

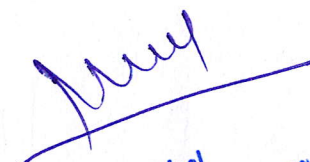


Pharm. D (Post Baccalaureate)

Rules-Regulations & Curriculum

(w.e.f. 2025-26)


REGISTRAR
Sai Tirupati University
Udaipur (Raj.)


Principal
Venkateshwar Institute of Pharmacy
Vijaya Road, Umarda, Udaipur (Raj.) 313015

Venkateshwar Institute of Pharmacy

(A Constituent Unit of Sai Tirupati University, Udaipur)

Rules and Regulations

Pharm. D. (Post Bacalaureate)

Eligibility Criteria

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 program

Pharm. D. (PB): The duration of the program 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 course separately. The candidate shall complete the prescribed program 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 program outcome, need to be evaluated as per standard rubrics and documented. Final score may be included in the continuous assessment as indicated in individual program syllabus.
- 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 program, or repeat the program 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 (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 (PB) 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 (4), (5) and (6) below.

Program Scheme

I Year

S. No	Name of Course	Course Codes	No. of hrs of Theory	No. of hrs of Practical	No. of hrs of tutorial	Lab	S. No	Course codes
(1)	(2)	(3)	(4)	(5)	(6)		(7)	(8)
1.1	Pharmacotherapeutics I & II	501PB101	3	3	1	✓	1.8	501PB108
1.2	Pharmacotherapeutics-III	501PB102	3	3	1	✓	1.9	501PB109
1.3	Hospital Pharmacy	501PB103	2	3	1	✓	1.10	501PB110
1.4	Clinical Pharmacy	501PB104	3	3	1	✓	1.11	501PB111
1.5	Biostatistics and research methodology	501PB105	2	--	1		---	-----
1.6	Biopharmaceutics and pharmacokinetics	501PB106	3	3	1	✓	---	501PB112
1.7	Clinical toxicology	501PB107	2	--	1		---	-----
	Total hours		18	15	7= (40)			

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)
2.1	Clinical Research	501PB201	3	-	1
2.2	Pharmacoepidemiology and Pharmacoeconomics	501PB202	3	-	1
2.3	Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring	501PB203	2	-	1
2.4	Clerkship	501PB204	-	-	1
2.5	Project work (Six Months)	501PB205	-	20	
	Total hours		8	20	4= (32)

* Attending ward rounds on daily basis.

III Year

Internship (501PB301)

Internship or residency training including postings in specialty 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 course or course shall be declared to have passed in that course
- b) Theory and Practical of a particular course are considered as individual course for the purpose of pass criteria. Those candidates who fail in one or more course shall have to appear only in the course so failed, in the subsequent examinations.

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

Candidates of Pharm. D. (PB) 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

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 course, theory and practical 's secured by the candidates 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 Pharm D. (PB).

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 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 authorized 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 utilization 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-titles 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.

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15

Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks are 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Award of Ranks

Ranks and Medals shall be awarded on the basis of aggregate of all the two university examinations. However, candidates who fail in one or more subjects during the Pharm program shall not be eligible for award of ranks.

Moreover, the candidates should have completed the Pharm. D program in minimum prescribed number of years, (two years) 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 program 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.

Detail Syllabus

FIRST YEAR

PHARMACOTHERAPEUTICS I & II (THEORY)

Theory: 3Hrs/week

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases.

- 1. Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidemias, Electrophysiology of heart and Arrhythmias
- 2. Respiratory system:** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
- 3. Endocrine system:** Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
- 4. General prescribing guidelines for**
 - a. Pediatrics patients
 - b. Geriatric patients
 - c. Pregnancy and breast feeding
- 5. Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
- 6. Introduction to rational drug use** Definition, Role of pharmacist Essential drug concept Rational drug formulations
- 7. Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
- 8. Musculoskeletal disorders** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- 9. Renal system** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
- 10. Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 11. Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

PHARMACOTHERAPEUTICS – I & II (PRACTICAL)

Practicals: 3 Hrs./Week

Practicals: Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for

evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments: Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

PHARMACOTHERAPEUTICS – III (THEORY)

Theory: 3 Hrs. /Week

1. **Scope:** 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.
2. **Objectives:** At completion of this subject, it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualized therapeutic plans based on diagnosis;
 - e. 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);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualized therapeutic plans based on diagnosis; and
 - j. 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).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical: 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours are required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Hematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, anxiety disorders, sleep disorders, obsessive compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics

allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice-based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William.E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. Lecture wise programme:

Topics

- 1 **Hospital - its Organisation and functions**
- 2 **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

3 The Budget – Preparation and implementation

4 Hospital drug policy

- a) Pharmacy and Therapeutic committee (PTC)
- b) Hospital formulary
- c) Hospital committees
 - Infection committee
 - Research and ethical committee
- d) developing therapeutic guidelines
- e) Hospital pharmacy communication - Newsletter

5 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
- c) Drug distribution in the hospital
 - i) Individual prescription method
 - ii) Floor stock method
 - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

- a) Sterile formulations – large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

7 Continuing professional development programs

Education and training

8 Radio Pharmaceuticals – Handling and packaging

9 Professional Relations and practices of hospital pharmacist

HOSPITAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.

3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well, equipped with various resources of drug information.

CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

1. Objectives of the Subject:

Upon completion of the subject student shall be able to (Know, do, appreciate) –

- a. monitor drug therapy of patient through medication chart review and clinical review;
- b. obtain medication history interview and counsel the patients;
- c. identify and resolve drug related problems;
- d. detect, assess and monitor adverse drug reaction;
- e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
 - a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
 - b. Ward round participation
 - c. Adverse drug reaction management
 - d. Drug information and poisons information
 - e. Medication history
 - f. Patient counseling
 - g. Drug utilisation evaluation (DUE) and review (DUR)
 - h. Quality assurance of clinical pharmacy services
3. **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.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
 - a. Hematological, Liver function, Renal function, thyroid function tests
 - b. Tests associated with cardiac disorders
 - c. Fluid and electrolyte balance
 - d. Microbiological culture sensitivity tests
 - e. Pulmonary Function Tests
5. **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
 - d. Preparation of written and verbal reports
 - e. Establishing a Drug Information Centre
 - f. Poisons information- organization & information resources
6. **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.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
 8. Pharmaceutical care concepts
 9. Critical evaluation of biomedical literature
 10. Medication errors

CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 **Research Methodology**

- a) Types of clinical study designs:
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
- d) Report writing and presentation of data

2 **Biostatistics**

2.1 a) Introduction

- b) Types of data distribution
- c) Measures describing the central tendency distributions- average, median, mode
- d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 **Data graphics**

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots

2.3 **Basics of testing hypothesis**

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation coefficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 **Statistical methods in epidemiology**

Incidence and prevalence, relative risk, attributable risk

3. **Computer applications in pharmacy**

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record 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

Computerizing the Prescription Dispensing process

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

Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. New York.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich, 3rd edition, McGraw Hill Publications 2006

BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
 - a. Absorption of drugs from gastrointestinal tract.
 - b. Drug Distribution.
 - c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
 - a. Mathematical model
 - b. Drug levels in blood.
 - c. Pharmacokinetic model
 - d. Compartment models
 - e. Pharmacokinetic study.
3. One compartment open model.
 - a. Intravenous Injection (Bolus)
 - b. Intravenous infusion.
4. Multicompartment models.
 - a. Two compartment open model.
 - b. IV bolus, IV infusion and oral administration
5. Multiple – Dosage Regimens.

- a. Repetitive Intravenous injections – One Compartment Open Model
 - b. Repetitive Extravascular dosing – One Compartment Open model
 - c. Multiple Dose Regimen – Two Compartment Open Model
6. Nonlinear Pharmacokinetics.
 - a. Introduction
 - b. Factors causing non-linearity.
 - c. Michaelis-Menton method of estimating parameters.
 7. Noncompartmental Pharmacokinetics.
 - a. Statistical Moment Theory.
 - b. MRT for various compartment models.
 - c. Physiological Pharmacokinetic model.
 8. Bioavailability and Bioequivalence.
 - a. Introduction.
 - b. Bioavailability study protocol.
 - c. Methods of Assessment of Bioavailability

BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical: 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. 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.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bio equivalency studies on the different drugs marketed. (e.g.) Tetracycline, Sulphathiazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- c. Pharmacokinetics: By Milo Gibaldi Donald, R. MerceL Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
 - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti-inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.

- i) Caustics: inorganic acids and alkali.
- j) Radiation poisoning
- 8. Clinical symptoms and management of chronic poisoning with the following agents
 - Heavy metals: Arsenic, lead, mercury, iron, copper
- 9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
- 10. Plants poisoning. Mushrooms, Mycotoxins.
- 11. Food poisonings
- 12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants: amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

References:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

SECOND YEAR

CLINICAL RESEARCH (THEORY)

Theory: 3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. 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
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

References:

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. 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.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory: 3 Hrs. /Week

1. Pharmacoepidemiology:

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

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, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. Pharmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

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

3. Applications of Pharmacoeconomics

Software and case studies

CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs. /Week

1. Introduction to Clinical pharmacokinetics.

2. 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.

3. Pharmacokinetics of Drug Interaction:

- a. Pharmacokinetic drug interactions
- b. Inhibition and Induction of Drug metabolism
- c. Inhibition of Biliary Excretion.

4. Therapeutic Drug monitoring:

- a. Introduction
- b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs).
- c. Indications for TDM. Protocol for TDM.
- d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
- e. TDM of drugs used in the following disease conditions: cardiovascular

disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

5. Dosage adjustment in Renal and hepatic Disease.

- a. Renal impairment
- b. Pharmacokinetic considerations
- c. General approach for dosage adjustment in renal disease.
- d. 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.

6. Population Pharmacokinetics.

- a. Introduction to Bayesian Theory.
- b. Adaptive method or Dosing with feedback.
- c. Analysis of Population pharmacokinetic Data.

7. Pharmacogenetics

- a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
- b. Genetic Polymorphism in Drug Transport and Drug Targets.
- c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic consideration

Pharm. D. (Post Baccalaureate)

Year	Name of Course	Corse Code
I Year	Pharmacotherapeutics I &II	501PB101
	Pharmacotherapeutics-III	501PB102
	Hospital Pharmacy	501PB103
	Clinical Pharmacy	501PB104
	Biostatistics and research methodology	501PB105
	Biopharmaceutics and pharmacokinetics	501PB106
	Clinical toxicology	501PB107
	Pharmacotherapeutics I &II Lab	501PB108
	Pharmacotherapeutics-III Lab	501PB109
	Hospital Pharmacy Lab	501PB110
	Biostatistics and research methodology Lab	501PB111
	Clinical toxicology Lab	501PB112
II Year	Clinical Research	501PB201
	Pharmacoepidemiology and Pharmacoeconomics	501PB202
	Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring	501PB203
	Clerkship	501PB204
	Project work (Six Months)	501PB205
III Year	Internship	501PB301