d Edi. New York: Marcel dekker;1990.
2. Liberman, HA, Rieger, Banker. Pharmaceutical dosage forms: Disperse systems Vol I, II & III. 2d Edi. New York: Marcel dekker;1998.
3. Avis, Lachman L, Liberman HA. Pharmaceutical dosage forms: Pareneteral medication Vol I & II. 2d Edi. New York: Marcel dekker;1993
4. Roop K Khar, Vyas SP, Farhan J Ahmed, Gaurav K Jain. Lachman & Liberman's The Theory and Practice of Industrial Pharmacy. 4th Edi. New Delhi: CBS Publishers; 2013.
5. Turco S. Sterile dosage forms- Their preparation and Clinical Application. 1st Edi. New Delhi: Wolters Kluwer; 1994.
6. Remintons-The science and Practice of Pharmacy. 22d Edi. London: Pharmaceutical Press; 2013.
7. Patrick J-Sinko. Martin's Physical Pharmacy and Pharmaceutical Sciences. 5th Edi. New Delhi: Wolters Kluwer; 2006ic press New York and London
8. Singh B. and Ahuja A. Response Surface Optimization of Drug Delivery Systems. In Controlled and Novel Drug Delivery Systems, Jain N.K. Ed., CBS, New Delhi. Latest Edition

Program /Year/Sem	M. Pharm (Pharmaceutics)
Year /Semester	First year / 2nd semester
Name of the course	Biopharmaceutics and Pharmacokinetics
Course Code	16MCP201
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

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 modelling, 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

Unit	Topics
I (2 weeks)	**Bioavailability and Bioequivalence of Drug Products:** Factors affecting, Assessment, Experimental designs and protocol for bioavailability and bioequivalence studies
	In vitro and in vivo correlation of bioavailability, methods to enhance bioavailability. Statistical considerations in comparative bioavailability studies
II (2 weeks)	**Physicochemical properties affecting bioavailability**: pH-partition theory, dissolution, surface area.
	Adsorption, Complexation, polymorphism and techniques of enhancing dissolution rate.

III (2 weeks)	Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals.
	Liquid orals and topical dosage forms. *In vitro* methods to estimate absorption.
IV (2 weeks)	**Basic concepts of pharmacokinetics:** Review of fundamentals, terminology, Pharmacokinetics of drugs following one/ two compartment open models with first order elimination kinetics as applied to rapid intravenous injection, Intravenous infusion and oral administration. Determination of absorption rate constant using Wagner-Nelson, Loo Riegelman methods. Flip-flop models, method of residual. Urinary excretion data and its application in pharmacokinetic characterization of drugs.
	Pharmacokinetics of multiple dosing. Superposition rule, problem solving. **Non-compartmental pharmacokinetics.** Graphical methods of calculating pharmacokinetic parameters
V (2 weeks)	**Non-linear pharmacokinetics:** Concepts of linear and non-liner pharmacokinetics, Michaelis-Menten Kinetics characteristics.
	Basic Kinetic parameters, possible causes of non linear pharmacokinetics, non-linear binding, and non-linearity of pharmacological responses.
VI (2 weeks)	**Chronopharmacokinetics:** Introduction, principles of chronopharmacokinetics, biological rhythms, circadian rhythms.
	Methodological aspects of chronopharmacokinetic study, applications.
VII (2 weeks)	**Clinical pharmacokinetics:** Altered kinetics in pregnancy, child birth, infants.
	Geriatrics, liver and renal disease states.
VIII (2 weeks)	**Protein and Tissue binding:** Factors affecting protein binding, kinetics of protein binding, determination of rate constant and different plots (direct, scatchard and reciprocal).
	Implication of protein binding on pharmacokinetic parameters.

Assessment methods and weightage

Assessment type	**Assessment tool**	**Distribution**
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

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.

Course code 16MCP202: Regulatory aspects of Pharmaceutical process (Theory): Course description, course learning outcomes, course contents and Assessment methods and weightage refer above the specialization of Pharmaceutical Analysis and Quality Assurance

Programme	M. Pharm (Pharmaceutics)
Year /Semester	First year / 2[d] semester
Name of the course	Controlled and Targeted Drug Delivery Systems
Course Code	16MPC203
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description: Controlled and Targeted Drug Delivery Systems course is designed to provide the information about the principles, strategies and materials used in the design of controlled drug delivery systems. This course will provide students with a basic understanding of the rationale behind the engineering of controlled drug delivery systems. The course covers the fundamentals of drug delivery, including physiology of target site , pharmacokinetics/pharmacodynamics, drug diffusion and permeation and biomaterials used in drug delivery.

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

CO 1: Demonstrate the fundamentals of controlled drug delivery and their design.
CO 2: Inspect the rationale behind the engineering of controlled drug delivery systems
CO 3: Compose and demonstrate various targeted drug delivery systems
CO4: Choose feasible delivery strategies for the physiological environments for which delivery is desired.
CO5:Evaluate various release systems, GRDDS, Colon specific systems and transdermal patches.

Theory Course: Contents

Unit	Topics
I (2 weeks)	**Fundamentals of controlled drug delivery systems**: Terminology of Controlled release, Rationale of sustained/Controlled drug delivery. Factors influencing the design and performance of sustained/controlled release products.
	Pharmacokinetic and pharmacodynamic basis of CDD. Polymers used in design of sustained/controlled release products.
II (2 weeks)	**Per oral controlled release drug delivery system:** Principle involved in design and fabrication of oral dosage forms- Diffusion system, reservoir devices.
	Systems utilizing ion exchange resins, pH-independent formulations, osmotically controlled release systems.
III (2 weeks)	**Gastro retentive drug delivery systems:** Floating, High density systems
	Mucoadhesive, Expandable and modified shape, magnetic systems and super porous hydrogels

IV (2 weeks)	**Transmucosal drug delivery systems:** Buccal drug delivery systems and medicated wafers.
	Ocular drug delivery systems and Medicated chewing gums.
V (2 weeks)	**Transdermal drug delivery systems:** Permeation across skin, Matrix and reservoir systems, Enhancement of drug permeation through skin by permeation enhancers.
	Iontophoresis, Electrophoresis, ultra sound and micro needles. Implantable drug delivery systems
VI (2 weeks)	**Prodrugs and Colon specific systems:** Types, purposes, approaches to prodrugs. Site specific prodrug approaches – By chemical modification, Targeting through antibodies.
	Factors to be considered in design of CDDS. Azo & glucuronide conjugates, Cyclodextrin conjugates, drug release based on microflora, In vitro & In vivo evaluation.
VII (2 weeks)	**Targeted drug delivery systems:** Principles, Approaches of drug targeting, Bone marrow targeting, Brain targeting
	Tumour targeting, Drug targeting through chemical drug delivery approaches to different organs like lungs, liver and eyes.
VIII (2 weeks)	**Carrier based delivery systems:** Liposomes, microspheres, micelles/reverse micelles, liquid crystals.
	Self-emulsifying drug delivery systems, Aquasomes, nanoparticles, carbon nanotubes.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Robinson JR, Lee VHI. Controlled drug delivery – Fundamentals and Applications. 2d Edi. New York: Marcel Dekker; 1982.
2. Jain NK. Progress in Controlled and Novel Drug Delivery Systems .1st Edi. New Delhi: CBS Publishers; 2005.
3. Jain NK. Controlled and Novel drug delivery. 1st Edi. New Delhi: CBS Publishers; 2012.
4. Chein YW, Novel drug delivery systems. 2d Edi. New York: Informa health care; 2011.
5. Vyas SP, Khar RK. Targeted and Controlled and Controlled Drug Delivery-Novel Carrier Systems. 1st Edi. New Delhi: CBS Publishers; 2010.

6. Roseman TJ, Mansdrif SZ. Controlled release drug delivery systems, 1st Edi. New York: Marcel dekker; 1983.
7. Xialo Ling L, Bhaskar RJ. Design of controlled releasese drug delivery systems 1st Edi. New York: McGraw Hill; 2006.

Review articles

Programme	M. Pharm (Pharmaceutics)
Year /Semester	First year / 2nd semester
Name of the course	Advanced Drug Delivery Systems
Course Code	16MPC204
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description: This course is dealing with the basic mechanisms involved in cellular transport, nucleic acid based technologies used for genetic diseases and vaccine delivery. The course covers the applications of bioinformatics in genomics, proteomics. The course also gives knowledge in advances and developments taking place biotechnology based drugs and drug targeting areas.

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

CO 1: Discusses the importance of cell and molecular mechanisms involved in drug transport. It deals with nucleic acid based therapeutic delivery systems.

CO2: Demonstrate the techniques of Gene therapy, techniques of protein engineering and vaccine delivery system formulations

CO 3: Propose the reasons for genetic diseases and current gene therapy methods.

CO 4: Plan regulatory and intellectual property rights for biotechnological innovations.

Theory: Course Contents

Unit	Topics
I (2 weeks)	**Cell membrane**: drug absorption and physiological factors affecting oral bio availability. Plasma membrane-phospholipids bilayered, Epithelia- Cell junctions-structure and its role in drug absorption.
	Role of membrane proteins. M cells and Peyer's patches in GIT, Lymphatic transport of drugs, Permeation enhancers-classification, mode of action
II (2 weeks)	**Formulation and Delivery Issues of Therapeutic Proteins:** rDNA technology, Specificity and Potency, Molecular medicine, Stability of Therapeutic proteins,
	Immunological properties of Protein therapeutics, Formulation and delivery approaches to overcome PK issues.

III (2 weeks)	**Nucleic Acid Based Therapeutics:** Introduction to Genetic diseases, Gene therapy, gene delivery systems, potential target diseases for gene therapy.
	Antisense chemistries, antisense molecules, Aptamers, Ribozymes etc. Current gene therapy of genetic diseases
IV (2 weeks)	**Biopharmaceuticals:** Preformulation studies, site specific proteins, protein post translational modifications.
	Process validation of biopharmaceuticals, Study of rDNA products Lispro, tPA, Myelotarg, Herceptin and Absciximab etc.
V (2 weeks)	**Formulation and Delivery aspects of Vaccines:** Principles of Immunity, mechanism of uptake and transport of antigens. Delivery systems used to promote uptake, requirements for an Ideal vaccine.
	Types of modern vaccines, vaccine adjuvant, micro particles for vaccine development, single dose vaccine delivery systems using bio degradable polymers.
VI (2 weeks)	**Bio molecules as delivery systems:** Monoclonal antibodies and engineered antibodies for drug delivery. Antibody-drug conjugates, limitations of antibody targeting.
	Overview of stem cells, artificial cells and their applications. Introduction to Microarrays in Drug Discovery and Development.
VII (2 weeks)	**Genomics, proteomics**: Definitions of genomics and proteomics and bio-informatics. Brief knowledge of human genome project.
	pharmaco genomics-genetic polymorphisms influencing drug disposition and effect on drug response
VIII (2 weeks)	**Regulatory assessment of controlled release products:** Bioavailability problems of oral controlled release products. Dissolution rate assessment, biopharmaceutical considerations in the regulatory assessment.
	Overview of intellectual property rights available for biotechnological innovations.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week.

Recommended Texts/Reference books:

1. Goldberg P E. Targeted Drugs, 1st ed. USA: John Wiley & Sons; 1983.
2. Dubey RC. Cell Biology, 1st ed. India: S. Chand Publishers; 2013.

3. Grietje Molema, Dirk KF,Meijer. Drug Targeting-Organ Specific Strategies, ISBN: 9783527600069. USA: Wiley online library; 2001.
4. Walker J M. The Protein Protocols Hand Book, 3rd ed. USA: Humana Press; 2009.
5. Crommelin DJA. Pharmaceutical Biotechnology, 4th ed. USA: Springer; 2013.
6. Kokate, Jalapure, Hurakadle. Pharmaceutical Biotechnology, 1st ed. India: Elsevier; 2011.
7. Cooper GM, Hausman RE. The Cell-A Molecular Approach, 6th ed. USA: Sinauer Associates Inc.; 2013.
8. Gerald Karp. Cell and Molecular Biology, 7th ed. USA: Wiley International; 2013.

Program /Year/Sem	M. Pharm (Pharmaceutics)
Year /Semester	First year / 2nd semester
Name of the course	Biopharmaceutics and Pharmacokinetics Practical
Course Code	16MPC205
Credits	4
Hours /week	6 hours
Pre / co-requisite/s	NIL

Course Description: The Biopharmaceutics and Pharmacokinetics practical 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.
CO2: 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

Week	Topics
1	To determine the effect of solid dispersion technique on dissolution rate of slightly soluble drug.
2	To perform the permeation study of given drug.
3	To determine the effect of solvent deposition technique on dissolution rate of slightly soluble drug.
4	To determine the effect of surfactant on dissolution of given drug.
5	Comparison of dissolution profiles of two different marketed products/brands
6	To determine the effect of complexation on solubility and dissolution of poorly soluble drug.
7	To determine the effect of polymorphism on solubility and dissolution of poorly soluble drug.

8	To determine the protein binding nature of a highly protein bound drug.
9	To determine the protein binding nature of a poorly protein bound drug.
10	Absorption studies in animal inverted intestine using various drugs.
11	Bioavailability studies and bio equivalence studies of the selected drug by salivary data.
12	To calculate the pharmacokinetic parameters of drug after IV bolus administration data
13	Calculation of K_a, K_e, $t_{1/2}$, C_{max}, T_{max} for two sets of data.
14	Calculation of absorption rate constant by Wagner Nelson method
15	Calculation of AUC and Bioequivalence from the given data of two drugs.
16	**Revision**

Assessment methods and weightage

Assessment type	**Assessment tool**	**Distribution**
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

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/

Programme	M. Pharm (Pharmaceutics)
Year /Semester	First year / 2^{d} semester
Name of the course	Controlled and Targeted Drug Delivery Systems Practical
Course Code	16MPC206
Credits	4
Hours /week	6 hours (laboratory)
Pre / co-requisite/s	Nil

Course Description: Novel Drug Delivery Systems practical course is aimed to train the students on skills of designing and preparation various novel drug delivery systems viz., microspheres, matrix tablets, transdermal systems etc. This course also deals with the evaluation of controlled drug delivery systems. It also emphasizes the study of drug release through various biological membranes.

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

CO 1: Demonstrate the skills on advanced techniques adopted in preparation and evaluation of various novel drug delivery systems.

CO2: Distinguish the study of drug permeation through various biological membranes

CO3: Formulate various navel drug delivery systems

CO 4: Evaluate microcapsules, microspheres, osmotic systems and other controlled release systems for standards.

Practical Course: Contents

Week	Topics
1	Preparation and Evaluation of microcapsules
2	Preparation and Evaluation of transdermal patch of drug
3	Preparation and evaluation of liposomal drug delivery systems
4	Preparation and evaluation of Bioadhesive tablets for gastric retention
5	Preparation and evaluation of microspheres
6	Preparation and evaluation of buccal patch of drug
7	Design of protein and peptide drug delivery
8	Development of matrix type sustained release drug delivery
9	Development of controlled release dosage form for oral use(elementary Osmotic pump)

10	Preparation and evaluation of oral disintegrating tablets
11	Preparation and evaluation of floating drug delivery systems
12	Preparation and evaluation of liposomes
13	Studying the role of permeation enhancers in drug transport across biological membranes.
14	Preparation and evaluation of drug immune conjugate (Demo)
15	Studying the drug transport across porcine buccal mucosa/ skin (hydrophilic lipophilic drugs)- (demo).

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Robinson JR, Lee VHI. Controlled drug delivery – Fundamentals and Applications. 2d Edi. New York: Marcel Dekker; 1982.
2. Jain NK. Progress in Controlled and Novel Drug Delivery Systems .1st Edi. New Delhi: CBS Publishers; 2005.
3. Jain NK. Controlled and Novel drug delivery. 1st Edi. New Delhi: CBS Publishers; 2012.
4. Chein YW, Novel drug delivery systems. 2d Edi. New York: Informa health care; 2011.
5. Vyas SP, Khar RK. Targeted and Controlled and Controlled Drug Delivery-Novel Carrier Systems. 1st Edi. New Delhi: CBS Publishers; 2010.
6. Roseman TJ, Mansdrif SZ. Controlled release drug delivery systems, 1st Edi. New York: Marcel dekker; 1983.
7. Xialo Ling L, Bhaskar RJ. Design of controlled releasese drug delivery systems 1st Edi. New York: McGraw Hill; 2006.
8. Research articles.

M.Pharmacy - Pharmacology

Program	Master of Pharmacy (M. Pharm)
Specialization	Pharmacology
Approved by	Academic council
Effective from	Students admitted from AY 2016-17

Plan of Study (Semester Wise)

M. Pharm: I-YEAR; SEM-1

Course code	Paper	Name of the course	Hrs /week	Credits
16MCP101	Theory	Modern methods of Pharmaceutical Analysis	4	4
16MCP102	Theory	Research methodology and Intellectual property rights	4	4
16MPL103	Theory	Basic and Molecular Pharmacology	4	4
16MPL104	Theory	Advanced Pharmacology and Toxicology	4	4
16MCP105	Practical	Modern methods of Pharmaceutical Analysis Practical	6	4
16MPL106	Practical	Advanced Pharmacology and Toxicology Practical	6	4
16MPL107	Research	Mini Project	4	2
16MPL108	Seminar	Presentations	--	1

M. Pharm: I-YEAR; SEM-2

Course code	Paper	Name of the course	Hrs /week	Credits
16MCP201	Theory	Biopharmaceutics and Pharmacokinetics	4	4
16MPL202	Theory	Cell and Molecular biology	4	4
16MPL203	Theory	Clinical Pharmacology & Pharmacotherapeutics	4	4
16MPL204	Theory	Screening methods in Pharmacology and clinical research	4	4
16MPL205	Practical	Clinical Pharmacology & Molecular Biology- Practical	6	4
16MPL206	Practical	Screening methods in Pharmacology and clinical research - Practical	6	4
16MPL207	Research	Mini-project	4	2
16MPL208	Seminar	Presentations	--	1

M. Pharm: II-YEAR; SEM-1

Course code	Paper	Name of the course	Hrs /week	Credits
16MPL301	Assignment	Assignment (Problem based Exercise)	6	3
16MPL302	Seminar	Presentation (Journal club)	--	2
16MPL303	Research	Dissertation (Continuation to semester 2)	--	--

M. Pharm: II-YEAR; SEM-2

Course code	Paper	Name of the course	Hrs /week	Credits
16MPL401	Research	Dissertation / Defence VIVA	--	16

For Modern Methods of Pharmaceutical Analysis (Theory & Practical): Course description, course learning outcomes, course contents and Assessment methods and weightage refer above the specialization of Pharmaceutical Analysis and Quality Assurance

For Research methodology and Intellectual property rights (Theory): Course description, course learning outcomes, course contents and Assessment methods and weightage refer above the specialization of Pharmaceutical Analysis and Quality Assurance

programme	M. Pharm (Pharmacology)
Year /Semester	First year / 1st semester
Name of the course	Basic and Molecular Pharmacology
Course Code	16MPL103
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:
This course aimed to provide the knowledge on molecular mechanism and stereo selectivity of drug action. This course emphasizes biological role and functions of inflammatory mediators such as autacoids, nitric oxide and cytokines. This course also covers about immune cells, immune organs, immune system, immunomodulators and various aspects of prodrug design.

Course Learning Outcomes: Upon successful completion of this course, the student should be able to:
CO 1: Discuss the importance of receptors and their role in drug discovery and development
CO 2: Interpret the role of mediators in inflammation and allergy
CO 3: Describe the importance of immune cells, immune organs and immunomodulators
CO 4: Summarize the concept of prodrugs and various aspects governing prodrug design

Theory: Course Contents

Unit	Topics
I (2 weeks)	Receptor Pharmacology: Drug receptor interaction theories, spare receptors, silent receptors, orphan receptors, presynaptic and postsynaptic receptors.
	Receptor characterization methods, receptor down regulation and upregulation.
II (2 weeks)	Stereo selectivity of drug action, structural activity relationships, pharmacodynamic and pharmacokinetic aspects of chiral drugs.
	Allosteric binding, thermodynamics of drug interactions with the receptors.
III (2 weeks)	Neurotransmitter receptor mechanism: G-protein linked receptors, Ionotropic receptors, Enzymatic receptors and Nuclear receptors.
	Receptor expression and regulation with specific emphasis on adrenergic, dopaminergic, cholinergic, seratonergic, histaminenargic, opioid, GABA and excitatory aminoacid receptors and their sub types with agonists and antagonists.
IV (2 weeks)	Mediators of inflammation and allergy: Autacoids (histamine, bradykinin, PAF, eicosanoids and related compounds), nitric oxide/EDRF, vascular substances, oxygen free radicals and their scavengers.

	Cytokines and their actions, Cox-I, Cox-II inhibitors and their load in inflammatory process, anti-inflammatory agents, asthma and COPD.
V (2 weeks)	Immunopharmacology: a) Basic principles- Types of immunity, cells of immune system, organs of immune system, immune tolerance, autoimmunity, hypersensitivity reactions.
	b) Immunomodulators (immunosuppressants and immunostimulants), AIDS and Rheumatoid arthritis.
VI (2 weeks)	Principles of drug action: Receptor mediated and nonreceptor mediated drug action
	Drug action through stimulation, depression, irritation, adsorption and chelation
VII (2 weeks)	Microbial conversions as tools in the preparation of drugs: Introduction, practical aspects of microbial transformation.
	Theoretical aspects of microbial transformation, Microbial transformation of steroids and conversion by microorganisms.
VIII (2 weeks)	Prodrugs: Definition, applications of prodrugs, classification of prodrugs and various aspects governing prodrug design.
	Prodrug approaches for enhancing administration, permeability, absorption and distribution of drugs. Prodrug approaches for CNS delivery and targettability.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

1. Tripathi KD. Essentials of Medical Pharmacology. 6thed. New Delhi: Jaypee Brothers; 2009.
2. Rang HP, Dale MM and Ritter JM. Pharmacology.6thed.Edinburgh: Churchill living stone; 2003.
3. David E. Golan, Armen H. Tashjian and April W. Armstrong. Principles of pharmacology: the pathophysiological basis of drug therapy.2nded. Philadelphia: Lippincott Williams & Wilkins; 2008.
4. Bertram G. Katzung. Basic and clinical pharmacology. 10thed. New York: Mc Graw-Hill; 2006.

5. Satoskar RS, Bhandarkar SD and Nirmala N.Rege. Pharmacology and Pharmacotherapeutics.19th ed. Mumbai: Popular prakashan; 2005.
6. Hardman JG and Lee E. Limbard. Good Man & Gillman's the Pharmacological basis of therapeutics. 11th ed.USA: Mc Grawhill; 2006.
7. Karen Whalen, Richard Finkel and Thomas A Panavelil. Illustrated reviews Pharmacology. 6th ed. China: Lippincott, Williams and Wilkins; 2014.
8. Thomas L.Lemke and David A.Williams. Foye's Principles of Medicinal Chemistry.7th ed. Philadelphia: Lippincott, Williams and Wilkins; 2012.
9. Charles Owens Wilson, John Marlowe Beale and Jr. John H.Block. Textbook of organic medicinal and pharmaceutical chemistry by Wilson and Gisvold. 12th ed. Philadelphia: Lippincott Williams and Wilkins; 2012.
10. Anthony Fauci, Dennis Kasper, Stephen Hauser, Dan Longo, Larry Jameson and Mc Graw Hill. Harrison's Principles of internal medicine.19th ed. New York: Mc Gram Hill; 2015.

Programme	M. Pharm (Pharmacology)
Year /Semester	First year / 1st semester
Name of the course	Advanced Pharmacology and Toxicology
Course Code	16MPL104
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:
This course aimed to provide the knowledge on drugs acting on various systems and organs such as nervous system, circulatory system, respiratory tract, gastrointestinal tract and kidney. This course covers recent developments in chemotherapeutic agents. This course also emphasizes about general principles of toxicology and treatment of different poisoning conditions.

Course Learning Outcomes: Upon successful completion of this course, the student should be able to:
CO 1: Explain pharmacology of drugs acting on various systems and organs
CO 2: Relate recent developments in chemotherapy to avoid multi drug resistance
CO 3: Identify the new targets for the treatment of various diseases and disorders
CO 4: Describe the treatment of different poisoning conditions

Theory: Course Contents

Unit	Topics
I (2 weeks)	Drugs acting on central nervous system: Antiparkinsonism agents, antipsychotics, antidepressants and antiepileptics.
	Antialzheimer's agents, analgesics, anxiolytics, hypnotics and general anaesthetics.
II (2 weeks)	Drugs acting on autonomic nervous system: Sympathomimetics, sympatholytics and parasympathomimetics.
	Parasympatholytics, neuromuscular junction blockers and ganglionic blockers.
III (2 weeks)	Drugs acting on cardiovascular system: Antihypertensives and cardiotonics.
	Antiarrhythmics, antianginals and antiatherosclerotic agents.
IV (2 weeks)	a. Drugs acting on hormones: Thyroid, male and female sex hormones. Antithyroid drugs and antidiabetics.
	b. Blood and blood forming agents: Coagulants, anticoagulants, antiplatelet drugs, fibrinolytics and antifibrinolytics.

V (2 weeks)	Drugs acting on GIT, respiratory tract and kidney: GIT- Antiulcer agents, emetics, antiemetics, laxatives and antidiarrheal agents
	Respiratory tract- Antiasthmatics, Kidney- Diuretics and antidiuretics
VI (2 weeks)	Recent developments in chemotherapeutic agents: Mechanism of multi drug resistance (MDR), antibacterial and antiviral agents
	Antiprotozoal agents, anthelmintics and cancer chemotherapy.
VII (2 weeks)	Toxicology: Definition, scope and general principles of toxicology. Dose-response relationship, factors influencing toxicity.
	Target organ toxicity- Neuronal, behavioural, kidney, pulmonary, hepatic, cutaneous, ototoxicity, haematotoxicity, mutagenicity, carcinogenicity and reproductive toxicity.
VIII (2 weeks)	Pharmacotherapy of alcohol, barbiturate, opioid and organophosphorous poisoning.
	Pharmacotherapy of paracetamol, heavy metal poisoning and snake bite.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

1. Tripathi KD. Essentials of Medical Pharmacology. 6thed. New Delhi: Jaypee Brothers; 2009.
2. Rang HP, Dale MM and Ritter JM. Pharmacology.6thed.Edinburgh: Churchill living stone; 2003.
3. David E. Golan, Armen H. Tashjian and April W. Armstrong. Principles of pharmacology: the pathophysiological basis of drug therapy.2nded. Philadelphia: Lippincott Williams & Wilkins; 2008.
4. Bertram G. Katzung. Basic and clinical pharmacology. 10thed. New York: Mc Graw-Hill; 2006.

5. Satoskar RS, Bhandarkar SD and Nirmala N.Rege. Pharmacology and Pharmacotherapeutics.19th ed. Mumbai: Popular prakashan; 2005.
6. Hardman JG and Lee E. Limbard. Good Man & Gillman's the Pharmacological basis of therapeutics. 11th ed.USA: Mc Grawhill; 2006.
7. Karen Whalen, Richard Finkel and Thomas A Panavelil. Illustrated reviews Pharmacology. 6th ed. China: Lippincott, Williams and Wilkins; 2014.
8. Thomas L.Lemke and David A.Williams. Foye's Principles of Medicinal Chemistry.7th ed. Philadelphia: Lippincott, Williams and Wilkins; 2012.
9. Charles Owens Wilson, John Marlowe Beale and Jr. John H.Block. Textbook of organic medicinal and pharmaceutical chemistry by Wilson and Gisvold. 12th ed. Philadelphia: Lippincott Williams and Wilkins; 2012.
10. Anthony Fauci, Dennis Kasper, Stephen Hauser, Dan Longo, Larry Jameson and Mc Graw Hill. Harrison's Principles of internal medicine.19th ed. New York: Mc Gram Hill; 2015.

Programme	M. Pharm (Pharmacology)
Year /Semester	First year / 1st semester
Name of the course	Advanced Pharmacology and Toxicology Practical
Course Code	16MPL106
Credits	4
Hours /week	6 hours
Pre / co-requisite/s	NIL

Course Description:
This course designed to provide laboratory skill on handling of animals, routes of administration of drugs in animals and collection of blood samples by different techniques. This course deals with recording of dose response curves and conducting different bioassays. This course also provides the knowledge on estimation of haematological parameters and their clinical importance.

Course Learning Outcomes: Upon successful completion of this course, the student should be able to:
CO 1: Demonstrate the handling of animals, routes of administration of drugs in animals and collection of blood samples.
CO 2: Estimate the unknown concentration of drug by employing different bioassays
CO 3: Analyze the different haematological parameters for their role in diseased states

Practical: Course Contents

Week	Topics
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 anaesthetics in laboratory animals.
5	Study the routes of administration of drugs in animals (Rats, Mice, Rabbits)
6	Collection of blood samples by various techniques
7	Effect of mydriatics and miotics on rabbit eye
8	Record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
9	Study of agonistic and antagonistic effects of drugs using isolated ileum/ rectus abdominis muscle preparation

10	To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
11	To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by matching method.
12	To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
13	To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by four point method
14	Effect of various drugs on rat uterus preparation
15	Cumulative dose response curve of acetylcholine on isolated ileum/rectus abdominis muscle preparation
16	Estimation of haematological parameters by using semiautoanalyser

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Gerhard Vogel H, Wolfgang H. Vogel, Bernward A. Scholkens, Jurgen Sandow and gunter Muller. Drug Discovery and Evaluation: Pharmacological Assays. 3rd ed. New York: Spinger-Verlag Berlin Heidelberg; 2008.
2. Parmar N. S and Shiv Prakash. Screening Methods in Pharmacology. 2nd ed. Oxford U K: Alpha science international; 2015.
3. Robert Arnold Turner. Screening Methods in Pharmacology two volumes. 2nd ed. New York: Academic press; 2009.
4. Gupta S K. Drug Screening Methods.2nd ed. New Delhi: Jaypee brothers medical publishers; 2009.
5. Avanapu Srinivasa Rao and Namburi Bhagya Lakshmi. Pharmacological Screening Methods and Toxicology.1st ed. Hyberabad: PharmaMed press; 2014.

For Biopharmaceutics and Pharmacokinetics (Theory): Course description, course learning outcomes, course contents and Assessment methods and weightage refer above the specialization of Pharmaceutics.

programme	M. Pharm (Pharmacology)
Year /Semester	First year / 2nd semester
Name of the course	Cell & Molecular Biology
Course Code	16MPL202
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:

This course discusses role of gene in cells, elucidation of genetic code, gene expression, genetic elements that control gene expression. The course also emphasizes r-DNA biotechnological aspects. This course further recognises the advances and new strategies for the treatment of cancer.

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

CO 1: Discuss the importance of cell and molecular biology by acquiring knowledge of rDNA, pharmacokinetics and pharmacodynamics of peptides and protein based drugs.

CO 2: Illustrates the techniques of DNA isolation, transformation, mutagenicity and drug interaction.

CO 3: Propose the reasons for genetic diseases based on the type of gene function, gene expression, regulation and mutations.

CO 4: Explains the basics of cancer and genetics associated with cancer.

Theory: Course Contents

Unit	Topics
I (2 weeks)	**The Cell**: Structure of Cell, functions of Plasma membrane: Transport of nutrients, ions and macromolecules across membranes. Diseases related to ion channels.
	Transporters, Cell cycle- Different phases of cell cycle, Controls and Check points, Cellular ageing, Apoptosis-PCD, Diseases related Cellular ageing.
II (2 weeks)	**Cell Communication**: General principles of signalling–endocrine, exocrine & synaptic signaling, surface and intracellular receptors.
	G-proteins and generation of secondary messenger, mode of action of cAMP and ca^{++} calmodulin, mechanisms of signal transduction.
III (2 weeks)	**Genome organization:** Gene concept, replication, recombination, mutation, fine structure of gene and role of genes in cells.
	Special features of eukaryotic gene structure, genetic code, gene expression and regulation.

IV (2 weeks)	**r-DNA aspects**: Gene Cloning Vectors, Plasmids, bacteriophages, phagemids, cosmids, artificial chromosomes, Monoclonal antibodies (Mab), Stem cells, Alternative Strategies of Gene Cloning.
	Nucleic acid microarray, construction and screening of genomic libraries, Current methods in gene therapy.
V (2 weeks)	**Molecular Mapping of Genome**: Genetic and physical maps, physical mapping, sequencing of gene. Southern and fluorescence insitu hybridization for genome analysis. Molecular markers in genome analysis.
	Restriction Fragment Length Polymorphism (RFLP), Random Amplified Polymorphic DNA (RAPD) and Amplified Fragment Length Polymorphism (AFLP) analysis, Polymer Chain Reactions (PCR) based analysis; molecular markers linked to disease resistance genes.
VI (2 weeks)	**Advanced Immunology**: Regulation of immune response, Antigen processing and presentation, Generation of humoral and cell mediated immune responses-Activation of B- and T-lymphocytes
	Cytokines and their role in immune regulation, T-cell regulation, MHC restriction-Immunological tolerance, immunogenecity of protein therapeutics
VII (2 weeks)	**Nucleic acid hybridization**: Principles and applications, preparation of probes, principles of nucleic acid hybridization.
	Nucleic acid hybridization assays and micro assays. ELISA, protein gel electrophoresis.
VIII (2 weeks)	**Cancer:** Basic properties of a cancer cell, causes of cancer, the genetics of cancer, oncogenes, tumour-suppressor genes.
	New strategies for combating cancer, inhibiting the activity of cancer promoting proteins.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

1. Hardman JG, Lee E. Limbard. Good Man & Gillman's the Pharmacological basis of therapeutics. 11th ed.USA: Mc Grawhill; 2006.
2. Kokate, Jalalpure , Hurakadle. Pharmaceutical Biotechnology, 1st edition. India: Elsevier; 2011.
3. Dubey RC. Advanced Biotechnology, 1st ed. India: S.Chand Publishers; 2014.
4. Gerald Karp. Cell and Molecular Biology, 8th ed. USA: Wiley International Inc; 2016.
5. Robertis EDP. Cell and Molecular Biology, 8th ed. USA: Lippincott Williams &Wilkins; 2013.
6. Rang H. P, Dale MM, Ritter JM. Pharmacology, 4th ed. UK: Churchill Livingston; 2001.
7. Richard AG, Kuby J. Immunology, 5th ed. USA: W.H.Freeman& Co Ltd; 2002.
8. Gupta PK. Genetics, 3rd ed. India: Rastogi publications; 2005.
9. Arugumam N. Cell Biology & Molecular Biology, 1st ed. India: Saras Publications; 2014.

Programme	M. Pharm (Pharmacology)
Year /Semester	First year / 2nd semester
Name of the course	Clinical Pharmacology and Pharmacotherapeutics
Course Code	16MPL203
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:
This course aimed to impart knowledge and skill necessary for quality use of medicine. This course covers basic principles of pharmacokinetics, pathophysiology and therapeutics of various diseases. This course enables the student to understand about therapeutic drug concentration monitoring and influence of renal and hepatic diseases on pharmacokinetics. This course also emphasizes about drug Interactions, adverse drug reactions and pharmacovigilance.

Course Learning Outcomes: Upon successful completion of this course, the student should be able to:
CO 1: Describe the etiology and pathogenesis of various diseases and disorders
CO 2: Explain the pathophysiology of various diseases and disorders and their rational for drug therapy
CO 3: Identify the drug interactions and adverse drug reactions
CO4: Enumerate the drug therapy in Geriatrics, Paediatrics, Pregnancy and Lactation

Theory: Course Contents

Unit	Topics
I (2 weeks)	Principles of Pharmacokinetics: a. Revision of basic concepts b. Mechanism and factors affecting drug absorption, distribution, metabolism and elimination.
	c. Drug Selection, dosage regimen design and patient compliance d. Influence of renal and hepatic diseases on pharmacokinetics e. Therapeutic drug concentration monitoring
II (2 weeks)	Drug interactions: Drug-drug interactions, drug-food interactions and drug-herb interactions
	Adverse drug reactions, ADR monitoring and Pharmacovigilance.
III (2 weeks)	Pathophysiology and drug therapy of the following disorders: Schizophrenia, depression, epilepsy, parkinson's and alzheimer's diseases.
	Hypertension, congestive heart failure, angina pectoris, arrhythmias, atherosclerosis and myocardial infraction.

IV (2 weeks)	Pathophysiology and drug therapy of the following disorders: Tuberculosis, leprosy, leukaemia, solid tumours, lymphomas, psoriasis and endocarditis.
	Fungal infection, HIV infection, rheumatoid arthritis, glaucoma and menstrual disorders.
V (2 weeks)	Drug therapy in Geriatrics: Introduction, pharmacokinetic and pharmacodynamic alterations in geriatrics.
	Physiological variables in geriatrics and dose adjustment in geriatrics
VI (2 weeks)	Drug therapy in Paediatrics
	Drug therapy in Pregnancy & Lactation
VII (2 weeks)	Pharmacogenetics: Genotype, phenotype and genetic polymorphism
	Inter-racial and individual variability in drugs metabolism, slow metabolizers, fast metabolizers and their clinical importance
VIII (2 weeks)	Orphan diseases and its management: Definition for orphan diseases and orphan drugs, orphan drug act, orphan drug status.
	Hazards of orphan drugs, orphan devices, orphan receptors and orphan vaccines.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

1. Tripathi KD. Essentials of Medical Pharmacology. 6thed. New Delhi: Jaypee Brothers; 2009.
2. Rang HP, Dale MM and Ritter JM. Pharmacology.6thed.Edinburgh: Churchill living stone; 2003.
3. David E. Golan, Armen H. Tashjian and April W. Armstrong. Principles of pharmacology: the pathophysiological basis of drug therapy.2nded. Philadelphia: Lippincott Williams & Wilkins; 2008.
4. Bertram G. Katzung. Basic and clinical pharmacology. 10thed. New York: Mc Graw-Hill; 2006.

5. Satoskar RS, Bhandarkar SD and Nirmala N.Rege. Pharmacology and Pharmacotherapeutics.19th ed. Mumbai: Popular prakashan; 2005.
6. Hardman JG and Lee E. Limbard. Good Man & Gillman's the Pharmacological basis of therapeutics. 11th ed.USA: Mc Grawhill; 2006.
7. Karen Whalen, Richard Finkel and Thomas A Panavelil. Illustrated reviews Pharmacology. 6th ed. China: Lippincott, Williams and Wilkins; 2014.
8. Thomas L.Lemke and David A.Williams. Foye's Principles of Medicinal Chemistry.7th ed. Philadelphia: Lippincott, Williams and Wilkins; 2012.
9. Charles Owens Wilson, John Marlowe Beale and Jr. John H.Block. Textbook of organic medicinal and pharmaceutical chemistry by Wilson and Gisvold. 12th ed. Philadelphia: Lippincott Williams and Wilkins; 2012.
10. Anthony Fauci, Dennis Kasper, Stephen Hauser, Dan Longo, Larry Jameson and Mc Graw Hill. Harrison's Principles of internal medicine.19th ed. New York: Mc Gram Hill; 2015.

Programme	M. Pharm (Pharmacology)
Year /Semester	First year / 2nd semester
Name of the course	Screening Methods in Pharmacology and Clinical Research
Course Code	16MPL204
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description:
This course aimed to provide knowledge on drug research and drug development process. This course covers about various aspects of drug discovery process, bioassays, toxicity studies and preclinical screenings models. This course also discuss about alternative methods to animal screening procedures in drug discovery process.

Course Learning Outcomes: Upon successful completion of this course, the student should be able to:
CO 1: Enumerate the various preclinical models employed in the screening of new drugs.
CO 2: State the basic principles of bioassays and biological standardization of vaccines and hormones
CO 3: Summarize the protocol for toxicity evaluation and determination of LD_{50} value
CO4: Adapt alternative methods to animal screening procedures in drug discovery process.

Theory: Course Contents

Unit	Topics
I (2 weeks)	Drug discovery process: Principles, techniques and strategies used in new drug discovery. High throughput screening.
	Regulations for laboratory animal care and ethical requirements. Medical Writing and clinical data management.
II (2 weeks)	Bioassays: Basic principles of bioassays, official bioassays, experimental models and statistical designs employed in biological standardization. Biological standardization of vasopressin, digitalis and oxytocin.
	Biological standardization of acetylcholine, adrenaline, insulin, d-tubocurarine, HCG, hyaluronidase, corticotrophin, pertussis, rabies and plague vaccine.
III (2 weeks)	Preclinical models employed in the screening of new drugs belonging to following categories-I: Antifertility agents, Sympathomimetics, parasympathomimetics, sedatives and hypnotics.
	Antiarrhythmic agents, antihypertensives, cardioprotectives, cardiotonics, bronchodilators and antihistaminics.

IV (2 weeks)	Preclinical models employed in the screening of new drugs belonging to following categories-II: Antipsychotic agents, antianxiety agents, nootropic drugs, antidepressant drugs, antiparkinsonian agents and antiepileptics.
	Analgesics, antiinflammatory agents, antiulcer agents, antiatherosclerotic drugs and hepatoprotectives.
V (2 weeks)	Preclinical models employed in the screening of new drugs belonging to following categories-III: Antimalarials, anthelmintics and antidiabetics.
	Models for Rheumatoid arthritis, urolithiasis and status epilepticus. Transgenic animals.
VI (2 weeks)	Alternatives to animal screening procedures: Cell-line technique and patch – clamp technique
	In-vitro models and molecular biology techniques.
VII (2 weeks)	Principles of toxicity evaluations: ED_{50}, LD_{50} and TD values
	ICH recommendations for toxicity and safety evaluation
VIII (2 weeks)	Drug development process: Clinical trials, WHO and Drugs control authorities, preparation of IND/NDAs
	Statistical design in clinical trials, data analysis technique and presentation skills

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Recommended Texts/Reference books:

1. Gerhard Vogel H, Wolfgang H. Vogel, Bernward A. Scholkens, Jurgen Sandow and gunter Muller. Drug Discovery and Evaluation: Pharmacological Assays. 3rd ed. New York: Spinger-Verlag Berlin Heidelberg; 2008.

2. Parmar N. S and Shiv Prakash. Screening Methods in Pharmacology. 2nd ed. Oxford U K: Alpha science international; 2015.

3. Robert Arnold Turner. Screening Methods in Pharmacology two volumes. 2nd ed. New York: Academic press; 2009.

4. Gupta S K. Drug Screening Methods.2nd ed. New Delhi: Jaypee brothers medical publishers; 2009.

5. Avanapu Srinivasa Rao and Namburi Bhagya Lakshmi. Pharmacological Screening Methods and Toxicology.1st ed. Hyberabad: PharmaMed press; 2014.

programme	M. Pharm (Pharmacology)
Year /Semester	First year / 2nd semester
Name of the course	Clinical Pharmacology and Molecular Biology Practical
Course Code	16MPL205
Credits	4
Hours /week	6 hours
Pre / co-requisite/s	NIL

Course Description: This course aimed to provide laboratory skills on mutagenicity based chromosomal aberrations, transformation of bacteria, and isolation of plasmid DNA. This course also designed to provide basic concepts of bio analytical studies. This course also deals with wet laboratory based experiments on antigen-antibody reactions, HPLC and bioinformatics tools.

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

CO 1: Demonstrate the skills involved in isolation of DNA, Cell culture techniques.

CO2: Distinguishes appropriate procedure and bio analytical methods required in pharmaceutical research.

CO 3: Proposes software's related to bioinformatics for interpretations.

Practical: Course Contents

Week	Topics
1	Isolation of DNA from bacterial cells and its quantification.
2	Isolation, purification, quantification and separation of plasmidDNA
3	Preparation of Tissue culture medium & membrane filtration
4	Isolation of DNA from cell culture
5	Testing for microbiological quality of potable water (Coliform test)
6	Gel electrophoresis of DNA and BSA
7	Micro-hemagglutinationTest
8	Sandwitch Enzyme-Linked Immuno-Sorbent Assay(ELISA) to test antigen concentration
9	Quantitative determination of proteins by Biuret and Lowry's methods or Ninhydrin test
10	Separation and Identification of bio molecules by thin layer chromatography

	(TLC)/ gel filtration.
11	Separation and identification of biochemical compounds by HPLC
12	Drug mutagenicity studies using mice bone-marrow chromosomal aberration tests.
13	Online searching of various databases (nucleic acids, proteins, organisms) using different bioinformatics tools.
14	Minimum Inhibitory Concentration of Streptomycin / Penicillin.
15	Revision

Assessment methods and weightage

Assessment type	**Assessment tool**	**Distribution**
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Rana SVS. Biotechniques, 1st ed. India: Rastogi Publications; 2005.
2. Dubey RC, Maheswari DK. Practical Microbiology, 2nd ed. India: S. Chand & Company Ltd; 2006.
3. John MW. The Protein Protocols Hand Book, 3rded.USA: Humana Press; 2009.
4. Carson, Susan. Molecular Biology Techniques, 3rd ed. Netherlands: Science Direct-Elsevier Inc; 2012.

Programme	M. Pharm (Pharmacology)
Year /Semester	First year / 2nd semester
Name of the course	Screening Methods in Pharmacology and Clinical Research Practical
Course Code	16MPL206
Credits	4
Hours /week	6 hours
Pre / co-requisite/s	NIL

Course Description:
This course designed to provide knowledge on various preclinical screening models which are necessary for drug discovery and drug development process. This course deals with organization of screening which include simple screening, programmed screening and blind screening. This course also provides the knowledge on determination of PA_2 value for antagonists.

Course Learning Outcomes: Upon successful completion of this course, the student should be able to:
CO 1: Perform various preclinical screening procedures
CO 2: Estimate PA_2 value for antagonists
CO 3: Differentiate simple screening, programmed screening and blind screening

Practical: Course Contents

Week	Topics
1	Organization of screening
2	Screening of analgesic activity by thermal methods
3	Screening of analgesic activity by acetic acid induced writhing method
4	Screening of antiinflammatory activity by using carrageenan induced paw oedema method in rats
5	Screening of CNS stimulant and CNS depressant activity by using Actophotometer
6	Screening of antidepressant activity by forced swimming test
7	Screening of antidepressant activity by Tail suspension test
8	Screening of psychotropic agents by using Pole climbing response apparatus
9	Screening of antianxiety activity by using Elevated plus maze

10	Screening of antianxiety activity by Stair case test
11	Screening of muscle relaxant property by using Rota rod apparatus
12	Screening of General anaesthetics
13	Screening of Antiulcer agents
14	Screening of Diuretic agents
15	Screening of Anthelmintics
16	Determination of PA2 value of Atropine using Acetylcholine as agonist employing Rat ileum preparation.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Gerhard Vogel H, Wolfgang H. Vogel, Bernward A. Scholkens, Jurgen Sandow and gunter Muller. Drug Discovery and Evaluation: Pharmacological Assays. 3rd ed. New York: Spinger-Verlag Berlin Heidelberg; 2008.

2. Parmar N. S and Shiv Prakash. Screening Methods in Pharmacology. 2nd ed. Oxford U K: Alpha science international; 2015.

3. Robert Arnold Turner. Screening Methods in Pharmacology two volumes. 2nd ed. New York: Academic press; 2009.

4. Gupta S K. Drug Screening Methods.2nd ed. New Delhi: Jaypee brothers medical publishers; 2009.

5. Avanapu Srinivasa Rao and Namburi Bhagya Lakshmi. Pharmacological Screening Methods and Toxicology.1st ed. Hyberabad: PharmaMed press; 2014.

M. Pharmacy – Pharmacy Practice

Programme	Master of Pharmacy (M. Pharm)
Specialization	Pharmacy Practice
Approved by	Academic council
Effective from	Students admitted from AY 2016-17

Plan of Study: Semester wise

M. Pharm: I-YEAR; SEM-1

Course code	Paper	Name of the course	Hrs /week	Credits
16MCP101	Theory	Modern methods of Pharmaceutical Analysis	4	4
16MCP102	Theory	Research methodology and Intellectual property rights	4	4
16MPP103	Theory	Pharmacotherapeutics-I	4	4
16MPP104	Theory	Hospital and Community Pharmacy	4	4
16MCP105	Practical	Modern methods of Pharmaceutical Analysis - Practical	6	4
16MPP106	Practical	Hospital and Community Pharmacy - Practical	6	4
16MPP107	Research	Mini Project	4	2
16MPP108	Seminar	Presentations	--	1

M. Pharm: I-YEAR; SEM-2

Course code	Paper	Name of the course	Hrs /week	Credits
16MCP201	Theory	Biopharmaceutics and Pharmacokinetics	4	4
16MPP202	Theory	Pharmacotherapeutics-II	4	4
16MPP203	Theory	Clinical Pharmacy Practice	4	4
16MPP204	Theory	Clinical Research and Development	4	4
16MPP205	Practical	Pharmacotherapeutics-II Practical	6	4
16MPP206	Practical	Clinical Pharmacy Practice Practical	6	4
16MPP207	Research	Mini-project	4	2
16MPP208	Seminar	Presentations	--	1

M. Pharm: II-YEAR; SEM-3

Course code	Paper	Name of the course	Hrs /week	Credits
16MPP301	Assignment	Assignment (Problem based Exercise)	6	3
16MPP302	Seminar	Presentation (Journal club)	--	2
16MPP303	Research	Dissertation (Continuation to semester 2)	--	--

M. Pharm: II-YEAR; SEM-4

Course code	Paper	Name of the course	Hrs /week	Credits
16MPP401	Research	Dissertation / Defence VIVA	--	16

For Modern Methods of Pharmaceutical Analysis (Theory & Practical): Course description, course learning outcomes, course contents and Assessment methods and weightage refer above the specialization of Pharmaceutical Analysis and Quality Assurance

For Research methodology and Intellectual property rights (Theory): Course description, course learning outcomes, course contents and Assessment methods and weightage refer above the specialization of Pharmaceutical Analysis and Quality Assurance

program	M. Pharm (Pharmacy Practice)
Year /Semester	First year / 1st semester
Name of the course	Pharmacotherapeutics-I (Theory)
Course Code	16MPP103
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description: The course progression is to provide the student with the foundational concepts and skills work desired to practice pharmacy in the current scenario as the role of the pharmacist the profession which is expanding and continuously changing. In addition to the knowledge of the scientific basis of practice, the capacity to communicate and be an effective health care team member is critical to the pharmacist's role as an educator, clinician, and member of the health-care team. Likewise, the student will experience the process of individual and group-assessment, team progress, and the use of effective communication strategies through discussions, assignments, role-playing, and case studies.

Course Learning Outcomes: Upon completion of the course, it is expected that students will be able to

CO 1: Describe the Pathophysiology of selected disease states and explain the rationale for drug therapy.

CO 2: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence.

CO 3: Use standard clinical guidelines as part of evidence based medicine.

CO 4: Discuss the preparation of individualized therapeutic plans.

CO 5: 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 outcomes)

Theory: Course Contents

Unit	Topics
I (2 weeks)	**Haematological diseases:** Blood and body fluids, complications of blood transfusion and blood substitutes, Anaemia, Drug induced haematological disorder.
II (2 weeks)	**Immunology:** Immune disease – pathogenesis, immunoglobulins, mechanism of action of drugs, immunosuppressive actions in tissue as well as organ transplantation, auto-immunity, mechanism of autoimmune disease, pathogenesis of autoimmunity.
III (2 weeks)	**Pain management:** Pathophysiology of inflammation and repair, pain pathways, Analgesics and NSAIDs, opiates, local anaesthetics, neuralgia and skeletal muscle relaxants.

IV (2 weeks)	**Bone and joint Disorders:** Osteoporosis, rheumatoid arthritis, Osteoarthritis, gout, Paget's disease of bones.
V (2 weeks)	**Endocrine system:** Diabetes, thyroid diseases, liver disorders, Disorders of pituitary gland and hormone replacement therapy.
VI (2 weeks)	**Gastrointestinal system:** Classification and pathogenesis of different types of Ulcer diseases and its management, inflammatory bowel diseases, diarrhoea and constipation.
VII (2 weeks)	**Nervous system:** Epilepsy, Parkinson's and Alzheimer's diseases, stroke and transient ischemic attacks, headache and migraine.
VIII (2 weeks)	**Psychiatric disorders:** Schizophrenia, mania and depression, anxiety disorders and sleep disorders.

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Learning Resources/Recommended Texts/Reference books/web resources

1. 1. Roger Walker, Cate Whittles. Clinical Pharmacy and Therapeutics. 4th ed. Churchill Livingstone; 2012.
2. Joseph T Dipiro et. al. Pharmacotherapy: A Pathophysiological approach. 6th ed. McGraw hill Publication. 2011
3. Robins S L, W B. Saunders. Pathologic Basis of Disease. Stanley Leonard Robbins. 5th ed. W. B. Saunders Company; 2004
4. Russell J Greene, Norman D Harris. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice. 3rd ed. Pharmaceutical Press; 2008.
5. Eric T Herfindal, Joseph L Hirschman. Clinical Pharmacy and therapeutics. 5th ed. Williams and Wilkins Publication; 1992.
6. Lloyd Young, Koda-Kimble M A. Applied Therapeutics: the clinical use of drugs. 3rd ed. Lippincott Williams and Wilkins publication; 1983. [ISBN 0 333-65881-7]
7. T M Speight, N H Holford. *Avery's Drug Treatment.* 4th ed. Auckland. Wiley - Black well - Adis international limited; 1997.

Program	M. Pharm (Pharmacy Practice)
Year /Semester	First year / 1st semester
Name of the course	Hospital and Community Pharmacy (Theory)
Course Code	16MPP104
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

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

Unit	Topics
I (2 weeks)	The role of the hospital pharmacy department and its relationship to other hospital departments and staff. Hospital drug policy, Drug Committees, Pharmacy & Therapeutics committee, Infection Control committee and Formulary development.
II (2 weeks)	**Hospital Pharmacy Management:** Staff (professional and non-professional), Materials (drugs, non-drugs, consumables), Financial (drug budget, cost centers, sources of revenue, revenue collection), Policy and planning, Infrastructure requirements (building, furniture and fittings, specialised equipment, maintenance and repairs), Workload statistics.
III (2 weeks)	**Organisation of Hospital Pharmacy Services:** Drug distribution, Purchasing, Warehousing (storage conditions, expiry date control, recycling of drugs, stocktaking, drug recalls), Drug distribution methods (ward stock, individual patient dispensing, unit dose)

IV (2 weeks)	Specific requirements for inpatients, outpatients, Casualty/Emergency, Operation Theatres, ICU/CCU, Drugs of dependence, Hospital waste management, Drug stores management, organization of Drug Store, Purchase and Procurement, Inventory control (Principles, methods of inventory control) and stores management.
V (2 weeks)	The role of the community pharmacy and its relationship to other local health care providers and services to nursing homes and clinics. Prescribed medication order-interpretation and legal requirements. Communication skills-communication with prescribers and patients.
VI (2 weeks)	Over-the-counter (OTC) sales, Rational use of common OTC medications (Vitamins and tonics, iron preparations, analgesics, NSAIDs, cough mixtures, anti-diarrhoeal preparations)
VII (2 weeks)	**Primary Health Care in Community Pharmacy:** Family planning, First aid, Smoking cessation, Health Screening programs **Community Pharmacy Management:** Financial materials, staff, infrastructure requirements, drug information resources, computers
VIII (2 weeks)	**Education and Training:** Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, formal and informal meetings and lectures, Drug and therapeutics newsletter.

Assessment methods and weightage

Assessment type	**Assessment tool**	**Distribution**
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Learning Resources/Recommended Texts/Reference books/web resources

1. William E Hassan. Hospital pharmacy. 5th ed. Philadelphia - Lea & Febiger; 1974.
2. S H Merchant, J S Qadry, R K Goyal, R K Parikh A text book of Hospital Pharmacy. 10th ed. B S Shah Prakashan; 2008 – 2009. ISBN – 81-8416-008-9
3. Pratibha nand, Roop K Khar. A text book of hospital and clinical pharmacy – Theory and Practical. 6th ed. Birla publlicatins Pvt. Ltd; 2007 – 2008.
4. H P Tipnis, Amrita Bajaj. Clinical Pharmcy. First ed. reprint. Nasik: Career Publications; 2006.
5. A V Yadav, B V Yadav. Hospital and Clinical Pharmacy. 15th ed. reprint. Pune: Nirali prakashan; 2008.
6. Martin Stephens. Hospital Pharmacy. 2nd ed. London: Pharmaceutical press; 2011. ISBN 9780853699002.
7. Robin J Harman. Handbook of Pharmacy Health Education. 2nd ed. London: Pharmaceutical press; ISBN 100853694710.

Program	M. Pharm (Pharmacy Practice)
Year /Semester	First year / 1st semester
Name of the course	Hospital and Community Pharmacy (Practical)
Course Code	16MPP106
Credits	4
Hours /week	6 hours
Pre / co-requisite/s	NIL

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.
CO 2: 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	Critical study of two community pharmacies in the neighbourhood for schedule M Compliance.
2	Comparison of prescription handling in two community pharmacies.
3	Audit of OTC sales over a 24 hour period in a local hospital pharmacy.
4	Develop a report on social awareness programmes like health education, family planning, first aid, smoking cessation, screening programmes, immunisation, etc. and report.
5	Comparative study of two pharmacies situated in hospital settings.
6	Summation of the advice and recommendations at the community pharmacy.
7	Summation of the advice and recommendations at the hospital pharmacy.

8	Report on the establishment of a drug information centre in a multispecialty hospital.
9	Report on hospitals drug and therapeutic committee and its role.
10	Layout and workflow patterns in the dispensary.
11	Data on procurements and storage of vaccine, sera and biological preparations.
12	Counselling to in-patients suffering from asthma, hypertension, diabetes, tuberculosis, peptic ulcer, anaemia and AIDS.
13	Development of patient information leaflets.
14	Adverse Drug Reactions identification and reporting at hospital pharmacy setups.
15	Problem based exercise /Revision.
16	**Revision**

Assessment methods and weightage

Assessment type	**Assessment tool**	**Distribution**
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. William E Hassan. Hospital pharmacy. 5th ed. Philadelphia - Lea & Febiger; 1974.
2. S H Merchant, J S Qadry, R K Goyal, R K Parikh A text book of Hospital Pharmacy. 10th ed. B S Shah Prakashan; 2008 – 2009. ISBN – 81-8416-008-9
3. Pratibha nand, Roop K Khar. A text book of hospital and clinical pharmacy – Theory and Practical. 6th ed. Birla publlicatins Pvt. Ltd; 2007 – 2008.
4. H P Tipnis, Amrita Bajaj. Clinical Pharmcy. First ed. reprint. Nasik: Career Publications; 2006.
5. A V Yadav, B V Yadav. Hospital and Clinical Pharmacy. 15th ed. reprint. Pune: Nirali prakashan; 2008.
6. Martin Stephens. Hospital Pharmacy. 2nd ed. London: Pharmaceutical press; 2011. ISBN 9780853699002.
7. Robin J Harman. Handbook of Pharmacy Health Education. 2nd ed. London: Pharmaceutical press; ISBN 100853694710.

For Biopharmaceutics and Pharmacokinetics (Theory): Course description, course learning outcomes, course contents and Assessment methods and weightage refer above the specialization of Pharmaceutics.

program	M. Pharm (PHARMACY PRACTICE)
Year /Semester	First year / 2nd semester
Name of the course	Pharmacotherapeutics-II (Theory)
Course Code	16MPP202
Credits	4
Hours /week	4 hours (lectures)
Pre / co-requisite/s	Nil

Course Description: Pathophysiology and pharmacotherapy of diseases associated with following systems/diseases and special references to the drug of choice in conditions like pregnancy, lactation, geriatrics and paediatrics'. Which allows the pharmacist to face multifaceted challenges from the different phases of the community and to act as decision making professional?

Course Learning Outcomes: Upon completion of the course, it is expected that students will be able to,

CO 1: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy.

CO 2: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence.

CO 3: Use standard clinical guidelines as part of evidence based medicine.

CO 4: Discuss the preparation of individualized therapeutic plans.

CO 5: 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 outcomes)

Theory Course: Contents

Unit	Topics
I (2 weeks)	Cardiovascular system: Hypertension, Congestive cardiac failure, Ischemic Heart disease, Myocardial infarction, Arrhythmias.
II (2 weeks)	Hyperlipidaemias ,Respiratory system Asthma, Drug induced pulmonary diseases, Chemotherapy of lung cancer Chronic obstructive airways disease.
III (2weeks)	Oncology: General principles of cancer chemotherapy, haematological malignancies. Management of nausea and vomiting commonly used cytotoxic drugs.
IV (2weeks)	Renal system ,Acute and Chronic renal failure, Renal dialysis and transplantation,
V (2 weeks)	Drug induced renal disease, Ophthalmology. Glaucoma, Eye infections General Prescribing Guidelines: Paediatric and geriatric patients.
VI (2 weeks)	General Prescribing Guidelines Pregnancy and breast feeding Infectious diseases: General guidelines for the rational use of antibiotics, Meningitis, Respiratory tract infections, Gastroenteritis.
VII	Septicaemia, Otitis media, Urinary tract infections, Tuberculosis, Malaria,

(2 weeks)	Helmenthiasis, Fungal infections
VIII (2weeks)	Skin and sexually transmitted diseases: Psoriasis, Eczema and scabies, HIV and opportunistic infections, Syphilis and Gonorrhoea, Drug related skin reactions Revision

Assessment patterns and weightage

Assessment pattern	Assessment pattern	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Learning Resources/Recommended Texts/Reference books/web resources

1. Roger Walker, Cate Whittles. Clinical Pharmacy and Therapeutics. 4th ed. Churchill Livingstone; 2012.
2. Joseph T Dipiro et. al. Pharmacotherapy: A Pathophysiological approach. 6th ed. McGraw hill Publication. 2011
3. Robins S L, W B. Saunders. Pathologic Basis of Disease. Stanley Leonard Robbins. 5th ed. W. B. Saunders Company; 2004
4. Russell J Greene, Norman D Harris. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice. 3rd ed. Pharmaceutical Press; 2008.
5. Eric T Herfindal, Joseph L Hirschman. Clinical Pharmacy and therapeutics. 5th ed. Williams and Wilkins Publication; 1992.
6. Lloyd Young, Koda-Kimble M A. Applied Therapeutics: the clinical use of drugs. 3rd ed. Lippincott Williams and Wilkins publication; 1983. [ISBN 0 333-65881-7]
7. T M Speight, N H Holford. *Avery's Drug Treatment.* 4th ed. Auckland. Wiley - Black well - Adis international limited; 1997.

Program	M. Pharm
Year /Semester	First year / 2nd semester
Name of the course	PHARMACOTHERAPEUTICS – II (PRACTICAL)
Course Code	16MPP205
Credits	4
Hours /week	3 hours (PRACTICAL)
Pre / co-requisite/s	Nil

Course Description:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow-up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 10 cases should be presented and recorded covering most common diseases. The list of clinical cases should include follow-up of the clinical cases mentioned below from the day of admission till discharge. The same cases should be entered in the practical records following SOAP [Subjective, Objective, Assessment, Plan] format for cases in clinical pharmacy setting and FARM [Findings, Assessment, Resolution, Monitoring] format for cases in community pharmacy settings which involve treating patients with non-prescription drugs in minor ailments.

Course Learning Outcomes: Upon successful completion of this course, the student should be able to:
CO 1: Discuss the preparation of individualized therapeutic plans.
CO2: Identify the patient-specific parameters relevant in initiating drug therapy.
CO 3: monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse outcomes)

Practical Course: Contents

Week	Topics
1	Introduction to ward round participation and case collection on
2	Hypertension
3	CCF(congestive cardiac failure)
4	Hypothyroidism
5	Hyperthyroidism
6	Acute renal failure
7	Chronic renal failure
8	Asthma
9	Depression diseases
10	Anxiety
11	Epilepsy
12	Parkinson's disease

13	Stroke
14	Infectious [any five]
15	GENERAL CASE EVALUATION /EXAMINATION EXCERSICE
16	**Revision**

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Participation	5 %
	Lab work (day to day)	10 %
	Mid-semester Examination	15%
End Assessment	End Practical examination	70 %
	TOTAL	**100%**

Mid-semester to be conducted after 8th week.

Learning Resources/Recommended Texts/Reference books/web resources

1. Roger Walker, Cate Whittles. Clinical Pharmacy and Therapeutics. 4th ed. Churchill Livingstone; 2012.
2. Joseph T Dipiro et. al. Pharmacotherapy: A Pathophysiological approach. 6th ed. McGraw hill Publication. 2011
3. Robins S L, W B. Saunders. Pathologic Basis of Disease. Stanley Leonard Robbins. 5th ed. W. B. Saunders Company; 2004
4. Russell J Greene, Norman D Harris. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice. 3rd ed. Pharmaceutical Press; 2008.
5. Eric T Herfindal, Joseph L Hirschman. Clinical Pharmacy and therapeutics. 5th ed. Williams and Wilkins Publication; 1992.
6. Lloyd Young, Koda-Kimble M A. Applied Therapeutics: the clinical use of drugs. 3rd ed. Lippincott Williams and Wilkins publication; 1983. [ISBN 0 333-65881-7]
7. T M Speight, N H Holford. *Avery's Drug Treatment.* 4th ed. Auckland. Wiley - Black well - Adis international limited; 1997.

JOURNALS

1. British Medical Journal.
2. New England Journal of Medicine.
3. Annals of Pharmacotherapy.
4. Lancet.

Program	M. Pharmacy (Pharmacy Practice)
Year /Semester	First year / 2nd semester
Name of the course	Clinical Pharmacy Practice (Theory)
Course Code	16MPP203
Credits	4
Hours /week	4 Hrs (Lectures)
Pre / co-requisite/s	Nil

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.

Theory: Course Contents

Unit	Topics
I (2 weeks)	Definitions, development and scope of clinical pharmacy
	Clinical Pharmacy Services: Introduction to daily activities of a clinical pharmacist, Pharmaceutical care, Ward round participation**,** Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)**,** Medication history
II (2 weeks)	**Clinical Pharmacy Services:** Patient counselling**,** Drug information and poison information**,** Adverse drug reaction management**,** Drug utilization evaluation (DUE) and review (DUR)**,** Quality assurance of clinical pharmacy services.
	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 nonverbal Communications, its applications in patient care services.
III	**Patient Data & Practice Skills*:*** medication history interview and presentation

(2 weeks)	of cases. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results:** Haematological tests
	Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results: Renal function tests, Liver function tests, Tests associated with cardiac disorders
IV (2 weeks)	**Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results:** Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, and microbiological culture sensitivity tests
	Pharmacoepidemiology: Definitions and scope, Methods [Sources of data, study design, drug utilisation studies, Meta-analysis] Social, cultural and economic factors influencing drug use. Systems for monitoring drug effects, advantages and disadvantages of Pharmacoepidemiology
V (2 weeks)	**Pharmacoepidemiology:** Systems for monitoring drug effects, advantages and disadvantages of Pharmacoepidemiology
	Drug & Poison information: Introduction to drug information and Drug Information resources, Systematic approach in answering DI queries
VI (2 weeks)	**Drug & Poison information:** Introduction to drug information and Drug Information resources, Systematic approach in answering DI queries
	Drug & Poison information: Critical evaluation of drug information and literature, Preparation of written and verbal reports, Establishing a Drug Information Centre, Poison information- organization & information resources.
VII (2 weeks)	**Pharmacoeconomics:** Definitions and scope, types of economic evaluation, cost models and cost effectiveness Analysis
	Pharmacoeconomics: Cost models and cost effectiveness Analysis
VIII (2 weeks)	**Therapeutic Drug Monitoring:** Theoretical basis for TDM service and its applications
	Therapeutic Drug Monitoring: Theoretical basis for TDM service and its applications

Assessment methods and weightage

Assessment type	Assessment tool	Distribution
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

Learning Resources/Recommended Texts/Reference books/web resources

1. Roger Walker, Cate Whittles. Clinical Pharmacy and Therapeutics. 4th ed. Churchill Livingstone; 2012.
2. Joseph T Dipiro et. al. Pharmacotherapy: A Pathophysiological approach. 6th ed. McGraw hill Publication. 2011
3. Robins S L, W B. Saunders. Pathologic Basis of Disease. Stanley Leonard Robbins. 5th ed. W. B. Saunders Company; 2004
4. Russell J Greene, Norman D Harris. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice. 3rd ed. Pharmaceutical Press; 2008.
5. Eric T Herfindal, Joseph L Hirschman. Clinical Pharmacy and therapeutics. 5th ed. Williams and Wilkins Publication; 1992.
6. Lloyd Young, Koda-Kimble M A. Applied Therapeutics: the clinical use of drugs. 3rd ed. Lippincott Williams and Wilkins publication; 1983. [ISBN 0 333-65881-7]
7. T M Speight, N H Holford. *Avery's Drug Treatment.* 4th ed. Auckland. Wiley - Black well - Adis international limited; 1997.

Program	M. Pharmacy (Pharmacy Practice)
Year /Semester	First year / 2nd semester
Name of the course	Clinical Pharmacy Practice (Practicals)
Course Code	16MPP206
Credits	4
Hours /week	6 Hrs (Practicals)
Pre / co-requisite/s	Nil

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.

List of practical's / hospital postings

Week	Name of the experiments
01	Patient Medication Interviews
02	Answering Drug Information Queries.
03	Patient Medication Counselling
04	Literature Evaluation
05	Therapeutic Drug Monitoring (Any two drugs)
06	Problem solving in Clinical Pharmacokinetics
07	Ward Round Participation.
08	Medication order review.
09	Detection and assessment of adverse drug reactions and their documentation
10	Case presentations

11	Prescription auditing
12	Detection, assessment, monitoring and reporting of ADR' s

Learning Resources/Recommended Texts/Reference books/web resources

1. Roger Walker, Cate Whittles. Clinical Pharmacy and Therapeutics. 4th ed. Churchill Livingstone; 2012.
2. Joseph T Dipiro et. al. Pharmacotherapy: A Pathophysiological approach. 6th ed. McGraw hill Publication. 2011
3. Robins S L, W B. Saunders. Pathologic Basis of Disease. Stanley Leonard Robbins. 5th ed. W. B. Saunders Company; 2004
4. Russell J Greene, Norman D Harris. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice. 3rd ed. Pharmaceutical Press; 2008.
5. Eric T Herfindal, Joseph L Hirschman. Clinical Pharmacy and therapeutics. 5th ed. Williams and Wilkins Publication; 1992.
6. Lloyd Young, Koda-Kimble M A. Applied Therapeutics: the clinical use of drugs. 3rd ed. Lippincott Williams and Wilkins publication; 1983. [ISBN 0 333-65881-7]
7. T M Speight, N H Holford. *Avery's Drug Treatment.* 4th ed. Auckland. Wiley - Black well - Adis international limited; 1997.

Program	M. Pharm (Pharmacy Practice)

Year /Semester	First year / 2nd semester
Name of the course	Clinical Research and Development (Theory)
Course Code	16MPP204
Credits	4
Hours /week	4 hours (Lectures)
Pre / co-requisite/s	Nil

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: This course provides to the 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.
CO2: 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

Unit	Topics
I (2 weeks)	**Introduction to Clinical Research:** Definitions and terminology used in clinical trials, Historical development in clinical research practice. **Drug development process:** Investigational new drug development and Hatch Waxman Act
II (2 weeks)	**Ethics in Biomedical Research:** Ethical Issues in Biomedical Research – Principles of ethics in biomedical research Ethical committee [institutional review board], its constitution and functions. **Guidelines for Good Clinical Practices:** [ICH GCP guidelines, Schedule Y (CDSCO regulations), EMEA, MHRA, and USFDA guidelines in the conduct of clinical trials]
III (2 weeks)	**Safety Monitoring in Clinical Trials (ICH E2):** Adverse event and serious adverse event reporting in clinical trials, emphasis on SUSAR"s and managing and reporting of events.
IV	**Research Design Methods:**

(2 weeks)	Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification)
V (2 weeks)	**Research Design Methods:** Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods). Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study) Health outcome measures (Clinical & Physiological, Humanistic and Economic)
VI (2 weeks)	**Clinical research:** Establishing and functioning of Contract Research Organisation (CRO), Roles and responsibilities of clinical trial personnel, Trial initiation, volunteer recruitment, trial supplies and site management, Designing of clinical trial documents
VII (2 weeks)	Analysis and reporting of clinical trials (ICH E3 and ICH E9). Monitoring and auditing of clinical trials, Trial report generation, Site closure
VIII (2 weeks)	Medical Writing and Ethics of publication Clinical data management (Data entry, data interpretation, data monitoring and auditing)

Assessment methods and weightage

Assessment type	**Assessment tool**	**Distribution**
Continuous Assessment	Class test	10%
	Assignments	5 %
	Mid-semester Examination	15%
End Assessment	End theory examination	70 %
	TOTAL	**100%**

Note: Class tests to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week.

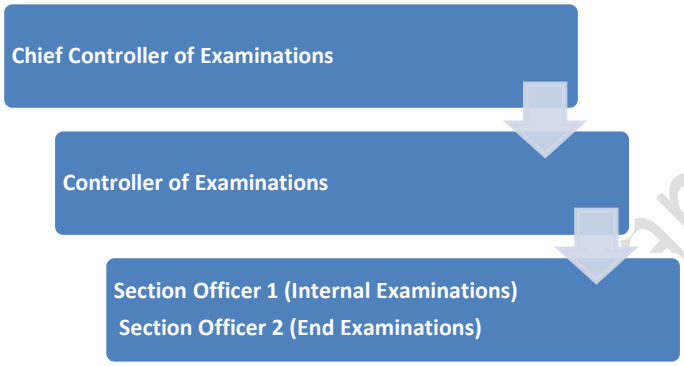
Learning Resources/Recommended Texts/Reference books/web resources

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. R K Rondels, S A Varley, C F Webbs. Clinical Data Management. 2nd ed. Wiley Publications; 2000.
4. JG Hardman, LE Limbard, Goodman & Gilman: The Pharmacological basis of therapeutics. 10th ed.. Mc Graw Hill Publications; 2001.
5. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
6. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6; 1996.

7. Ethical Guidelines for Biomedical Research on Human Subjects 2000. New Delhi: Indian Council of Medical Research.

7.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 survillence
- 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.**

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.

End Examinations	B.Pharm	M.Pharm*	Pharm.D
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
Practical Examiner 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
Practical Examiner 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

e) **Recommended assessment tools**

B.Pharm	M.Pharm	Pharm. D
Class tests	Class tests	Class tests
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 to be conducted at 4th and 14th Week; Mid-semester to be conducted after 8th week

8. Annexure-I: Class test rubrics / Question Paper model

Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)
Awarding University: JNT University, Anantapur (JNTUA)

Cousre Name: Cousre Code:
Date of Examination: Total Marks: 20 M

Section-A

I. Multiple Choice Questions (MCQ's) 1× 10 = 10 M

Section-B

II. Answer any TWO out of THREE questions 2× 5 = 10 M

9. Annexure - II: Rubrics for Assignment Assessment

Assignment - Evaluation / Marking Schemes (10 Marks)

Parameter	Very good (2)	Good (1)	Satisfactory (0.5)	Not satisfactory (0)
Relevance of content to Topic (2)				
Reliable resources used (2)				
Presentation of content (2)				
Similarity Index (2)				
Total				
Total (8)				
Submission Date	Before Due date (2)		After due date (1)	

10. Annexure - III: Mid – Term examinations

a) Mid – Examination Rubrics (Theory)

Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)
Awarding University: JNT University, Anantapur (JNTUA)

Course Name: Course Code:
Date of Examination: Total Marks: 30 M

Section-A

I. Short answer questions (All Compulsory) 2× 5 = 10 M

Section-B

II. Answer any TWO out of THREE questions 2× 10 = 20 M

b) (Mid – Examination Rubrics (Practical)

Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)
Awarding University: JNT University, Anantapur (JNTUA)

Practical question paper pattern

Course Name: *Course Code:*
Date of Examination: *Total Marks: 30 M*

I. Synopsis	*5 M*
II. Experiment	*15 M*
III. Viva voce and Record	*10 M*

11. Annexure-IV:

a) End Examinations - Theory question paper rubrics

Raghavendra Institute of Pharmaceutical Education and Research(Autonomous)
Awarding University: JNT University, Anantapur (JNTUA)

Course Name: *Course Code:*
Date of Examination: *Total Marks: 70 M*

Section-A

I. Answer the following questions *8 × 2 = 16 M*

Section-B

II. Answer any SIX out of EIGHT questions *6 × 9 = 54 M*

b) End examinations - Practical question paper rubrics

Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)
Awarding University: JNT University, Anantapur (JNTUA)

Practical question paper pattern

Subject Name: *Subject Code:*
Date of Examination: *Total Marks: 70 M*

I. Synopsis	*10 M*
II. Major Experiment	*25 M*
III. Minor Experiment	*20 M*
IV. Viva voce and Record	*15 M*

12. Annexure – V : Research Project / Presentation / Seminar Assessment Rubrics

Project / Presentation - Marking Schemes (10 Marks)

Parameter	Very good (2)	Good (1)	Satisfactory (0.5)	Not satisfactory (0)
Skill in Experiment and presentation of data (2)				
Adequacy of literature (2				
Performance / efficiency in Interpretation of data (2)				
Presentation of content / Result (2)				
VIVA (2)				
Total				
Total (10)				

Appropriate medication is allowed.

13. **Annexure – VI: Grading and ranking**

- Semester Grade point Average (SGPA) 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.

14. Annexure VII: Malpractices / Punishments

- As per the regulations and guidelines of awarding university from time to time.