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 Doctor of Pharmacy (Pharm. D) & Pharm. D. (Post Baccalaureate) 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	
		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	
		Pro. N. Devanna (Member) JNTUA	— ABSENT —
6	Faculty member (Member secretary)	Dr. C. Sowmya	

Doctor of Pharmacy

Pharm. D is the doctoral programme with specialization of pharmacy practice introduced by Pharmacy Council of India (PCI) approved by Government of India (GOI) Ministry of Health and Family Welfare, Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948), Published in the Gazette of India, No.19, PART III, SECTION 4 dated 10th May 2008. The Pre-PhD, post-graduate professional doctoral program (Pharm. D) was introduced to improve clinical pharmacy services in India and it is the only pharmacy service which is in direct contact with patient health care system.

Raghavendra Institute of Pharmaceutical Education and Research (RIPER), is one of the premier and renowned pharmacy institute in India, running the Doctor of Pharmacy program approved by the Pharmacy Council of India (PCI), New Delhi., India and affiliated to the Jawaharlal Nehru Technological University Anantapur (JNTUA), Anantapuramu, Andhra Pradesh, India. RIPER offers both Pharm. D (06 years) & Post Baccalaureate Pharm. D (03 years) from 2008 successfully and gained its reputation as the best private pharmacy institute of Andhra Pradesh.

Program Outcome (PO's)

PO 01: Graduates will demonstrate knowledge of Pharmaceutical sciences

PO 02: Graduates will demonstrate an ability to identify, formulate and resolve difficulties in pharmaceutical industry, community and hospital Pharmacy.

PO 03: Graduates will conduct analyze and interpret data of experiments in production, analytical and clinical aspects.

PO 04: Graduates will enter into the practice of pharmacy to serve society as ethical and caring professionals.

PO 05: Graduates will apply knowledge of drugs and drug therapy to resolve medication related problems and make decisions on behalf of their patients for better patient care.

PO 06: Graduates will educate, communicate, and collaborate with patients and health care professionals.

PO 07: Graduates will assume a leadership role in the future direction of the profession and practicing with international standards.

PO 08: Graduates will demonstrate knowledge of professional and ethical responsibilities liable to the profession and society.

PO 09: Graduate will understand and implement the professional knowledge in research team and or alone in multidisciplinary tasks.

PO 10: Graduates will develop professional practice as a lifelong learning experience.

Introduction

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 board 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 feedback from alumni, employers, faculty, students, parents and other experts from allied area.

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

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

- To improve the academic regulations and course structure.
- To strengthen the Industry-Institute interaction.
- To comply with rules and regulations of regulatory bodies like JNTUA, PCI, AICTE etc.,
- To meet the requirements of accreditation council and board.
- To enhance the quality of teaching-learning process and assessments.
- To provide career support programs, training for enhancing quality in placements and higher education.
- To place improved systems for feedback, self-appraisal of faculty and staff.
- To create bench marking with other institutes of repute.

Preamble

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 and course structure"** for Raghavendra Institute of Pharmaceutical Education and Research (RIPER).

b) These regulations shall be in force from the batch admitted from 2016 -2017 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***" 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 college as per the guidelines stipulated from time to time by the regulations of State Government of Andhra Pradesh and the Government of India for admissions into various courses of study and the affiliating university, i.e., Jawaharlal Nehru Technological University, Anantapur (JNTUA), Ananthapuramu, Andhra Pradesh.

iii. "***Academic Council***" means the Academic council constituted as per the guidelines of UGC.

iv. "***Board of Studies***" means Board of Studies constituted in each department as per the guidelines of UGC.

v. ***"Principal"*** means the Head of the institution

vi. ***"Head of the Department"*** means the Head of an Academic Department of the College.

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

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

ix. *"**Course**" individual subjects described with content for instructions to the students.*

x. ***"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.

Academic Regulations – 2016

Raghavendra Institute of Pharmaceutical Education and Research (RIPER)

An Autonomous Institution under JNT University Anantapur (JNTUA)

Program	Doctor of Pharmacy (Pharm. D) & Post Baccalaureate (Pharm. D-PB)
Approved by	Academic council
Effective from	Students admitted from AY 2016-17

As per the Academic council of Raghavendra Institute of Pharmaceutical Education and Research, (Autonomous Institution) and as directed by the University grant commission (UGC), the Jawaharlal Nehru technological University Anantapur (JNTUA), shall confer the post graduate degree in Doctor of Pharmacy (Pharm. D) and post baccalaureate (Pharm. D-PB) with the fulfilment of all the requirements for the award of degree.

These regulations shall be called as "The Regulations for the Pharm. D and Pharm. D. (Post Baccalaureate) Degree courses of the Raghavendra Institute of Pharmaceutical Education and Research, Anantapur". They shall come into force from the Academic Year 2016 – 2017. The regulations and syllabi framed are subject to modifications from time to time by the Academic Council.

Minimum Qualification for admission to the course

a) Pharm. D

A pass in any of the following examinations –

1. 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the two subjects: Mathematics or Biology.
2. A pass in D. Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

3. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.
4. Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.
5. Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

b) Pharm. D. (Post Baccalaureate)

1. A pass in B. Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:
2. Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

Duration of the course

a) **Pharm. D**: The duration of the course shall be six academic years (five years of study and one year of internship or residency). The period of six years duration is divided into two phases –

Phase I – **consisting** of First, Second, Third, Fourth and Fifth academic year.

Phase II –consisting of internship or residency training during sixth year involving posting in specialty units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision of a preceptor so that he or she may become capable of functioning independently.

b) **Pharm. D. (Post Baccalaureate):** The duration of the course shall be for three academic years (two years of study and one-year internship or residency). The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.

Phase II – consisting of Internship or residency training during third year involving posting in specialty units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision of a preceptor so that he or she may become capable of functioning independently.

Medium of Instruction and Examinations

Medium of Instruction and Examination shall be English.

Working days in the academic year

Each academic year shall consist of not less than 200 working days.

Attendance and Progress

A candidate is required to put in at least 80% attendance in theory and practical subjects separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

Distribution and Weightage of Marks:

i. The performance of a student in each year shall be evaluated course-wise with a maximum of 100 marks for theory and 100 marks for practical subject.
ii. For theory subjects the distribution shall be 30 marks for Continuous assessment (Class test, midterm exam, assignment) and 70 marks for the End assessment (End-Examination).
iii. For theory subjects, during the year there shall be 2 class tests, which include both objective and descriptive questions for a duration of 45 minutes. One class test should be conducted before first-midterm and one should be after second midterm tests. The test may be conducted for 20 marks and best score need to be converted to 10 for continuous assessment.

iv. For theory subject, the midterm examination shall be conducted after the 12th week of instruction. There will be three midterm theory examinations should be conducted for 30 marks. It has to be converted to 15, best of two averages is considered for continuous assessment.

v. For theory subject, there will be one or two assignments in relevance to course outcome, need to be evaluated as per standard rubrics and documented. Final score may be included in the continuous assessment as indicated in individual course syllabi.

vi. For practical subjects, there shall be a continuous day to day evaluation based on lab work / record (10 marks), participation based on portfolio and attendance (5 marks) and there will be a midterm examination along with midterm theory examinations. The midterm practical examinations should be conducted for 30 marks. It has to be converted to 15, best of two averages is considered for continuous assessment.

vii. Laboratory marks and the sessional 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 sessional and laboratory marks awarded by the College 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 and internal test papers 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.

viii. In case, the student does not secure the minimum academic requirement in any course (i.e. 40 % in end examination and 50 % aggregate of the overall subject in the year), 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 continuous assessment marks remain same.

NOTE: In case any candidates continue assessment is low only if due to absenteeism to attend mid -term examinations, 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 the committee fails to allow, a prescribed fee is paid to the examination section, to undertake a midterm examination, scheduled by the Controller of examinations.

ix. Clerkship (V Pharm. D) examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion.

x. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

** 30 marks – viva-voce (oral), 70 marks – Thesis work

Course of study

The course of study for Pharm. D shall include the subjects as given in the Tables 1 to 5. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

Pharm D PB I Year

S. No	Name of Subject	Subjects Codes	No. of hrs of Theory	No. of hrs of Practical	No. of hrs of tutorial	Lab	S. No	Subjects codes
(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**		**(7)**	**(8)**
4.1	Pharmacotherapeutics-III	16PB101	3	3	1	✓	4.8	16PB108
4.2	Hospital Pharmacy	16PB102	2	3	1	✓	4.9	16PB109
4.3	Clinical Pharmacy	16PB103	3	3	1	✓	4.10	16PB110
4.4	Biostatistics and research methodology	16PB104	2	---	1		---	----
4.5	Biopharmaceutics and pharmacokinetics	16PB105	3	3	1	✓	---	16PB111
4.6	Clinical toxicology	16PB106	2	--	1		---	-----
4.7	Pharmacotherapeutics I &II*	16PB107	3	3	1	✓	4.11	16PB112
	Total hours		**18**	**15**	**7 = (40)**			

Pharm D PB II Year

S. No.	Name of Subject	Subject Code	No. of hours of Theory	No. of hours of Hospital posting	No. of hours of seminar
(1)	**(2)**	(3)	(4)	**(5)**	**(6)**
5.1	Clinical Research	16PB201	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	16PB202	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring	16PB203	2	-	1
5.4	Clerkship*	16PB204	-	-	1
5.5	Project work (Six Months)	16PB205	-	20	
	Total hours		**8**	**20**	**4 = (32)**

***** *Attending ward rounds on daily basis.*

Pharm D PB III Year

Internship (16PB301)

Internship or residency training including postings in speciality units. Student should provide the clinical pharmacy services to the allotted wards, under the supervision of a preceptor.

(i) Six months in General Medicine department, and

(ii) Two months each in three other specialty departments

Criteria for pass

a) Candidates who have secured a minimum of 50% marks in the Theory (40 % in end examination) and Practical (40 % in end examination) separately in any subject or subjects shall be declared to have passed in that subject/s.

b) Theory and Practical of a particular subject are considered as individual subjects for the purpose of pass criteria. Those candidates who fail in one or more subjects shall have to appear only in the subject so failed, in the subsequent examinations.

Conditions under which candidates are permitted to proceed to next higher class:

a) **Pharm. D**

1. Candidates of I Pharm. D are permitted to carry not more than any two subjects (Two Theory/ Two Practicals/ One theory & one practical of same or different subjects) to II Pharm. D and appear for II Pharm. D examination concurrently along with failed subjects of I Pharm. D. However, these candidates have to pass all the failed subjects of I Pharm. D to become eligible to III Pharm. D.
2. Similarly, candidates of II Pharm. D who have completely passed all the subjects of I Pharm. D but have failed in II Pharm. D are permitted to carry not more than any two subjects (Two Theory/ Two Practicals/ One theory & one practical of same or different subjects) of II Pharm. D to III Pharm. D and appear for III Pharm. D concurrently along with failed subjects of II Pharm. D. However, these candidates have to pass all the failed subjects of II Pharm. D to become eligible to proceed to IV Pharm. D.
3. Candidates of III Pharm. D who have completely passed all the subjects of II Pharm. D but have failed in III Pharm. D are permitted to carry not more than any two subjects (Two Theory/ Two Practicals/ One theory & one practical of same or different subjects) of III Pharm. D to IV Pharm. D and appear for IV Pharm. D examination concurrently

along with failed subjects of III Pharm. D. However, these candidates have to pass all the failed subjects of III Pharm. D to become eligible to proceed to V Pharm. D.

4. Candidates of IV Pharm. D who have completely passed all the subjects of III Pharm. D but have failed in IV Pharm. D are permitted to carry not more than any two subjects (Two Theory/ Two Practicals/ One theory & one practical of same or different subjects) of IV Pharm. D to V Pharm. D and appear for V Pharm. D examination concurrently along with failed subjects of IV Pharm. D. However, these candidates have to pass all the failed subjects of IV and V Pharm. D to become eligible to proceed to VI Pharm. D., to undergo internship.

b**) Pharm. D. (Post Baccalaureate)**

Candidates of Pharm. D. (Post Baccalaureate) admitted directly to IV Year course are permitted to carry not more than any two subjects (Two Theory/ Two Practicals/ One theory & one practical of same or different subjects) to V Pharm. D. and appear for V Pharm. D. examination concurrently along with failed subjects of IV Pharm. D. However, these candidates have to pass all the subjects of IV & V Pharm. D to become eligible to proceed to VI Pharm. D., to undergo internship.

Declaration of class

a) **Pharm. D**

The result of the successful candidate shall be classified at the end of the final year examination on the basis of the aggregate of all subjects, theory and practical's, secured by the candidate in the I to V year examinations and completes the course in 5 years, as indicated below.

I Class : 60% and above

II Class : 50%-59%

Candidate securing aggregate of 75% or above marks and have passed in all the subjects in a year in first attempt shall be declared to have obtained Distinction.

b) **Pharm. D. (Post Baccalaureate)**

The result of the successful candidate shall be classified at the end of the final year examination on the basis of the aggregate of all subjects, theory and practical's, secured by the candidate in the IV & V year examinations and completes the course in 2 years, as indicated below.

I Class : 60% and above

II Class: 50%-59%

Candidate securing aggregate of 75% or above marks and have passed in all the subjects in a year in first attempt shall be declared to have obtained Distinction.

Internship

Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and healthcare and acquires skills under the supervision so that he or she may become capable of functioning independently. Every student has to undergo one-year internship as per Pharmacy Council of India regulations.

Practical training

1. **Hospital posting**: Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course of Pharm. D and in first and second year of Pharm. D. (Post Baccalaureate). Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.
2. **Project work**:
   (i) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth-year classes of Pharm. D and second year of Pharm. D. (Post Baccalaureate). Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
   (ii) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.
3. **Objectives of project work**: The main objectives of the project work are to:
   (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
   (ii) develop the students in data collection, analysis and reporting and interpretation skills.
4. **Methodology**: To complete the project work following methodology shall be adopted,

namely:

(i) Students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;

(ii) Project topic shall be approved by the Head of the Department or Head of the Institution;

(iii) Project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, Pharmacovigilance or pharmacoeconomics;

(iv) Project work shall be approved by the institutional ethics committee;

(v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and

(vi) Two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

5. Reporting:

(i) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorized teacher, Head of the Department as well as by the Head of the Institution

(ii) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorized teacher with font size 14.

(iii) Submission of the project report shall be done at least one month prior to the

commencement of annual or supplementary examination.

6. **Evaluation**: The following methodology shall be adopted for evaluating the project work

(i) Project work shall be evaluated by internal and external examiners.

(ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).

(iii)Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:	**Marks**
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)

(v) Final evaluation of project work shall be done on the following items: **Marks**

a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation: For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

Award of Ranks

Ranks and Medals shall be awarded on the basis of aggregate of all the five and two university examinations of Pharm. D. and &Pharm. D. (Post Baccalaureate), respectively. However, candidates who fail in one or more subjects during the Pharm. D/ Pharm. D. (Post Baccalaureate) courses shall not be eligible for award of ranks.

Moreover, the candidates should have completed the Pharm. D course in minimum prescribed number of years, (five years for Pharm. D and two years for Pharm. D. (Post Baccalaureate)) for the award of Ranks.

Award of degree

Candidates who fulfil the requirements mentioned above will be eligible for award of degree during the ensuing convocation.

Duration for completion of the course of study

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

Withholding of results:

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

Program	**Pharm D PB**
Year	**I Year**
Name of the course	**Pharmacotherapeutics III**
Course Code	**16PB101**
Paper	**Theory**
Hours /week	**3+1 hours (lectures)**
Pre / co-requisite/s	**Nil**

Course Description:

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management

Course Learning Outcomes:

At completion of this subject it is expected that students will be able to explain

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualized therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (Including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse Effects);

CO 6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO 7: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy;

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis; and

CO 10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Theory Course: Contents

S. No	Topics
I (3 weeks)	**Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease.
II (3weeks)	**Liver disorders** - Alcoholic liver disease, Viral hepatitis including jaundice
III (3 weeks)	**Hematological system:** Anaemias, Venous thromboembolism,
IV (3weeks)	**Nervous system:** Epilepsy, Parkinsonism.
V (3weeks)	**Nervous system:** Stroke, Alzheimer's disease.
VI (3 weeks)	**Psychiatry disorders :** Schizophrenia, Affective disorders,
VII (3 weeks)	**Psychiatry disorders**: Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
VIII	Pain management including Pain pathways.

(3 weeks)	
IX (3 weeks)	Neuralgias and headache.
X (3 weeks)	Evidence Based Medicine
XI (3 weeks)	Drug induced liver disorders
XII (3 weeks)	Drug induced blood disorders.

Assessment methods and weightage

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

Note: Class tests & three Sessional examinations to be conducted periodically throughout the year.

Learning Resources/Recommended Texts/Reference books/web resources

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8th ed. lippincot Williams;2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach.9th ed. Mcgraw-hill education; 2012.

3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10th ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5th ed. Churchill livingstone;2011
5. Green,Russells,Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3rd ed. Pharmaceutical press:2008

Program	**Pharm D PB**
Year	**I Year**
Name of the course	**Pharmacotherapeutics III (Lab)**
Course Code	**16PB108**
Paper	**Practical**
Hours /week	**3 hours (laboratory)**
Pre / co-requisite/s	**Nil**

Course Description:

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management

Course Learning Outcomes: At completion of this subject it is expected that students will be able to understand –

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualized therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (Including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse Effects);

CO 6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO 7: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy;

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis; and

CO 10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Practical Course: Contents

Week	**Topics**
1	Introduction to ward round participation and case collection.
2	Peptic Ulcer
3	Gastro- esophageal reflex disorder
4	Inflammatory bowel disorder
5	Hepatitis
6	Alcoholic Liver disorder
7	Drug induced liver disorder
8	Anemia
9	Venous thromboembolism
10	Drug induced hematological disorder
11	Epilepsy
12	Parkinsonism
13	Stroke
14	Alzheimer’s disease
15	Schizophrenia

16	Affective disorder
17	Anxiety disorders
18	Sleep disorders
19	Obsessive Compulsive disorders
20	Pain management
21	Neuralgia
22	Head ache
23	Case studies on Multiple disorders
24	Case studies on Multiple disorders
25	Case studies on Multiple disorders
26	Case studies on Multiple disorders
27	Drug club I
28	Drug club II
29	Drug club III
30	Journal club I
31	Journal Club II
32	Journal club III
33	Evidence based medicine (Critical appraisal of RCT)
34	Evidence based medicine (Critical appraisal of Cohort study)
35	Evidence based medicine (Critical appraisal of Case control study)
36	REVISION/Assessment

Assessment methods and weightage

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

Three Sessional examinations to be conducted periodically throughout the year.

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

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8th ed. lippincot Williams;2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach.9th ed. Mcgraw-hill education; 2012.
3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10th ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5th ed. Churchill livingstone;2011
5. Green, Russells, Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3rd ed. Pharmaceutical press:2008.

Program	**Pharm D PB**
Year	**I Year**
Name of the course	**Hospital Pharmacy**
Course Code	**16PB102**
Paper	**Theory**
Hours /week	**2+1 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

S. No.	Topics
I (3 weeks)	• **Hospital - its Organisation and functions** • **Hospital pharmacy-Organisation and management** a) Organizational Structure-Staff, Infrastructure & work load statistics b) Management of materials and finance c) Roles & responsibilities of hospital pharmacist
II (3 weeks)	• **The Budget – Preparation and implementation** • **Hospital drug policy** a) Pharmacy and Therapeutic committee (PTC) b) Hospital formulary c) Hospital committees - Infection committee
III (3 weeks)	• **Hospital drug policy** - Research and ethical committee d) Developing therapeutic guidelines e) Hospital pharmacy communication – Newsletter
IV (3 weeks)	• **Hospital pharmacy services** a) Procurement & warehousing of drugs and Pharmaceuticals

	b) Inventory control Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock
V (3 weeks)	• **Hospital pharmacy services** c) Drug distribution in the hospital i) Individual prescription method ii) Floor stock method iii) Unit dose drug distribution method
VII (3 weeks)	• **Hospital pharmacy services** d) Distribution of Narcotic and other controlled substances e) Central sterile supply services – Role of pharmacist
VIII (3 weeks)	• **Manufacture of Pharmaceutical preparations** a) Sterile formulations – large and small volume parenterals b) Manufacture of Ointments, Liquids, and creams
IX (3 weeks)	• **Manufacture of Pharmaceutical preparations** c) Manufacturing of Tablets, granules, capsules, and powders d) Total parenteral nutrition
X (3 weeks)	• **Continuing professional development programs** Education and training
XI (3 weeks)	• **Radio Pharmaceuticals – Handling and packaging** • **Professional Relations and practices of hospital pharmacist**
XII (3 weeks)	Revision / Assessment

Assessment methods and weightage

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

Note: Class tests & three Sessional examinations to be conducted periodically throughout the year.

Learning Resources/Recommended Texts/Reference books/web resources

1. Merchant & Qadrys.A textbook of hospital pharmacy.ed:10th .B.S.Shah Prakashan.
2. William Hassan.E, Hospital Pharmacy.ed:5th Phialdelphia:Lea and Febiger;1986.
3. Parthasarathi .G.Karin Nyfort-Hansen,Milap C Nahata.A textbook of clinical pharmacy practice: essential concept and skills:ed.2nd :university press:2012.
4. Prathibha Nand,Roop khar.K . A text book of Hospital and Clinical pharmacy.ed:6th ,birla:2008.

Program	**Pharm D PB**
Year	**I Year**
Name of the course	**Hospital Pharmacy (Lab)**
Course Code	**16PB109**
Paper	**Practical**
Hours /week	**3 hours (laboratory)**
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.

CO2: Differentiate various classes of drugs along with their procurement and storage conditions.

CO 3: Perform lab activities related to the unit dose and bulk dose preparations.

CO 4: Demonstrate skills related to the identification, assessing and reporting of adverse drug reactions.

Practical Course: Contents

Week	Topics
1	Introduction to laboratory safety techniques and the use of glass wares and chemicals.
2	Preparation of sterile water for injection. (500 ml)
3	Preparation of 5% dextrose solution for injection. (500 ml)
4	Preparation of 0.9% Normal saline solution for injection. (500 ml)
5	Preparation of N Dextrose-Normal saline solution for injection. (500 ml)
6	Preparation of Compound Normal saline solution for injection. (500 ml)
7	Preparation of Compound Normal saline solution for injection and ampoule sealing technique. (5 ml)
8	Preparation of salicylic acid dusting powder. (10 gms)
9	Preparation of ORS. (10 gms)
10	Introduction to Adverse Drug Reactions and Drug – Drug Interactions.
11	Identification and causality assessment of Clinically identified Adverse Drug Reaction.
12	Identification and causality assessment of Clinically identified Adverse Drug Reaction.
13	Identification and reporting of Drug – Drug reaction.
14	Identification and reporting of Drug – Drug reaction.
15	Inventory management through ABC, VED, EOQ, Lead time and Buffer stock
16	**Revision**

Assessment methods and weightage

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

Three Sessional examinations to be conducted periodically throughout the year.

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

1. Merchant & Qadrys.A textbook of hospital pharmacy.ed:10th .B.S.Shah Prakashan.
2. William Hassan.E, Hospital Pharmacy.ed:5th Phialdelphia:Lea and Febiger;1986.
3. Parthasarathi .G.Karin Nyfort-Hansen,Milap C Nahata.A textbook of clinical pharmacy practice: essential concept and skills:ed.2nd :university press:2012
4. Prathibha Nand,Roop khar.K . A text book of Hospital and Clinical pharmacy.ed:6th ,birla:2008

Program	Pharm D PB
Year	I Year
Name of the course	Clinical Pharmacy
Course Code	16PB103
Paper	Theory
Hours /week	3+1 hours (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.

CO 5: Clinical design making.

Theory Course: Contents

S. No	Topics
I (3 weeks)	Definitions, development and scope of clinical pharmacy Introduction to daily activities of a clinical pharmacist
II (3weeks)	Introduction to daily activities of a clinical pharmacist: Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions) b. Ward round participation c. Adverse drug reaction management
III (3 weeks)	Introduction to daily activities of a clinical pharmacist: Drug information and poisons information e. Medication history f. Patient counselling.
IV (3weeks)	Introduction to daily activities of a clinical pharmacist: Drug utilisation evaluation (DUE) and review (DUR) h. Quality assurance of clinical pharmacy services
V (3weeks)	**Patient data analysis** The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
VI (3 weeks)	**Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results:** a. Haematological, Liver function, Renal function, thyroid function tests b. Tests associated with cardiac disorders.
VII (3 weeks)	**Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results:** Fluid and electrolyte balance d. Microbiological culture sensitivity tests e. Pulmonary Function Tests

VIII (3 weeks)	**Drug & Poison information:** a. Introduction to drug information resources available b. Systematic approach in answering DI queries c. Critical evaluation of drug information and literature & Preparation of written and verbal reports e. Establishing a Drug Information Centre f. Poisons information- organization & information resources
IX (3 weeks)	**Pharmacovigilance** a. Scope, definition and aims of pharmacovigilance b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used] c. Reporting, evaluation, monitoring, preventing & management of ADRs d. Role of pharmacist in management of ADR.
X (3 weeks)	Communication skills, including patient counselling techniques, medication history interview, presentation of cases. Pharmaceutical care concepts
XI (3 weeks)	Critical evaluation of biomedical literature Medication error
XII (3 weeks)	Revision/Assessment

Assessment methods and weightage

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

Note: Class tests & three Sessional examinations to be conducted periodically throughout the year.

Learning Resources/Recommended Texts/Reference books/web resources

1. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
2. Scott LT. Basic skills in interpreting laboratory data. American Society of Health System Pharmacists Inc.
3. David H Lawson, R Michael E. Richards. Clinical Pharmacy and Hospital Drug Management – 1982. Champan and Hall.
4. Dr. H.P.Tipnis, Dr. Amrita Bajaj. Clinical Pharmacy – 1st ed. Career Publications.
5. Leon Shargel, Susanna Wu Pong, Andrew B C Yu. Applied Biopharmaceutics and Pharmacokinetics. 5th ed. McGrawHill Companies; 2005.
6. G. Parthasarathi, Karin Nyfor-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice: Essential concepts and skills.2nd ed. India: Universities Press (India) Private Limited; 2012.
7. Mary Lee. Basic skills in interpreting laboratory data – 5th ed. American Society of Health System Pharmacist®.
8. Rowland M, Tozer TN. Clinical Pharmacokinetics: Concepts and Applications: Lippincott Williams & Wilkins; 1995.
9. Susan Foran. Australian drug information - Procedure manual – 1996. Society of Hospital Pharmacists of Australia.
10. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

Program	**Pharm D PB**
Year	**I Year**
Name of the course	**Clinical Pharmacy (Lab)**
Course Code	**16PB110**
Paper	**Practical**
Hours /week	**3 hours (laboratory)**
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.

C**ourse Learning Outcomes:**

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

CO 1: Monitor drug therapy of patient through medication chart review and clinical review and counsel the patients.

CO 2: Detection, assessment, monitoring, reporting and documentation of ADR's.

CO 3: Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states and designing appropriate drug therapy regimen.

CO 4: Identify and resolve drug related problems.

Practical Course: Contents

Week	**Topics**
1 to 10	Answering Drug Information Query
11 & 12	PMHI (Patient Medication History Interview)
13 to 18	
19 to 28	Case Presentations
29 to 36	Patient Counseling

Assessment methods and weightage

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

Three Sessional examinations to be conducted periodically throughout the year.

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

1. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
2. Scott LT. Basic skills in interpreting laboratory data. American Society of Health System Pharmacists Inc.
3. David H Lawson, R Michael E. Richards. Clinical Pharmacy and Hospital Drug Management – 1982. Champan and Hall.
4. Dr. H.P.Tipnis, Dr. Amrita Bajaj. Clinical Pharmacy – 1st ed. Career Publications.
5. Leon Shargel, Susanna Wu Pong, Andrew B C Yu. Applied Biopharmaceutics and Pharmacokinetics. 5th ed. McGrawHill Companies; 2005.
6. G. Parthasarathi, Karin Nyfor-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice: Essential concepts and skills.2nd ed. India: Universities Press (India) Private Limited; 2012.
7. Mary Lee. Basic skills in interpreting laboratory data – 5th ed. American Society of Health System Pharmacist®.
8. Rowland M, Tozer TN. Clinical Pharmacokinetics: Concepts and Applications: Lippincott Williams & Wilkins; 1995.
9. Susan Foran. Australian drug information - Procedure manual – 1996. Society of Hospital Pharmacists of Australia.
10. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

Program	**Pharm D PB**
Year	**I Year**
Name of the course	**Bio-Statistics and Research Methodology**
Course Code	**16PB104**
Paper	**Theory**
Hours /week	**2+1 hrs (lectures)**
Pre / co-requisite/s	**Nil**

Course Description:

The Bio Statistics and Research methodology course that provides an integrated presentation of Statistical methods and Research Methodologies. Information about each method is presented to explain the processes involved in Research Methodology and Bio statistical methods so that students will develop an understanding of the usage of the methods in Hospital Pharmacy. Students are able to interpret testing of hypothesis and Statistical methods and Computer applications in epidemiology and Pharmacy.

Course Learning Outcomes:

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

CO 1: Define Research Methodology, Biostatistics, data graphics, Basics of Testing of hypothesis

CO 2: Recognize types of clinical studies, types of data distribution, and Data graphics Statistical and computer applications in Pharmacy.

CO 3: Formulate Students test, chi-square test, Analysis of variance (One-way and two-ways)

Theory Course: Contents

S. No	Topics
I (3 weeks)	**Research Methodology-I** Types of clinical study designs: Case studies, Observational studies, interventional studies.
II (3weeks)	**Research Methodology-II** Designing the methodology, Sample size determination and power of a study Determination of sample size for simple comparative experiments.
III (3 weeks)	**Research Methodology-III** determination of sample size to obtain a confidence interval of specified width, power of a study, report writing and presentation of data
IV (3weeks)	**Biostatistics-I** Introduction, Types of data distribution, Measures describing the central tendency distributions-average, median, mode.
V (3weeks)	**Biostatistics-II** Measurement of the spread of data-range, variation of mean, standard deviation variance, coefficient of variation, standard error of mean.
VI (3 weeks)	**Biostatistics-III** **Data graphics** Construction and labelling of graphs, histogram, pie charts, scatter plots, semilogarthimic plots **Basics of testing hypothesis** Null hypothesis, level of significance, power of test.
VII (3 weeks)	**Biostatistics-IV** P value, statistical estimation of confidence intervals

	Level of significance (Parametric data)-students t test (paired and unpaired),chi Square test, Analysis of Variance(One way and two way)
VIII (3 weeks)	**Biostatistics-V** Level of significance (Non-Parametric data)-Sign test, Wilcoxon's signed test (Wilcoxon) rank sum test, Mann Whitney U test, Kruskal-Wall is test(One way ANOVA)
IX (3 weeks)	**Biostatistics-VI** Linear regression and correlation-Introduction, Pearson's and Spearman's correlation and correlation co efficient. Introduction to statistical soft ware: SPSS, Epi Info, SAS.
X (3 weeks)	**Biostatistics-VI** **Statistical methods in epidemiology** Incidence and prevalence, relative risk, attributable risk **Computer applications in Pharmacy-I** Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record
XI (3 weeks)	**Computer applications in Pharmacy-II** database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, Patient medication profiles, Inventory control, Management report & Statistics. Computer In Community Pharmacy
XII (3 weeks)	**Computer applications in Pharmacy-III** Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system Drug Information Retrieval & Storage :

	Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval

Assessment methods and weightage

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

Note: Class tests & three Sessional examinations to be conducted periodically throughout the year.

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

1. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd ed. publisher Marcel Dekker Inc. New York.
2. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich, 3rd ed. McGraw Hill Publications.

Program	**Pharm D PB**
Year	**I Year**
Name of the course	**Biopharmaceutics & Pharmacokinetics**
Course Code	**16PB105**
Paper	**Theory**
Hours /week	**3+1 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 modeling, mechanisms of renal clearance, and assessment of drug bioavailability.

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

CO 1: Underline the basic concepts of pharmacokinetics and biopharmaceutics.

CO 2: Explain the physiological, physicochemical and dosage form-related factors that affects drug absorption from different dosage forms.

CO 3: Describe the different pharmacokinetic models.

CO 4: Differentiate between compartmental and non-compartmental analysis.

CO 5: Estimate the basic pharmacokinetic parameters that describe drug absorption and disposition.

Theory Course: Contents

S. No.	Topics
I (3 weeks)	**Introduction to Biopharmaceutics** a. Absorption of drugs from gastrointestinal tract.
II (3weeks)	b. Drug Distribution. c. Drug Elimination
III (3 weeks)	**Introduction to Pharmacokinetics** a. Mathematical model b. Drug levels in blood. c. Pharmacokinetic model
IV (3weeks)	d. Compartment models e. Pharmacokinetic study.
V (3weeks)	**One compartment open model** a. Intravenous Injection (Bolus) b. Intravenous infusion.
VII (3weeks)	c. Extravascular administration
VIII (3weeks)	**Multicompartment models** a. Two compartment open model.
IX (3 weeks)	b. IV bolus and oral administration **Nonlinear Pharmacokinetics** a. Introduction

	b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters.
X (3weeks)	**Multiple – Dosage Regimens** a. Repetitive Intravenous injections – One Compartment Open Model b. Repetitive Extravascular dosing – One Compartment Open model
XI (3 weeks)	**Noncompartmental Pharmacokinetics** a. Statistical Moment Theory. b. MRT for various compartment models. c. Physiological Pharmacokinetic model.
XII (3 weeks)	**Bioavailability and Bioequivalence** a. Introduction. b. Bioavailability study protocol. c. Methods of Assessment of Bioavailability

Assessment methods and weightage

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

Note: Class tests & three Sessional examinations to be conducted periodically throughout the year.

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

1. Shargel L, Wu-Pong S, Yu AB. Applied biopharmaceutics & pharmacokinetics: McGraw-Hill; 2007.
2. Gibaldi M, Perrier D. Pharmacokinetics. Second ed: Marcel Dekker; 1975.
3. Wagner JG. Fundamentals of Clinical Pharmacokinetics: Drug Intelligence Publications; 1975.
4. Abdou HM. Dissolution, bioavailability & bioequivalence: Mack; 1989.
5. Gibaldi M, Gibaldi M. Biopharmaceutics and Clinical Pharmacokinetics: Laurier Books Limited; 2005.
6. Notari RE. Biopharmaceutics and pharmacokinetics: an introduction: M. Dekker; 1975.
7. Rowland M, Tozer TN. Clinical Pharmacokinetics: Concepts and Applications: Lippincott Williams & Wilkins; 1995.

Program	Pharm D PB
Year	I Year
Name of the course	Biopharmaceutics & Pharmacokinetics (Lab)
Course Code	16PB111
Paper	Practical
Hours /week	3 hours (laboratory)
Pre / co-requisite/s	Nil

Course Description:

The Biopharmaceutics and Pharmacokinetics laboratory course is designed to provide the students on laboratory skill for the demonstration of instrumentation based on principles of dissolution and solubility such as dissolution test apparatus, orbital shaker incubator etc. This course also deals with wet laboratory based experiments on dissolution enhancement, comparative dissolution, protein binding and *in vitro* absorption studies etc. This course also provides the skills for interpretation of plasma and urine drug concentration data after various routes of administration to determine necessary pharmacokinetic parameters.

Course Learning Outcomes:

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

CO 1: Demonstrate the skills on instrumentation related to dissolution and solubility.

CO 2: Compare the dissolution profiles of different marketed dosage forms and prepared formulations.

CO 3: Estimate various pharmacokinetic parameters of drugs following various compartment models after different routes of administration.

Practical Course: Contents

Week	Topics
1	Determination of solubility of the given drug by gravimetric and spectrophotometric method.
2	Determination of pK_a of the given drug by half neutralization method.
3	Improvement of dissolution characteristics of slightly soluble drugs by solid dispersion technique.
4	Improvement of dissolution characteristics of slightly soluble drugs by solid dispersion technique.
5	Improvement of dissolution characteristics of slightly soluble drugs by solvent deposition technique.
6	Improvement of dissolution characteristics of slightly soluble drugs by solvent deposition technique.
7	Improvement of solubility dissolution characteristics of slightly soluble drugs by micellar solubilization technique.
8	Improvement of solubility dissolution characteristics of slightly soluble drugs by micellar solubilization technique.
9	Comparison of dissolution studies of two different marketed products of same drug.
10	Comparison of dissolution studies of two different marketed products of same drug.
11	Influence of polymorphism on solubility and dissolution of poorly soluble drug.

12	Influence of polymorphism on solubility and dissolution of poorly soluble drug.
13	Influence of complexation on solubility and dissolution of poorly soluble drug.
14	Influence of complexation on solubility and dissolution of poorly soluble drug.
15	Protein binding studies of a highly protein bound drug.
16	Protein binding studies of a highly protein bound drug.
17	Protein binding studies of a poorly protein bound drug.
18	Protein binding studies of a poorly protein bound drug.
19	Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
20	Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
21	Effect of contact time on the plasma protein binding of drugs.
22	Effect of contact time on the plasma protein binding of drugs.
23	Absorption studies in animal inverted intestine using various drugs.
24	Absorption studies in animal inverted intestine using various drugs.
25	Bioavailability studies and bio equivalence studies of selected drug by salivary data.
26	Calculation of Ka, K_E, $t_{1/2}$, C_{max}, AUC, AUMC, MRT etc. from blood profile data.

27	Calculation of Ka, K_E, $t_{1/2}$, C_{max}, AUC, AUMC, MRT etc. from blood profile data.
28	Calculation of bioavailability from urinary excretion data for given drug.
29	Calculation of bioavailability from urinary excretion data for given drug.
30	Calculation of AUC and bioequivalence from the given data for the given drug.
31	Calculation of AUC and bioequivalence from the given data for the given drug.
32	Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
33	Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
34	Determination of absorption rate constant by Wagnor-Nelson method.
35	Determination of various pharmacokinetic parameters of a drug that is following two compartment model after IV bolus administration.
36	REVISION/Assessment

Assessment methods and weightage

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

Three Sessional examinations to be conducted periodically throughout the year.

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

1. Shargel L, Wu-Pong S, Yu AB. Applied biopharmaceutics & pharmacokinetics: McGraw-Hill; 2007.
2. Gibaldi M, Perrier D. Pharmacokinetics. Second ed: Marcel Dekker; 1975.
3. Wagner JG. Fundamentals of Clinical Pharmacokinetics: Drug Intelligence Publications; 1975.
4. Abdou HM. Dissolution, bioavailability & bioequivalence: Mack; 1989.
5. Gibaldi M, Gibaldi M. Biopharmaceutics and Clinical Pharmacokinetics: Laurier Books Limited; 2005.
6. Notari RE. Biopharmaceutics and pharmacokinetics: an introduction: M. Dekker; 1975.
7. Rowland M, Tozer TN. Clinical Pharmacokinetics: Concepts and Applications: Lippincott Williams & Wilkins; 1995.
8. https://www.boomer.org/c/p1/

Program	**Pharm D PB**
Year	**I Year**
Name of the course	**Clinical Toxicology**
Course Code	**16PB106**
Paper	**Theory**
Hours /week	**2+1 hours (lectures)**
Pre / co-requisite/s	**Nil**

Course Description:

This course will establish the scientific principles underlying the toxic actions of various substances and will introduce the various challenges within the field of toxicology. The chemical nature of injurious substances, their uptake and metabolism by non-target organisms, and their mode of toxic action will be studied in addition to the methods used in safety evaluations and risk assessment.

Course Learning Outcomes:

Upon completion of this course, the student will:

CO 1: Discuss the epidemiologic and demographic parameters that characterize toxic exposures in the United States.

CO 2: Discuss the role of the pharmaco-therapist in the evaluation and management of poisoned patients

CO 3: Utilize historical information and clinical patient assessments in the evaluation of the poisoned patient.

CO 4: Formulate a treatment plan based on history, time course of the exposure, presenting symptomatology, toxidrome recognition, and assessment of toxic potential.

CO 5: Discuss current philosophies, and cite the risks associated with, the use of various methods of gastrointestinal decontamination for ingested toxins. Choose the appropriate modality for specific poisoned/overdosed patients.

CO 6: Initiate appropriate diagnostic laboratory analyses and recommend the appropriate laboratory and physical assessments to aid in monitoring the progress of the toxic or suspected toxic exposure, correctly interpreting the results of such interventions.

CO 7: Discuss the indications for use and the risks associated with the various methods utilized to enhance elimination in the poisoned patient. Select the appropriate therapy based on the exposure and symptoms.

CO 8: Develop a therapeutic management and monitoring plan when the use of a pharmacologic antidote is indicated for the poisoned/overdosed patient.

CO 9: Define economic and therapeutic outcomes in poisoned patients

Theory Course: Contents

S. No.	Topics
I (3 weeks)	Introduction to toxicology General principles involved in the management of poisoning Food poisoning
II (3 weeks)	Antidotes and the clinical applications Supportive care in clinical Toxicology Envenomation's – Mushrooms, Mycotoxins

III (3 weeks)	Gut Decontamination Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries
IV (3 weeks)	Elimination Enhancement Clinical symptoms and management of acute poisoning with the following agents: a) Radiation Poisoning
V (3 week)	b) Opiates overdose c) Anti depressants d) Paracetamol and salicylates e) NSAID's f) Barbiturates & Benzodiazepines
VII (3 weeks)	g) Pesticide poisoning: Organophosphorus compounds, carbamates, Organo chlorines, pyrethroids h) Alcohol: ethanol, methanol
VIII (3 weeks)	i) Hydrocarbons: Petroleum product and PEG j) Caustics: inorganic acids and alkalies Heavy Metals: Arsenic, lead
IX (3weeks)	Mercury, iron and copper Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries

X (3 weeks)	Toxicokinetics
XI (3 weeks)	Substance abuse: a) CNS stimulants – amphetamine b) Opioids c) Tobacco
XII (3 weeks)	a) Hallucinogens – LSD b) Cannabis group c) CNS depressants

Assessment methods and weightage

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

Note: Class tests & three Sessional examinations to be conducted periodically throughout the year.

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

1. Matthew J Ellenhorn. Ellenhorns Medical Toxicology – Diagnosis and Treatment of Poisoning. 2nd ed. Williams and Willkins publication, London.
2. V VPillay. Handbook of Forensic Medicine and Toxicology. 13th ed. 2003 Paras Publication, Hyderabad.
3. Narayana reddy. Medical toxicology.13th edition.

Program	**Pharm D (P.B)**
Year	**I Year**
Name of the course	**Pharmacotherapeutics I & II**
Course Code	**16PB107**
Paper	**Theory**
Hours /week	**3+1 hours (lectures)**
Pre / co-requisite/s	**Nil**

Course Description:

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management

Course Learning Outcomes:

At completion of this subject it is expected that students will be able to describe

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualized therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (Including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse Effects);

CO 6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO 7: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy;

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis; and

CO 10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Theory Course: Contents

S. No.	Topics
I (3 weeks)	**Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction
II (3weeks)	Hyperlipidaemias, Electrophysiology of heart and Arrhythmia
III (3 weeks)	**Respiratory system:** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
IV (3weeks)	**Endocrine system:**

	Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
V (3weeks)	**General prescribing guidelines for** a. Pediatric patients b. Geriatric patients. Pregnancy and breast feeding **Ophthalmology:** Glaucoma,
VI (3 weeks)	Conjunctivitis **Introduction to rational drug use** Definition, viral & bacterial (Eye Infections)
VII (3 weeks)	Role of pharmacist Essential drug concept Rational drug formulations **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo
VIII (3 weeks)	**Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditic, Septicaemia.
IX (3 weeks)	Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
X (3 weeks)	**Musculoskeletal disorders** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
XI (3 weeks)	**Renal system** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

XII (3 weeks)	**Oncology:** Basic principles of Cancer therapy, General introduction to cancer Chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis & REVISION.

Assessment methods and weightage

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

Note: Class tests & three Sessional examinations to be conducted periodically throughout the year.

Learning Resources/Recommended Texts/Reference books/web resources

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8th ed. lippincot Williams;2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach.9th ed. Mcgraw-hill education; 2012.
3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10th ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5th ed. Churchill livingstone;2011
5. Green, Russells, Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3rd ed. Pharmaceutical press:2008.

Program	**Pharm D (P.B)**
Year	**I Year**
Name of the course	**Pharmacotherapeutics I & II (Lab)**
Course Code	**16PB112**
Paper	**Practical**
Hours /week	**3 hours (laboratory)**
Pre / co-requisite/s	**Nil**

Course Description:

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to describe the pathophysiology of common diseases and their management.

Course Learning Outcomes:

At completion of this subject it is expected that students will be able to understand –

CO 1: The pathophysiology of selected disease states and the rationale for drug therapy;

CO 2: The therapeutic approach to management of these diseases;

CO 3: The controversies in drug therapy;

CO 4: The importance of preparation of individualized therapeutic plans based on diagnosis;

CO 5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (Including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse Effects);

CO 6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

CO 7: Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

CO 8: Discuss the controversies in drug therapy;

CO 9: Discuss the preparation of individualized therapeutic plans based on diagnosis; and

CO 10: Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Practical Course: Contents

Week	**Topics**
1	Introduction to ward round participation and case collection
2	Hypertension
3	CCF (congestive cardiac failure)
4	Activity I
5	Hypothyroidism
6	Acute renal failure
7	Activity II (Drug utilization review).
8	Asthma
9	Depression diseases
10	Activity III
11	Epilepsy
12	Parkinson's disease
13	Activity IV
14	Infectious diseases [any five].

15	Chronic renal failure
16	Gastroenteritis,
17	Activity V
18	Malaria
19	Fungal infections
20	Activity VI
21	Anxiety
22	Psoriasis
23	Activity VII
24	Spondylitis
25	Hyperthyroidism
26	Activity VIII
27	Septicemia.
28	Osteoarthritis
29	Glaucoma
30	Activity IX
31	Tuberculosis.
32	Activity X
33	Stroke
34	HIV
35	Angina Pectoris
36	Revision/Assessment

Assessment methods and weightage

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

Three Sessional examinations to be conducted periodically throughout the year.

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

1. Eric Herfindal T. Textbook of therapeutics: drug and disease. 8th ed. lippincot Williams;2008.
2. Joseph Dipiro. Pharmacotherapy a pathophysiology approach.9th ed. Mcgraw-hill education; 2012.
3. Koda-kimble. Applied therapeutics: The clinical use of drugs. 10th ed. lippincot Williams;2012.
4. Roger walker, Clinical pharmacy and therapeutics. 5th ed. Churchill livingstone;2011
5. Green, Russells, Harris. Pathology and therapeutics for pharmacist: A basis for clinical pharmacy practice. 3rd ed. Pharmaceutical press:2008.

Program	**Pharm D PB**
Year	**II Year**
Name of the course	**Clinical Research**
Course Code	**16PB201**
Paper	**Theory**
Hours /week	**3+1 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: These courses provide students with a theoretical and practical understanding of the issues involved in the design, conduct, analysis and interpretation of preclinical and clinical trials in living beings.

CO 2: Skills to examine information, for critical analyses and carry out research, and to communicate effectively.

CO 3: Develop the capacity to understand and analyze the application of ICH – GCP guidelines clinically.

Theory Course: Contents

S. No.	Topics
I (3 weeks)	• **Drug development process:** Introduction Various Approaches to drug discovery 1. Pharmacological 2. Toxicological
II (3 weeks)	• **Drug development process:** Introduction Various Approaches to drug discovery 1. Drug characterization 2. Dosage form 3. IND Application
III (3 weeks)	• **Clinical development of drug:** 1. Introduction to Clinical trials 2. Various phases of clinical trial.
IV (3 weeks)	• **Clinical development of drug:** 1. Methods of post marketing surveillance 2. Abbreviated New Drug Application submission.
V (3 weeks)	• **Clinical development of drug:** 1. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines 2. Challenges in the implementation of guidelines 3. Ethical guidelines in Clinical Research

VII (3 weeks)	• **Clinical development of drug:** 1. Composition, responsibilities, procedures of IRB / IEC 2. Overview of regulatory environment in USA, Europe and India.
VIII (3 weeks)	• **Clinical development of drug:** Role and responsibilities of clinical trial personnel as per ICH GCP a. Sponsor b. Investigators c. Clinical research associate d. Auditors e. Contract research coordinators f. Regulatory authority
IX (3 weeks)	• **Clinical development of drug:** 1. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment) 2. Informed consent Process
X (3 weeks)	• **Clinical development of drug:** 1. Data management and its components
XI (3 weeks)	• **Clinical development of drug:** 1. Safety monitoring in clinical trials.
XII (3 weeks)	Revision / Assessment

Assessment methods and weightage

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

Note: Class tests & three Sessional examinations to be conducted periodically throughout the year

Learning Resources/Recommended Texts/Reference books/web resources

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
6. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
7. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

Program	**Pharm D PB**
Year	**II Year**
Name of the course	**Pharmacoepidemiology and Pharmacoeconomics**
Course Code	**16PB202**
Paper	**Theory**
Hours /week	**3+1 hours (lectures)**
Pre / co-requisite/s	**Nil**

Course Description:

This course is designed to improve knowledge regarding usage of pharmaco epidemiological methods to identify, assess, evaluate and manage drug induced risks. This course will enable the student about usage of Pharmacoeconomic principles in therapeutic decision making process.

Course Learning Outcomes: At completion of this subject it is expected that students will be able to understand

CO 1: Epidemic measures and outcome measures in drug use

CO 2: Application of Pharmacoepidemiology

CO 3: Designing of Pharmacoepidemiological methods

CO 4: Special application of Pharmacoepidemiological methods

CO 5: Sources of data to conduct Pharmacoepidemiological studies

CO 6: Usage Pharmacoeconomic tools in various conditions

CO 7: Application of Pharmacoeconomic principles in decision making

CO 8: Software's used in pharmacoeconomics and Pharmacoepidemiology

Theory Course: Contents

S. No.	Topics
I (3 weeks)	**Pharmacoepidemiology:** **Definition and scope:** Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.
II (3weeks)	**Measurement of outcomes in Pharmacoepidemiology** Outcome measure and drug use measures
III (3 weeks)	Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement
IV (3weeks)	**Concept of risk in pharmacoepidemiology** Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio
V (3weeks)	**Pharmacoepidemiological methods** Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies.
VI (3 weeks)	**Pharmacoepidemiological methods** Meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.
VII (3 weeks)	**Sources of data for Pharmacoepidemiological studies** Ad Hoc data sources and automated data systems

VIII (3 weeks)	**Selected special applications of pharmacoepidemiology** Studies of vaccine safety, hospital pharmacoepidemiology.
IX (3 weeks)	**Selected special applications of pharmacoepidemiology** Pharmacoepidemiology and risk management, drug induced birth defects.
X (3 weeks)	**Pharmacoeconomics:** **Definition, history, needs of pharmacoeconomic evaluations** Role in formulary management decisions
XI (3 weeks)	**Pharmacoeconomic evaluation** Outcome assessment and types of evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility
XII (3 weeks)	**Applications of Pharmacoeconomics** Software and case studies

Assessment methods and weightage

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

Note: Class tests & three Sessional examinations to be conducted periodically throughout the year.

Learning Resources/Recommended Texts/Reference books/web resources

1. Brian L Storm. Pharmacoepidemiology. 3rd ed. England: John Wiley & Sons Ltd. 2000.
2. F Randy Vogenberg. Introduction to Applied Pharmacoeconomics. McGraw-Hill. 2011.
3. Essentials of Pharmacoeconomics by Karen Rascati
4. Pharmacoeconomics: http://www.ispor.org/
5. Pharmacoepidemiology: http://www.pharmacoepi.org/

Program	**Pharm D PB**
Year	**II Year**
Name of the course	**Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring**
Course Code	**16PB203**
Paper	**Theory**
Hours /week	**2+1 hours (lectures)**
Pre / co-requisite/s	**Nil**

Course Description:

Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring course is designed to provide the student with exposure to the application of pharmacokinetic and pharmacodynamic principles of a variety of drug classes to clinical situations. The course will provide a review of clinical pharmacokinetic principles and provide background for the student to develop an approach to therapeutic drug monitoring. Situations and clinical conditions that are likely to alter the concentration: time and/or concentration: effect relationship will be emphasized. The remainder of the course will deal more specifically with the most common drug classes where therapeutic drug monitoring is applied in clinical practice.

Course Learning Outcomes:

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

CO: 1 Define important concepts of clinical pharmacokinetic and pharmacodynamic.

CO: 2 Understand the effect of pharmacokinetics and pharmacodynamic parameters and the observed drug concentration and clinical response.

CO: 3 Recommend dose adjustments of drugs based on renal and hepatic functions.

CO: 4 Provide patient-specific initial dosage recommendations for therapeutically monitored drugs and dosage adjustment based on plasma concentration.

Theory Course: Contents

S. No	Topics
I (3 weeks)	**Introduction to Clinical pharmacokinetics.**
II (3weeks)	**Design of dosage regimens:** Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
III (3 weeks)	**Pharmacokinetics of Drug Interaction:** a. Pharmacokinetic drug interactions
IV (3weeks)	**Pharmacokinetics of Drug Interaction:** Inhibition and Induction of Drug metabolism c. Inhibition of Biliary Excretion.
V (3weeks)	**Therapeutic Drug monitoring:** a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs). c. Indications for TDM. Protocol for TDM.
VII (3 weeks)	**Therapeutic Drug monitoring:** d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy. e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations

VIII (3 weeks)	**Dosage adjustment in Renal and hepatic Disease:** a. Renal impairment b. Pharmacokinetic considerations, General approach for dosage adjustment in Renal disease.
IX (3 weeks)	**Dosage adjustment in Renal and hepatic Disease:** Measurement of Glomerular Filtration rate and creatinine clearance. e. Dosage adjustment for uremic patients. f. Extracorporeal removal of drugs. g. Effect of Hepatic disease on pharmacokinetics
X (3 weeks)	**Population Pharmacokinetics.** a. Introduction to Bayesian Theory. b. Adaptive method or Dosing with feedback. c. Analysis of Population Pharmacokinetic Data.
XI (3 weeks)	**Pharmacogenetics** a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes. b. Genetic Polymorphism in Drug Transport and Drug Targets.
XII (3 weeks)	**Pharmacogenetics:** Pharmacogenetics and Pharmacokinetics/ Pharmacodynamic considerations

Assessment methods and weightage

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

Note: Class tests & three Sessional examinations to be conducted periodically throughout the year.

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

1. Larry A. Bauer. Applied Clinical Pharmacokinetics. McGraw-Hilll/Appleton & Lange. 2001.
2. Michael E. Winter. Basic Clinical Pharmacokinetics.3rd edition. Applied Therapeutics. 1994
3. Joseph T. Dipiro, William J. Spruill, Robert A. Bloum, Jane M. Pruemer, American Cancer Society, (Joan Heimann editors). Concepts in Clinical Pharmacokinetics. 3rd. edition. American Hospital Association. 2002.
4. Malcolm Rowland, Thomas N. Tozer, Randy Rowland (Editors). Clinical Pharmacokinetics: Concepts and Applications. 3rd edition. Lippincott1Williams & Wilkins. 1995
5. William E. Evans, Jerome J. Schentag, William J. Jusko (Editors). Applied Pharmacokinetics: Principles of Therapeutic Drug Monitoring. 3rd edition. Applied Therapeutics. 1992

Pharm D PB III Year

INTERNSHIP (16PB601)

1) **SPECIFIC OBJECTIVES:**

i) To provide patient care in cooperation with patients, prescribers, and other members of an inter professional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioural or administrative, and clinical sciences that may impact therapeutic outcomes.

ii) To manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.

iii) To promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an inter professional team of health care providers.

iv) To demonstrate skills in monitoring of the National Health Programme s and schemes, oriented to provide preventive and promotive health care services to the community.

v) To develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.

vi) To communicate effectively with patients and the community.

2) **OTHER DETAILS:**

i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.

ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee, a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

iii) Every candidate shall be required, after passing the final Pharm. D. or Pharm. D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm. D. or Pharm. D. (Post Baccalaureate) as the case may be.

3. ASSESSMENT OF INTERNSHIP:

i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practitioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.

ii) Satisfactory completion of internship shall be determined on the basis of the following:

(1) Proficiency of knowledge required for each case management SCORE 0-5

(2) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5

(3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5

(4) Ability to work in a team (Behaviour with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5

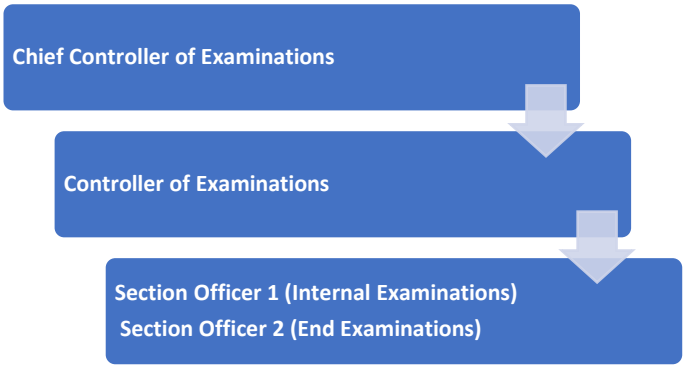
(5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

Examination Cell – Structure, Rules and Regulations

a) **Organization structure**



b) **Infra-structure / Security / confidential zone**

- Single entry with complete partitions for various sections of examinations under CCTV surveillance
- Single door entry & exit
- Confidential room attached to Controller of examinations
- Separate strong room for Used and Un-used examination material
- Evaluation Hall with toilet facility / water facility etc.
- Repo-graphic area
- Office section

C) Assurance of confidentiality

- Free entry is restricted in the premises.
- Question paper selection and Question paper moderation will be done just 30 minutes before the examination commencement. During moderation, electronic gadgets including mobiles and internet facility will not be entertained during question paper moderation.

- Question paper setting from Outside the University with minimum PG or preferably Ph.D. having five years of teaching experience in relevant subject. The obtained sets of question paper will be under the custody of controller of examinations.
- Question paper moderation will be done if required after consultation with the Chief controller of examination & after receiving inputs from of HOD's of concerned departments in CE chamber.
- All the experts involed in the moderation will be asked to be present in the chamber till the examination commences.
- Question papers will be carried in sealed covers by CE and will be handed over to Invigilators ten minutes before commencement examination.

d**) Eligibility criteria for experts in examination and evaluation.**

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

NOTE:

*Double Evaluation for M. Pharm, if there is a discrepancy of 15 % deviation between two evaluations, there will be third evaluation.

Challenge valuation will be adapted for end examinations results of all programs as per awarding university.

e) **Recommended assessment tools**

B. 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 & three Sessional examinations to be conducted periodically throughout the year.

Annexure-I: Class test rubrics

Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)

Awarding University: JNT University, Anantapur (JNTUA)

Subject Name: **Subject 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**

Annexure-II: Rubrics for Assignment / Seminar/ Project evaluation

Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)

Awarding University: JNT University, Anantapur (JNTUA

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)**	

Annexure-III: Mid – Examination Rubrics

Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)

Awarding University: JNT University, Anantapur (JNTUA)

Subject Name: **Subject Code:**

Date of Examination: **Total Marks: 30 M**

Section-A

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

Section-B

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

Annexure-IV: 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

Annexure-V: (Theory question paper rubrics) - End Examinations

Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)

Awarding University: JNT University, Anantapur (JNTUA)

Subject Name: **Subject Code:**

Date of Examination: **Total Marks: 70 M**

Section-A

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

Section-B

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

Annexure-VI: End examinations - Practical question paper rubrics

Raghavendra Institute of Pharmaceutical Education and Research (Autonomous)

Awarding University: JNT University, Anantapur (JNTUA)

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

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

Annexure – VII: Research Project / Presentation 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)				

Annexure – VIII: Rubrics for Grading and Ranking

Year Grade Point Average (GPA) and Cumulative Grade point average (CGPA) as per awarding university. Gold medal and ranking will be declared for those students who have passed all semesters in single attempt only.

Annexure IX: Malpractices / Punishments

As per the regulations and guidelines, of awarding university the malpractices and punishments will be changed from time to time.