

MOHAN BABU UNIVERSITY

Sree Sainath Nagar, Tirupati – 517 102



MBU

MOHAN BABU
UNIVERSITY

DREAM. BELIEVE. ACHIEVE

MB SCHOOL OF PHARMACEUTICAL SCIENCES

Pharm.D (Post Baccalaureate)

MBU23 Academic Regulations and Curriculum (Version 1.0)

(Academic Regulations are applicable to Pharm.D and Pharm.D(PB) Programs offered by MB School of Pharmaceutical Sciences in MBU from 2023-24 onwards)



MOHAN BABU UNIVERSITY

Vision

To be a globally respected institution with an innovative and entrepreneurial culture that offers transformative education to advance sustainability and societal good.

Mission

- ❖ Develop industry-focused professionals with a global perspective.
- ❖ Offer academic programs that provide transformative learning experience founded on the spirit of curiosity, innovation, and integrity.
- ❖ Create confluence of research, innovation, and ideation to bring about sustainable and socially relevant enterprises.
- ❖ Uphold high standards of professional ethics leading to harmonious relationship with environment and society.

MB SCHOOL OF PHARMACEUTICAL SCIENCES

Vision

To be a global leader in the field of Pharmaceutical Education and Health Care Management by providing Quality Education, Training, Research and Entrepreneurial Ecosystem.

Mission

- Developing competencies and skills to solve problems in the field of Pharmaceutical Sciences through contemporary Curriculum and congenial learning environment.
- Imbibing ethics and values in students for effective Pharmaceutical practice through curricular, co-curricular and extra-curricular activities.
- Encourage faculty and staff to excel in their respective fields and demonstrate the best of their abilities by way of continuing education, research and consultancy.

PROGRAM EDUCATIONAL OBJECTIVES

After few years of graduation, the graduates of Pharm. D (PB) will:

- PEO1.** Promulgate the compendious Pharm. D (PB) program with professional knowledge, skills, research and competencies to work in all the domains of pharmaceutical sciences
- PEO2.** Provide students with Knowledge and abilities to deliver pharmaceutical care in all clinical settings.
- PEO3.** Develop creative thinking in clinical pharmacy services and encourage adaptation to changing patterns in medical research.
- PEO4.** Instigate experiential learning practices and hands on training in advanced clinical pharmacy practice services.

PROGRAM OUTCOMES

On successful completion of the Program, the graduates of Pharm.D (PB) Program will be able to:

- PO1.** Apply the **knowledge** of pharmaceutical sciences and practice in providing solution of complex clinical pharmacy practice and pharmaceutical care.
- PO2.** Apply knowledge and skills to **analyze** day-to-day professional needs of the health care by serving hospital, community and industrial needs.
- PO3.** Design **solutions** in patient care area and clinical drug development by applying skills developed during pharmacy education.
- PO4.** Utilize research-based knowledge and research methods for **complex problems** by experiments, analysis and interpretation of data, and synthesis of the information to provide valid conclusions.
- PO5.** Utilize appropriate techniques, resources, and modern pharmaceutical and IT **tools** including drug information database, statistical analysis, PK/PD modeling prediction and bioinformatics modeling.
- PO6.** Create awareness regarding **societal**, health, safety, legal and cultural issues and the consequent responsibilities relevant to the professional Clinical pharmacy practice.
- PO7.** Understand the impact of the professional pharmaceutical solutions in societal and **environmental** contexts, and demonstrate the knowledge of, and need for sustainable development.
- PO8.** Apply **ethical** principles and commit to professional ethics and responsibilities and norms of the clinical Pharmacy practice.
- PO9.** Function **effectively** as an individual, and as a member or leader in diverse teams, and in multidisciplinary settings.

- PO10. Communicate** effectively on complex clinical problems with the pharmacy communicate and with society at large, such as, being able to comprehend and write effective reports and design documentation, make effective presentations, and give and receive clear instructions.
- PO11.** Demonstrate knowledge and understanding of the **project and financial management** principles and apply these to one's own work, as a member and leader in a team, to manage projects and in multidisciplinary environments.
- PO12.** Recognize the need for, and have the preparation and ability to engage in independent and **life-long learning** in the broadest context of modern medical sciences.

PROGRAM SPECIFIC OUTCOMES

On successful completion of the Program, the graduates of Pharm.D (P.B) Program will be able to:

- PSO 1.** Acquire knowledge in the field of synthetic and natural sources of drugs with their chemistries as well as formulation and evaluation including their regulatory requirements.
- PSO 2.** Understand the fundamentals in physiology, anatomy, biochemistry, microbiology and pathophysiology understand pharmacotherapy and able to explain the pharmacological and toxicological aspects of various drugs.
- PSO 3.** Apply their expertise in pharmacovigilance, clinical research, pharmacoepidemiology and economics.
- PSO 4.** Comprehend the role of pharmaceutical care concepts of hospital, community and clinical pharmacy for serving the society.

1. Preamble

Modern era students would like to take decisions on their own and plan their future accordingly. Students would like to pursue education as per their pace. On other hand, employers expect multidisciplinary competency, leadership skills and computer literacy along with lifelong learning skills from the students. The conventional learning system has narrow scope with regard to flexibility in choosing courses of their choice to become a well-rounded personality. It is essential that the present education system should address this and provide wide opportunities for students to choose programs and courses of their interest in order to realize their full potential which in turn leads to the nation development. Further, natural resources are depleted globally at a faster rate. Hence, sustainable development has become the agenda for the complete world to preserve natural resources and environment for the sake of future generations. In addition, the world is embracing disruptive technologies to improve the quality of life. Also, students should be nurtured with skills on higher order cognitive capacities, research, innovation, incubation and entrepreneurship; life skills; social consciousness, inclusiveness, equality, culture, languages, literature, ethics and values; basic arts, crafts, humanities, games, sports and fitness.

In this context, Mohan Babu University has taken initiative and brought out Academic Regulations addressing Choice Based Credit System, sustainable development, disruptive technologies, rapid change in knowledge landscape, change in employment landscape, change in global ecosystem and other areas of national and international importance to change country's educational landscape and in turn country's landscape.

MBU23 Academic Regulations embrace Choice Based Credit System, project-based learning, enhanced practical component, etc.

2. Scope

The rules and regulations stated herein shall be called "MBU23 Academic Regulations" in its complete form. MBU23 academic regulations as given in this document are applicable to students admitted in PG Programs offered under MBU from the academic year 2023-24 onwards. All academic programs under MBU23 shall be decided by the Academic council. MBU23 is applicable for both existing as well as new programs offered by the MBU, until and unless it is explicitly stated.

3. Regulations for Pharm.D and Pharm.D (P.B) Programs offered under MBU

These regulations shall be called "The Regulations for the Pharm.D and Pharm.D(P.B) Degree Programs". They shall come into effect in the academic year 2023-24. The regulations framed are subject to modifications from time to time by Mohan Babu University (MBU) in line with the Pharmacy Council of India (PCI).

4. Definitions and Nomenclature

'Degree' means the academic award conferred upon a student on successful completion of any program of study designed to achieve the defined attributes.

'Program' means cohesive arrangement of courses, co-curricular and extracurricular activities to accomplish predetermined objectives leading to the awarding of a degree in a branch or discipline. Some Degree programs also provide options to specialize in a specific domain of interest in a branch or discipline.

'Course' means any combination of lecture, tutorial, practical and project-based learning sessions of a subject studied in a year, like Pharmaceutics, Pharmaceutical Analysis, Pharmacology and Pharmacognosy, Pharmacotherapeutics etc.

5. Admission

5.1 Number of Seats: The number of seats in Pharm.D and Pharm.D(P.B) programs for which admission is to be made will be decided by the Board of Management, MBU with approval from Pharmacy Council of India.

5.2 Nationality and Age:

Resident Indian or Non-Resident Indian (NRI), holder of PIO or OCI card issued by Government of India is eligible to apply for Selection Process.

Note: NRIs, holders of PIO or OCI card issued by Government of India must apply under international student category only.

Student should have attained the age of 17+ years on the 31st December of the year in which he/she is seeking admission in Pharm.D.

Student should have attained the age of 21+ years on the 31st December of the year in which he/she is seeking admission in Pharm.D(PB).

5.3.a. Eligibility Criteria for Pharm.D Program

A Pass in the following examinations

- a) 10 + 2 examination with Physics and Chemistry as compulsory subjects along with either mathematics or Biology.
- b) A pass in D.Pharm course from an institution approved by Pharmacy Council of India under section 12 of Pharmacy Act
- c) Any other qualification approved by Pharmacy Council of India as equivalent to any of the above examinations

5.3.b. Eligibility Criteria for Pharm.D (P.B) Program

A Pass in the following examinations

- a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B. Pharm)
- b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (Bachelor of Pharmacy)

Candidates with valid scores in National level entrance exams like GPAT, PG CET is eligible for direct admission in Pharm.D (P.B)

5.4 Authority for Admission: Any matter related to admission to any program, the decision of the Admission Committee is final.

If, at any time after admission, it is found that a candidate has not fulfilled the requirements stipulated in the offer of admission, the concerned School Dean may revoke the admission of the candidate and report the matter to the Vice Chancellor.

In Addition to the above, admissions will be based on the rules and regulations of the UGC/Competent authorities in force at the time of admissions.

6. Academic System

6.1 Annual system

Pharm.D program offered by MB School of Pharmaceutical Sciences shall follow the year system. The Program is for 6 years (course work for five academic years and one-year internship).

Pharm.D(P.B) program offered by MB School of Pharmaceutical Sciences shall follow the year system. The Program is for 3 years (course work for two academic years and one-year internship).

6.2 Curriculum

The university Academic Regulations shall have 5-digit alpha-numeric representation that refers to University Name followed by last two digits of Calendar Year viz. MBU23 Regulations. Program Curriculum shall have the corresponding Academic Year representation. Students admitted into a program shall adopt a curriculum specified by the Academic Council for that academic year. Unless otherwise stated explicitly by the Academic Council, any curriculum changes will be applicable to the students admitted in the subsequent year and the existing batches continue to follow the curriculum prescribed at the time of their joining the program.

6.3 Course Classification

Courses may be classified as Theory, Practical, Project work, Clerkship and Internship.

6.4 Syllabus

The syllabus of a course provides what the student will learn in the course of study. Each course syllabus document contains course code, course title, L T P, course description, course outcomes, module-wise topics, duration to cover each module, text books, reference books, video lectures and web resources for additional learning.

6.5 Course Handout

A Course Handout consists of a detailed plan of lectures and its mode of delivery, List of Exercises/Experiential learning, Resources, Evaluation methods, Model Question paper and CO Attainment Targets.

7. Academic Calendar

The academic calendar includes the dates with regard to course registrations, spell of instructions, continuous internal assessment tests, year-end theory examinations, practical examinations and year holidays. The Registrar will communicate the Academic calendar to the Departments/Schools, and the same will be available on the website. The dates and schedules in the academic

calendar may change in specific programs due to regulatory and local requirements. In such cases, the concerned School Dean with prior authorization will communicate the changes to the students. The revised academic calendar will also be made available on the website.

8. Course Registration

Immediately after joining the University, each student shall be assigned a Mentor by the Department/School concerned. The mentor shall discuss with the student on their academic performance year-wise, periodically, and guide the student on nature and number of courses to be registered in the ensuing year, within the framework of that program curriculum.

- ❖ Through the course registration process, every year, it is mandatory for the students to register for the courses specified in the year as and when notified, with the approval of the mentor.
- ❖ Students shall not be permitted to register for the courses if the student has any outstanding dues to the University.

8.1 Arrear Examination:

- ❖ If a student failed in a course, then the student is allowed to register for arrear examinations as and when notified.
- ❖ If a student has backlog courses after completion of the program of study, a provision is given to clear the courses by appearing any number of arrear examinations upon the notifications within the stipulated program duration.

9. Attendance Requirements

- ❖ A student shall be eligible to appear for year-end examinations if he acquires a minimum of 80% of attendance in aggregate of all the courses in a year.
- ❖ Condonation of shortage of attendance in aggregate up to 10% (70% and above and below 80%) in each year may be granted by the School Dean.
- ❖ Shortage of attendance below 70% in aggregate shall in no case be condoned.
- ❖ Students whose shortage of attendance is not condoned in any year shall not be eligible to take their year-end examination and their registration shall stand cancelled.
- ❖ Student shall not be promoted to the next year unless he satisfies the attendance requirements of the year, as applicable. The student may seek readmission for the year when offered next. He will not be allowed to register for the courses of the year while he is in detention.
- ❖ Stipulated fee shall be payable to the university towards condonation of shortage of attendance.
- ❖ In the remaining 20% of attendance, the student shall manage medical/personnel/casual/official absence for organizing events/ seminars/ workshops/ technical/ cultural festivals/ competitions/ participation in co-curricular/ extra-curricular events/NCC/NSS activities or any other reason. However, attendance shall be given at actuals for participating in NCC/NSS activities at National level.

10. Academic requirement for promotion/completion of program of study

For Pharm.D

- A student shall not be promoted from first year to second year of program of study if he/she failed more than two courses/subjects in first year program of study.
- A student shall not be promoted from second year to third year of program of study if he not PASS all the courses/ subjects pertaining to first year program of study and failed more than two courses/subjects of second year program of study.
- A student shall not be promoted from third year to fourth year of program of study if he not PASS all the courses/ subjects pertaining to second year program of study and failed more than two courses/subjects of third year program of study.
- A student shall not be promoted from fourth year to five year of program of study if he not PASS all the courses/ subjects pertaining to third year program of study and failed more than two courses/subjects of fourth year program of study.
- A student shall not be promoted from fifth year to sixth year of program of study if he not PASS all the courses/ subjects pertaining to fourth year program of study and failed more than two courses/subjects of fifth year program of study.
- The student shall register for all the courses as per the course structure. Marks obtained in all the courses shall be considered for the calculation of award of CLASS.

A student who fails in completion of all courses as per the course structure with in maximum duration of program of study then the admission shall forfeit his seat in the program of study and his/her admission stands cancelled.

For Pharm.D (PB)

- A student shall not be promoted from first year to second year of program of study if he/she failed more than two courses/subjects in first year program of study.
- A student shall not be promoted from second year to third year of program of study if he not PASS all the courses/ subjects pertaining to first year program of study and failed more than two courses/subjects of second year program of study.
- The student shall register for all the courses as per the course structure. Marks obtained in all the courses shall be considered for the calculation of award of CLASS.
- A student who fails in completion of all courses as per the course structure with in maximum duration of program of study then the admission shall forfeit his seat in the program of study and his/her admission stands cancelled.

11. Evaluation Criteria

11.1 Scheme of Evaluation

All components in any Program of Study shall be evaluated through Internal Evaluation and/or Year End Evaluation.

Course Type	Marks	Examination and Evaluation	Scheme of Examination											
Theory	30	20 Mid Examination (60 Minutes)	<p>Three Mid Examinations each for 20 marks shall be conducted and average of best two among the three shall be considered for 20 Marks.</p> <ul style="list-style-type: none"> The question paper for Mid-I, II & III shall be of descriptive type with two parts i.e., Part A and Part B Part A contains 6 short answer questions [(Q 1 (a) to (f))] out of which student shall answer 5 questions and each shall be evaluated for 2 marks Part B contains 2 descriptive questions [(Q 2 (a) to (b))] out of which student shall answer 1 question and the same shall be evaluated for 10 marks. 											
		10 Continuous Assessment	<p>The student shall be assessed based on the following parameters three times in a year during mid examinations.</p> <ul style="list-style-type: none"> Attendance – Max. 4 Marks <table border="1"> <thead> <tr> <th>Percentage of Attendance</th> <th>Marks</th> </tr> </thead> <tbody> <tr> <td>95 – 100</td> <td>4</td> </tr> <tr> <td>90 – 94</td> <td>3</td> </tr> <tr> <td>85 – 89</td> <td>2</td> </tr> <tr> <td>80 – 84</td> <td>1</td> </tr> <tr> <td>Less than 80</td> <td>0</td> </tr> </tbody> </table> <ul style="list-style-type: none"> Academic activities – Max. 3 Marks <div style="border: 1px solid black; padding: 5px;"> <p>(Average of any 3 activities Eg. Quiz, Assignment, Open Book Test, Fieldwork, Group Discussion and Seminar)</p> </div> <ul style="list-style-type: none"> Student-Teacher interaction – Max. 3 Marks 	Percentage of Attendance	Marks	95 – 100	4	90 – 94	3	85 – 89	2	80 – 84	1	Less than 80
	Percentage of Attendance	Marks												
95 – 100	4													
90 – 94	3													
85 – 89	2													
80 – 84	1													
Less than 80	0													
<p>The internal marks are the sum of mid-exam marks and respective continuous assessment marks. Three internal examinations have to be conducted each for 30 marks, the average of the best two among the three internal examinations shall be the final marks.</p>														
70	Year End Examination (180 Minutes)	<p>The examination shall be conducted for 70 marks</p> <p>The question paper shall of descriptive type with two parts i.e., Part-A and Part-B.</p> <p>Part-A shall contain 10 short answer questions [Q. No. 1 (a) to (j)] out of which student should be answering 8 question and each shall be evaluated for 5marks.</p> <p>Part-B shall contain Four questions [totally Fourteen questions from Q. No. 2 to 5]] of which student has to answer 2 questions and each shall be evaluated for 15 marks.</p>												

Course Type	Marks	Examination and Evaluation	Scheme of Examination											
Practical	30	05	Day-to-day Evaluation Day-to-day evaluation based on the performance in the conduction of laboratory experiments and its records & Viva voce for 05 Marks											
		05	Attendance <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Percentage of Attendance</th> <th>Marks</th> </tr> </thead> <tbody> <tr> <td>95 - 100</td> <td>5</td> </tr> <tr> <td>90 - 94</td> <td>4</td> </tr> <tr> <td>85 - 89</td> <td>3</td> </tr> <tr> <td>80 - 84</td> <td>2</td> </tr> <tr> <td>Less than 80</td> <td>1</td> </tr> </tbody> </table>	Percentage of Attendance	Marks	95 - 100	5	90 - 94	4	85 - 89	3	80 - 84	2	Less than 80
	Percentage of Attendance	Marks												
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90 - 94	4													
85 - 89	3													
80 - 84	2													
Less than 80	1													
20	Internal Examination (240 Minutes) <ul style="list-style-type: none"> • Two Internal Examinations each for 20 marks shall be conducted and the best among the two shall be considered for 20 marks. • Evaluation shall be on the following parameters. <ul style="list-style-type: none"> ➤ Part A – Synopsis for 5 marks ➤ Part B – Major Experiment for 10 marks, ➤ Part C – Minor experiment for 3 marks ➤ Part D – Viva voce for 2 marks. The distribution of marks may be altered as per the course requirement.													
70	Year End Examination (240 Minutes) <ul style="list-style-type: none"> • Evaluation shall be on the following parameters. <ul style="list-style-type: none"> ➤ Part A – Synopsis for 15 marks ➤ Part B – Major Experiment for 25 marks, ➤ Part C – Minor experiment for 15 marks ➤ Part D – Viva voce for 15 marks. The distribution of marks may be altered as per the course requirement.													
Project Work	30	Internal Examination	Write up of the seminar - 7.5 marks Presentation of work (7.5) Communication skills (7.5) Question and answer skills (7.5)											
	70	Year End Examination	Write up of the seminar (17.5) Presentation of work (17.5) Communication skills (17.5) Question and answer skills (17.5)											
Clerkship	30	Internal Examination	Detailed in Section 11.3											
	70	Year End Examination												
Internship	-	Year End Evaluation	Detailed in Section 11.4											

11.2 Project work

A Student has to take up and complete project work. He or she has to identify the topic of project work, collect relevant literature, preliminary data, implementation tools/ methodologies, practical investigations, implementation, analysis of results, validation and report writing.

The student shall be allowed 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 faculty. The project topic must be approved by the Head of the Department or Head of the Institution. 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.

Internal Examination

A student has to present the progress of the Research Work to the Project Evaluation Committee (PEC). The performance of the student shall be evaluated on the basis of TWO reviews along with detailed discussions. Each review shall be conducted for a maximum of "30" marks. The average of two review marks shall be finalised for a maximum of 30 marks.

The Project Evaluation Committee (PEC) consisting of concerned supervisor and two senior faculty members shall monitor the progress of the project work of the student. The PEC is constituted by the respective School Dean on the recommendations of the Head of the Department

Year End Examination

The Year-end examination shall be conducted by a Committee consisting of an External Examiner, HOD and concerned Supervisor. If required, multiple committees shall be constituted for multiple sections with prior approval. The External Examiner shall be nominated by the respective School Dean from the panel of Examiners submitted by the Department.

- ❖ The Thesis report shall be made plagiarism check and the report only with less than 20% shall be accepted.
- ❖ It is mandatory that every student has to publish/submit acceptance letter of a paper in a peer reviewed Journal or Conference before year End Examinations. Otherwise, the student is not eligible for submission of thesis report.
- ❖ If the report of the examiner is not favourable, the dissertation should be revised and resubmitted after a minimum period of three months.
- ❖ The students who fail in Project work Viva-Voce examination shall have to re-appear for the Viva-Voce examination after three months.
- ❖ Extension of time for completing the project is to be obtained from the Chairman, Academic Council, MBU.

11.3. Clerkship

The student shall collect the Patient case records from various departments viz, General Medicine, General Surgery, Pediatrics, Psychiatry etc., of the designated hospital during second year of program of study.

Internal Examination

A student has to present the report on the above to the Clerkship Evaluation Committee (CEC). The performance of the student shall be evaluated on the basis of TWO reviews along with detailed discussions. Each review shall be conducted for a maximum of "30" marks. The average

of two review marks shall be finalised for a maximum of 30 marks.

Year End Examination

The Year-end examination shall be conducted by a Committee consisting of an External Examiner, HOD and concerned Supervisor. If required, multiple committees shall be constituted for multiple sections with prior approval. The External Examiner shall be nominated by the respective School Dean from the panel of Examiners submitted by the Department.

11.4 Internship

1. Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.
2. Every student has to undergo 12 months internship (Full third year of program of study).
3. 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 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 Dean of the School.
 - iii) Every candidate shall be required to undergo internship during the last year of study for the satisfaction of the 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 Bacalaureate) as the case may be.

4. Assessment of internship:

- i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practioner) 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 shall issue certificate of satisfactory completion of training, which is mandatory for award of degree.
- 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 (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5
 - (5) Initiative, participation in discussions, research aptitude.

SCORE 0-5

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

A Score of less than 3 in any of above items will declared as Fail in internship.

If a student is failed in internship, he has to undergo three months internship as extension and appear for reevaluation.

The result of internship Pass/Fail shall be notified in the Mark sheet.

12. Pass Marks:

A student shall be declared as "PASS" in a course if he/she secures a minimum of 50% of the total marks obtained from Internal assessment and year End Evaluation. Otherwise, he/she shall be declared as "FAIL" in that course. This is not applicable for internship.

12.1. Recounting /Revaluation/Personal Verification/ Challenging Evaluation:

Students shall be permitted to apply for Recounting /Revaluation/Personal Verification/ Challenging Evaluation of the Year End Examination answer scripts within a stipulated period after payment of the prescribed fee. After completion of the process of Recounting/ Revaluation/Personal Verification/ Challenging Evaluation, the records are updated with changes if any, and the student shall be issued a revised mark sheet. If there are no changes, the student shall be intimated the same through a notice.

12.2 Improvement of Internal Assessment

A student shall have the opportunity to improve his/ her performance only once in the mid exam component of internal assessment. The reconduct of mid exam shall be completed before the commencement of end examination of that year.

13. Withholding of Results

Results may be withheld in a year, if

- ❖ The student has any dues to the Department/ School/ University
- ❖ Action arising out of malpractice is pending
- ❖ Action arising out of indiscipline is pending
- ❖ The student whose result was withheld shall not be allowed/promoted to the next higher year.

After successful completion of the program and minimum pass mark requirements as specified in the program curriculum, a Provisional Certificate will be issued to eligible students. The degree will be conferred on the student during the subsequent Convocation. The degree certificate will indicate the name of the Program of study, in which the student has graduated. Example: 'Doctor of Pharmacy (Post Baccalaureate)

14. Award of Class

The marks requirement for the award of class is as follow

Percentage of marks Secured	Class Awarded
≥ 75	First Class with Distinction
≥60 and <74.99	First Class
≥50 and <59.99	Second Class

15. Migration / Transfer of Candidates

- ❖ If a student discontinued in any of the year and later, he wishes to continue in the same program, then the he shall follow the latest regulations and curriculum that is being implemented during readmission into the same year. However, the earned marks before discontinued shall be transferred and he has to complete his degree within the stipulated program duration.
- ❖ A similar procedure shall be adopted for the candidates who are seeking admission from other universities into various eligible programs of the University, subject to the condition that those Universities are recognized and approved for transfer by MBU.
- ❖ If the other Universities follow a different system, then the program School into which the student is seeking admission/ transfer shall work out on equivalence that are to be transferred with valid supporting documentation.
- ❖ The number of completed courses thus transferred will be considered for the minimum requirements of the program, but not considered for award of class calculations. The courses along with secured marks thus transferred will be indicated at the bottom of the Consolidated mark sheet as 'Total Courses Transferred from (Name of the Institute, place and Country)' and no breakup of courses will be listed.

Award of degree classification is purely based on the marks secured considering during the program of study with the MBU.

16. Program Duration

Minimum Duration: The minimum duration for Pharm.D and Pharm.D(PB) Programs is detailed below

A student is said to be completed the program only if he/she successfully pass all courses as specified in their program curriculum. However, the degree shall be awarded only upon the completion of minimum duration of the program concerned.

Maximum Duration: if a student has backlog courses even after the completion of the minimum duration limit, an additional grace period equivalent to double the period of minimum duration of the program of study shall be extended. Under no circumstances, the period of study shall be extended beyond the above limit and thereafter his/her studentship stands cancelled automatically. No separate intimation in this regard will be sent to the student.

17. Award of Degree

Eligibility: A student shall be eligible for the award of Pharm.D Degree or Pharm.D(PB) if he fulfills all the following conditions:

- Registered and successfully completed all the components prescribed in the Program of study to which he is admitted.
- Has NO DUES to the University, Hostel, Library etc. and to any other amenities provided by the University.
- No disciplinary action is pending against him.

After successful completion of the program and minimum pass requirements as specified in the program curriculum, a Provisional Certificate will be issued to eligible students. The degree will be conferred on the student during the subsequent Convocation.

18. Amendments to Regulations

The Academic Council headed by the Vice-Chancellor of the University has the right to revise, amend, or change any component of regulations from time to time. In case of any dispute arising in interpreting the rules, the Academic Council's interpretation shall be the final decision.

19. General

The words such as "he", "him", "his" and "her" shall be understood to include all students irrespective of gender connotation.

Note: Failure to read and understand the regulations is not an excuse.

**GUIDELINES FOR DISCIPLINARY ACTION FOR MALPRACTICES /
IMPROPER CONDUCT IN EXAMINATIONS**

Rule No.	Nature of Malpractices/Improper conduct	Punishment
	<i>If the candidate:</i>	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the course of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the course of the examination)	Expulsion from the examination hall and cancellation of the performance in that course only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that course only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the course of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that course and all other courses the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the courses of that Year. The Hall Ticket of the candidate is to be cancelled.
3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred for four consecutive years from class work and all Year-end examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the courses of the examination (including labs and project work) already appeared and shall not be allowed to appear for examinations of the remaining courses of that year. The candidate is also debarred for four consecutive years from class work and all Year-end examinations, if his involvement is established. Otherwise, The candidate is debarred for two consecutive years from class

Rule No.	Nature of Malpractices/Improper conduct	Punishment
	<i>If the candidate:</i>	
		work and all Year-end examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of performance in that course and all the other courses the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the courses of that year. The candidate is also debarred for two consecutive years from class work and all Year-end examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that course only.
6.	Refuses to obey the orders of the Chief Controller of Examinations/Controller of Examinations/any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the Controller of Examinations or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the Controller of Examinations, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that course and all other courses the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the courses of that year. If the candidate physically assaults the invigilator/Controller of the Examinations, then the candidate is also debarred and forfeits his/her seat. In case of outsiders, they will be handed over to the police and a police case is registered against them.

Rule No.	Nature of Malpractices/Improper conduct	Punishment
	<i>If the candidate:</i>	
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that course and all the other courses the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the courses of that year. The candidate is also debarred for two consecutive years from class work and all Year-end examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that course and all other courses the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the courses of that year. The candidate is also debarred and forfeits the seat.

Note: Whenever the performance of a student is cancelled in any course(s) due to Malpractice, then it shall be treated as failed in that course.

Course structure
Pharm. D (Post Bacalaureate)
I Year

S. No.	Course Code	Course Title	Contact Periods per Week				Scheme of Examination Max. Marks		
			L	T	P	Total	Int. Marks	Ext. Marks	Total Marks
1.	23PP201005	Pharmacotherapeutics-III	3	1	-	4	30	70	100
2.	23PP201006	Hospital Pharmacy	2	1	-	3	30	70	100
3.	23PP201007	Clinical Pharmacy	3	1	-	4	30	70	100
4.	23PY201005	Biostatistics and Research Methodology	2	1	-	3	30	70	100
5.	23PH201012	Biopharmaceutics and Pharmacokinetics	3	1	-	4	30	70	100
6.	23PP201008	Clinical Toxicology	2	1	-	3	30	70	100
7.	23PP201012	Pharmacotherapeutics - I & II	3	1	-	4	30	70	100
8.	23PP205003	Pharmacotherapeutics-III Practical		-	3	3	30	70	100
9.	23PP205004	Hospital Pharmacy Practical		-	3	3	30	70	100
10.	23PP205005	Clinical Pharmacy Practical		-	3	3	30	70	100
11.	23PH205006	Biopharmaceutics and Pharmacokinetics Practical		-	3	3	30	70	100
12.	23PP205006	Pharmacotherapeutics - I & II Practical		-	3	3	30	70	100
Total			18	07	15	40	360	840	1200

II Year

S. No.	Course Code	Course Title	Contact Periods per Week				Scheme of Examination Max. Marks		
			L	T	P	Total	Int. Marks	Ext. Marks	Total Marks
1.	23PP201009	Clinical Research	3	1	-	4	30	70	100
2.	23PP201010	Pharmacoepidemiology and Pharmacoconomics	3	1	-	4	30	70	100
3.	23PP201011	Clinical Pharmacokinetics and Pharmacotherapeutic Drug Monitoring	2	1	-	3	30	70	100
4.	23PP211001	Clerkship	-	-	3	3	30	70	100
5.	23PP209001	Project work	-	-	18	18	30	70	100
Total			8	3	21	32	150	350	500

III Year

S. No.	Course Code	Course Title	Contact Periods per Week				Scheme of Examination Max. Marks		
			L	T	P	Total	Int. Marks	Ext. Marks	Total Marks
1.	23PP211002	Internship	-	-	-	-	-	-	-

Internship period: 12 Months (The student has to undergo internship in the designated Hospital)

FIRST YEAR

Course Code	Course Title	L	T	P
23PP201005	PHARMACOTHERAPEUTICS – III	3	1	-
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course is designed to impart knowledge and skills necessary for imparting safe and effective use of medicines in patients. They also learn pharmacotherapy of diseases with etiopathogenesis, diagnostic criteria and drug therapy management practices. This also helps to understand and practice evidence-based medicine during disease management.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Assess and manage gastrointestinal disorders, including peptic ulcer disease, GERD, inflammatory bowel disease, liver disorders, and drug-induced liver damage.
- CO2.** Identify and treat hematological conditions such as anemias, venous thromboembolism, and drug-induced blood disorders effectively.
- CO3.** Diagnose and develop treatment plans for neurological disorders, including epilepsy, Parkinsonism, stroke, and Alzheimer's disease.
- CO4.** Implement pain management strategies, addressing pain pathways, neuralgias, and various types of headaches to improve patient outcomes.
- CO5.** Diagnose and manage psychiatric disorders, including schizophrenia, affective disorders, anxiety, sleep disorders, obsessive-compulsive disorders, and alcohol withdrawal syndrome.
- CO6.** Apply evidence-based medicine principles to evaluate and integrate the best available research evidence into clinical practice.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	3	2	-	-	-	-	-	2	-	-	-	-	-	2	-	-
CO2	3	2	-	-	-	-	-	2	-	-	-	-	-	2	-	-
CO3	3	2	-	-	-	-	-	2	-	-	-	-	-	2	-	-
CO4	3	2	-	-	-	-	-	2	-	-	-	-	-	2	-	-
CO5	2	2	-	-	-	-	-	2	-	-	-	-	-	2	-	-
CO6	2	3	3	-	-	-	-	2	-	2	-	2	-	2	-	-
Course Correlation Mapping	2.7	2.1	3	-	-	-	-	2	-	2	-	2	-	2	-	-

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: GASTROINTESTINAL SYSTEM

(16 Periods)

Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, Pancreatitis and Drug induced liver disorders.

Module 2: HEMATOLOGICAL SYSTEM

(11 Periods)

Anemias, Venous thromboembolism, Drug induced blood disorders.

Module 3: NERVOUS SYSTEM

(15 Periods)

Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,

Module 4: PAIN MANAGEMENT

(10 Periods)

Pain management including Pain pathways, neuralgias, headaches.

Module 5: PSYCHIATRY DISORDERS

(18 Periods)

Schizophrenia, Affective disorders, anxiety disorders, sleep disorders, obsessive compulsive disorders, Alcohol withdrawal syndrome

Module 6: EVIDENCE BASED MEDICINE

(05 Periods)

Evidence Based Medicine

Total Periods: 75

RESOURCES

TEXT BOOKS:

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

REFERENCES:

- 1 Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- 2 Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda -Kimble MA
- 3 Harrison's Principles of Internal Medicine, Twentieth Edition (Vol.1 & Vol.2) 20th Edition: - Volume I & Volume II

VIDEO LECTURES:

- 1 <https://www.youtube.com/watch?v=xogP0x97XUs>
- 2 <https://www.youtube.com/watch?v=Qku6kzDShhU>
- 3 <https://www.youtube.com/watch?v=hdTSx2KIYoA>
- 4 <https://www.youtube.com/watch?v=B1aoN5X8Hdw>

WEB RESOURCES:

- 1 <https://nhsrcindia.org/sites/default/files/2022-08/MNS%20Care%20for%20MO-%20Neurological%20Disorders.pdf>

- 2 https://sitn.hms.harvard.edu/wp-content/uploads/2015/04/Psych_DayCon_060315.2.pdf
- 3 <https://geekymedics.com/tag/psychiatry/>
- 4 <http://www.jiwaji.edu/pdf/ecourse/pharmaceutical/HAEMATOLOGICAL%20DISEASES,%20AN%20AEMIA.pdf>

Course Code	Course Title	L	T	P
23PP201006	HOSPITAL PHARMACY	2	1	-
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course provides a detailed discussion and hands-on experience on art, practice, and profession of choosing, preparing, storing, compounding, and dispensing medicines and medical devices, advising healthcare professionals and patients on their safe, effective and efficient use.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Manage hospital pharmacy operations, including organizational structure, staff, infrastructure, material management, and financial oversight, ensuring efficient pharmacy services.
- CO2.** Develop and implement hospital drug policies, including formulary management, committee involvement, therapeutic guidelines, and pharmacy communication strategies.
- CO3.** Oversee drug distribution methods, including individual prescriptions, floor stock, and module dose distribution, as well as manage central sterile supply services.
- CO4.** Handle hospital pharmacy services, including budget preparation, drug procurement, warehousing, and inventory control using methods like ABC, VED, and EOQ.
- CO5.** Manufacture various pharmaceutical products in a hospital setting, including sterile formulations, ointments, tablets, capsules, and total parenteral nutrition, ensuring quality and safety.
- CO6.** Engage in professional development and training, maintaining and enhancing skills, and fostering professional relationships within hospital pharmacy practice.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific Outcomes				
	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO10	PO11	PO12	PSO 1	PSO 2	PSO 3	PSO 4	
CO1	3	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2
CO2	3	2	-	-	-	-	-	2	-	-	-	-	-	-	-	-	2
CO3	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2
CO4	2	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	2
CO5	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2
CO6	2	-	-	-	-	-	-	-	2	3	-	3	-	-	-	-	-
Course Correlation Mapping	2.3	2	-	-	-	-	-	2	2	3	2	3	-	-	-	-	2

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: HOSPITAL PHARMACY (10 Periods)

Hospital - its organization and functions

Hospital Pharmacy-Organization and management

- a) Organizational Structure-Staff, Infrastructure & work load statistics
- b) Management of materials and finance
- c) Roles & responsibilities of hospital pharmacist.

Module 2: HOSPITAL DRUG POLICY (10 Periods)

- 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

Module 3: DRUG DISTRIBUTION AND CENTRAL STERILE SUPPLY SERVICES (10 Periods)

- a) Drug distribution in the hospital
 - i. Individual prescription method,
 - ii. Floor stock method,
 - iii. Module dose drug distribution method
- b) Distribution of Narcotic and other controlled substances
- c) Central sterile supply services – Role of pharmacist

Module 4: HOSPITAL PHARMACY SERVICES (10 Periods)

- a) The Budget – Preparation and implementation
- b) Procurement & warehousing of drugs and pharmaceuticals
- c) Inventory control Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock

Module 5: MANUFACTURING IN HOSPITAL PHARMACY (14 Periods)

- 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.
- e) Radio Pharmaceuticals – Handling and packaging.

Module 6: PROFESSIONAL DEVELOPMENT& RELATIONS (06 Periods)

Continuing professional development programs Education and training.
Professional Relations and practices of hospital pharmacist.

Total Periods: 60

RESOURCES

TEXT BOOKS:

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

REFERENCES:

1. William E. Hassan, JR. "Hospital Pharmacy" Fifth Edition. Lea and Febiger, Philadelphia.2003.
2. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh.
3. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
4. Martin Stephens, Hospital Pharmacy, Second Edition, Pharmaceutical press, 2011.

VIDEO LECTURES:

1. <https://www.youtube.com/watch?v=5s3vFzEyHY4>
2. <https://www.youtube.com/watch?v=mjyRUMY12cA>
3. https://www.youtube.com/watch?v=63_70Eed0Q8
4. <https://www.youtube.com/watch?v=o2dqaJ8aSgA>
5. <https://www.youtube.com/watch?v=jDI7ZGVe5mU>
6. <https://www.youtube.com/watch?v=spdtTCE599I>

WEB RESOURCES:

1. <https://noteskarts.com/wp-content/uploads/2023/03/Chapter-4-Hospital-and-Hospital-Pharmacy-Drug-distribution-complete-PDF-notes.pdf>
2. <https://noteskarts.com/wp-content/uploads/2022/11/Chapter-3-U-1-Hospital-pharmacy.pdf>
3. <https://archivepp.com/storage/models/article/DFIZVT7I7vmWU2Y75qnA4XrlyYFAk2OU52ddmMmkZ7ToOF8MorE080ZVJrxx/inventory-management-in-pharmacy-practice-a-review-of-literature.pdf>
4. <https://www.uv.mx/personal/izcamacho/files/2012/02/Pharmaceutical-Manufacturing-Handbook-Production-and-Processes-Wiley-2008.pdf>
5. https://pharmacyce.unm.edu/nuclear_program/neolibrary/libraryfiles/basicsofradiopharmacy.pdf

Course Code	Course Title	L	T	P
23PP201007	CLINICAL PHARMACY	3	1	-
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course provides a detailed discussion and hands-on experience on History and evolution of clinical pharmacy, clinical pharmacy activities, interpretation of laboratory tests, drug information, pharmaceutical care and medication errors.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Define and apply clinical pharmacy concepts, including drug therapy monitoring, ward round participation, adverse drug reaction management, and quality assurance of pharmacy services.
- CO2.** Analyze patient data effectively, including case history structure and medical abbreviations, to evaluate and optimize drug therapy in clinical settings.
- CO3.** Deliver clinical pharmacy services by implementing pharmaceutical care concepts, managing medication errors, enhancing patient communication, and critically evaluating biomedical literature.
- CO4.** Interpret laboratory data for disease evaluation, including tests related to hematology, liver, renal, thyroid functions, cardiac disorders, fluid balance, and microbiological cultures.
- CO5.** Utilize drug and poison information resources, systematically address drug information queries, evaluate literature, and establish and manage a Drug Information Centre.
- CO6.** Understand and apply pharmacovigilance principles, including ADR classification, causality assessment, reporting, monitoring, and management, and the pharmacist's role in ADR management.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	2
CO2	3	3	-	-	-	-	-	-	-	2	-	-	-	-	-	2
CO3	3	2	3	-	-	-	-	-	-	2	-	-	-	-	-	2
CO4	-	2	2	-	-	-	-	-	-	-	-	-	-	-	-	2
CO5	-	2	-	-	3	-	-	2	-	-	-	-	-	-	-	2
CO6	-	2	-	-	2	-	-	2	-	-	-	-	-	-	-	2
Course Correlation Mapping	3	2.3	2.5	-	2.5	-	-	2	-	2	-	-	-	-	-	2

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: EVOLUTION OF CLINICAL PHARMACY

(15 Periods)

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 utilization evaluation (DUE) and review (DUR)
 - h) Quality assurance of clinical pharmacy services.

Module 2: PATIENT DATA ANALYSIS

(10 Periods)

- a) The patient's case history, its structure and use in evaluation of drug therapy.
- b) Understanding common medical abbreviations and terminologies used in clinical practices.

Module 3: CLINICAL PHARMACY SERVICES

(12 Periods)

- a) Pharmaceutical care concepts
- b) Medication errors
- c) Patient communication - Communication skills, including patient counselling techniques, medication history interview, presentation of cases
- d) Critical evaluation of biomedical literature

Module 4: INTERPRETATION OF LABORATORY DATA

(14 Periods)

Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results

- a) Haematological, Liver function, Renal function and thyroid function tests.
- b) Tests associated with cardiac disorders.
- c) Fluid and electrolyte balance.
- d) Microbiological culture sensitivity tests.
- e) Pulmonary Function Tests.

Module 5: DRUG & POISON INFORMATION

(13 Periods)

- 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.

Module 6: PHARMACOVIGILANCE

(11 Periods)

- a) Scope, definition and aims of pharmacovigilance.
- b) Adverse drug reactions - Classification, mechanism and predisposing factors.
- c) Causality assessment [different scales used], Reporting, evaluation, monitoring, preventing & management of ADRs.
- d) Role of pharmacist in management of ADR.

Total Periods: 75

RESOURCES

TEXT BOOKS:

1. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
2. Rhonda M Jones Patient assessment in Pharmacy Practice, Lippincott Williams & Wilkins, 3rd edition, 2016.
3. Susan M Stein Boh's Pharmacy Practice Manual: A Guide to the Clinical Experience, Wolters Kluvers, 4e,2013.
4. Sherif Hanafy Mahmoud Patient Assessment in Clinical Pharmacy: A Comprehensive Guide, Sringer, 2019.

REFERENCE BOOKS:

1. Robert Cipolle, Linda Strand, Peter Morley, Pharmaceutical Care Practice: The Clinician's Guide McGraw-Hill Education / Medical; 2nd edition, 2004.
2. John Talbot and Jef F Rey K. Aronson, Stephens' Detection and Evaluation of Adverse Drug Reactions Principles and Practice. Sixth Edition, A John Wiley & Sons, Ltd., Publication, 2012.
3. Jeff Huges, Clinical Pharmacy a Practical Approach, The society of Hospital Pharmacists of Austaralia,2001.

VIDEO LECTURES:

1. <https://www.youtube.com/watch?v=JSGDHJbN8xs>
2. https://www.youtube.com/watch?v=w99qnRj_ZkY
3. <https://www.youtube.com/watch?v=1LKA7EpfruE>
4. <https://www.youtube.com/watch?v=Na7NAk-9tu0>

WEB RESOURCES:

1. [http://file.cop.ufl.edu/pop/hepler/apha/PhC Principles and Processes.pdf](http://file.cop.ufl.edu/pop/hepler/apha/PhC_Principles_and_Processes.pdf)
2. <https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/drug-poison-info-svcs.pdf>
3. <https://courseware.cutm.ac.in/wp-content/uploads/2022/12/Daily-activities-of-clinical-pharmacists-PDF.pdf>
4. <https://www.pastest.com/media/2159/look-inside-pages-data-interps-3e-lo-res.pdf>

Course Code	Course Title	L	T	P
23PY201005	BIostatISTICS AND RESEARCH METHODOLOGY	2	1	-
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course provides a detailed discussion on basic concepts of research and its methodologies, define appropriate research problem and parameters, organize and conduct research in a more appropriate manner.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Design and evaluate clinical studies using various methodologies, including case studies, observational studies, interventional studies, and determine sample size and report findings effectively.
- CO2.** Apply biostatistical methods to describe data distributions, central tendencies, and data spread using average, median, mode, standard deviation, and variance.
- CO3.** Create and interpret data graphics, including histograms, pie charts, scatter plots, and semilogarithmic plots, for effective visual representation of data.
- CO4.** Perform hypothesis testing using parametric and non-parametric methods, including t-tests, chi-square tests, ANOVA, and regression analysis, and utilize statistical software.
- CO 5** Utilize statistical methods in epidemiology to measure incidence, prevalence, relative risk, and attributable risk, aiding in the assessment of health outcomes.
- CO 6** Apply computer applications in pharmacy for hospital and community settings, including patient record management, medication order entry, inventory control, and drug information retrieval.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific Outcomes			
	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO 10	PO1 1	PO1 2	PSO 1	PSO 2	PSO 3	PSO 4
CO1	-	2	-	-	-	-	-	-	-	-	-	-	-	-	2	-
CO2	-	2	-	-	2	-	-	-	-	-	-	-	-	-	2	-
CO3	-	-	-	-	2	-	-	-	-	-	3	-	-	-	2	-
CO4	-	-	-	-	-	-	-	-	-	-	2	-	-	-	2	-
CO5	2	2	-	-	-	-	-	-	-	-	-	-	-	-	2	-
CO6	3	2	-	-	-	-	-	-	-	-	-	-	-	-	2	-
Course Correlation Mapping	2.5	2	2	-	2	-	-	-	-	-	2.5	-	-	-	2	-

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT:

Module 1: RESEARCH METHODOLOGY

(10 Periods)

- 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

Module 2: BIOSTATISTICS

(10 Periods)

- 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.

Module 3: DATA GRAPHICS

(08 Periods)

- a) Construction and labelling of graphs.
- b) Histogram, pie charts, scatter plots, semilogarithmic plots.

Module 4: BASICS OF TESTING HYPOTHESIS

(12 Periods)

- 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 co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

Module 5: STATISTICAL METHODS IN EPIDEMIOLOGY

(07 Periods)

- a) Incidence and prevalence.
- b) Relative risk.
- c) Attributable risk.

Module 6: COMPUTER APPLICATIONS IN PHARMACY

(13 Periods)

- a) 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.
- b) Computer In Community model Pharmacy - Computerizing the Prescription Dispensing process, Use of Computers for Pharmaceutical Care in community model pharmacy, Accounting and General ledger system.
- c) Drug Information Retrieval & Storage: Introduction – Advantages of Computerized Literature Retrieval, Use of Computerized Retrieval

Total Periods: 60

RESOURCES

TEXT BOOKS:

- 1 Kothari, C.R. & Garg, G. (2019). Research Methodology: Methods and Techniques. New Age International Publishers.
- 2 Murthy, P.V.S. (2018). Research Methodology in Pharmacy Practice. PharmaMed Press.
- 3 Mahajan, B.K. & Gupta, M.C. (2021). Textbook of Biostatistics. Jaypee Brothers.
- 4 Dawson, B., & Trapp, R.G. (2004). Basic & Clinical Biostatistics. McGraw-Hill.
- 5 Zar, J.H. (2010). Biostatistical Analysis. Pearson Education.
- 6 Hennekens, C.H. & Buring, J.E. (1987). Epidemiology in Medicine. Lippincott Williams & Wilkins.
- 7 Shargel, L., Wu-Pong, S., & Yu, A.B.C. (2012). Applied Biopharmaceutics & Pharmacokinetics. McGraw-Hill. (for drug info & retrieval systems)

REFERENCE BOOKS:

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

VIDEO LECTURES:

1. <https://youtu.be/ckltFkPu6co>
2. <https://youtu.be/6LqVrfEQWE8>
3. <https://youtu.be/JDtXkqYQntM>

WEB RESOURCES:

1. <https://www.researchgate.net/publication/319207471> HANDBOOK OF RESEARCH METHODOLOGY
2. <https://www.cabi.org/VetMedResource/ebook/20123404818>
3. <https://www.researchgate.net/publication/322520049> Computer Applications in Pharmacy

Course Code	Course Title	L	T	P
23PH201012	BIOPHARMACEUTICS AND PHARMACOKINETICS	3	1	-
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course provides various skills to carry out, design and apply the concepts like compartmental modeling, noncompartmental modeling, and other methods to study the processes of drug absorption, drug distribution, drug metabolism, drug elimination.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Analyze drug absorption, distribution, and elimination processes to understand their effects on drug efficacy and safety in biopharmaceutics.
- CO2.** Apply pharmacokinetic principles, including mathematical models and compartmental analysis, to study drug levels and optimize dosing regimens.
- CO3.** Utilize one-compartment and multi-compartment models to understand and predict drug behavior following intravenous and oral administration.
- CO4.** Evaluate and apply multiple-dose regimens using one-compartment and two-compartment models for effective drug therapy and management.
- CO5.** Implement noncompartmental and nonlinear pharmacokinetic methods to assess drug behavior and parameters, including statistical moment theory and Michaelis-Menten kinetics.
- CO6.** Conduct bioavailability and bioequivalence studies, including protocol design and assessment methods, to ensure drug products meet required standards.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	2	-	-	3	3	-	-	-	-	-	-	-	2	-	-	-
CO2	3	-	-	3	2	-	-	-	-	-	2	-	2	-	-	-
CO3	-	3	-	2	2	-	-	-	-	-	-	-	2	-	-	-
CO4	-	3	-	2	2	-	-	-	-	-	-	-	-	-	-	-
CO5	-	1	-	3	2	-	-	-	-	-	-	-	-	-	-	-
CO6	-	2	-	3	3	-	-	-	-	-	-	2	2	-	-	-
Course Correlation Mapping	2.5	2.3	-	2.7	2.3	-	-	-	-	-	2	2	2	-	-	-

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: BIOPHARMACEUTICS

(12 Periods)

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

Module 2: PHARMACOKINETICS

(13 Periods)

Introduction to Pharmacokinetics.

- a) Mathematical model
- b) Drug levels in blood.
- c) Pharmacokinetic model.
- d) Compartment models.
- e) Pharmacokinetic study.

Module 3: COMPARTMENTAL MODELING

(16 Periods)

- a) One compartment open model - Intravenous Injection (Bolus) and Intravenous infusion.
- b) Multicompartment model - Two compartment open model IV bolus, IV infusion and oral administration.

Module 4: MULTIPLE – DOSAGE REGIMENS

(08 Periods)

- a) Repetitive Intravenous injections – One Compartment Open Model.
- b) Repetitive Extravascular dosing – One Compartment Open model.
- c) Multiple Dose Regimen – Two Compartment Open Model.

Module 5: NONCOMPARTMENTAL AND NONLINEAR PHARMACOKINETICS

(16 Periods)

Noncompartmental pharmacokinetics

- a) Statistical Moment Theory.
- b) MRT for various compartment models.
- c) Physiological Pharmacokinetic model.

Nonlinear pharmacokinetics

- a) Introduction.
- b) Factors causing Non-linearity.
- c) Michaelis-menton method of estimating parameters.

Module 6: BIOAVAILABILITY AND BIOEQUIVALENCE

(10 Periods)

- a) Introduction.
- b) Bioavailability study protocol.
- c) Methods of Assessment of Bioavailability.

Total Periods: 75

RESOURCES

TEXT BOOKS:

1. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercei Dekker Inc.
2. Bio pharmaceuticals and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
3. Biopharmaceuticals and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inn, New York and Basel, 1987.

REFERENCE BOOKS:

1. Encyclopaedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Royle, Marcel Dekker Inc, New York 1996.
2. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
3. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.

VIDEO LECTURES:

1. <https://youtu.be/WuFy5r7B1pQ>
2. <https://youtu.be/x3dYISmnk5U>
3. <https://youtu.be/3S20pvn28ys>

WEB RESOURCES:

1. https://books.google.com/books/about/Biopharmaceuticals_and_Pharmacokinetics.html?id=LLpLxAEACAAJ
2. <https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/absorption-distribution-metabolism-excretion-study>
3. <https://www.sciencedirect.com/topics/engineering/pharmacokinetic-model#:~:text=A%20pharmacokinetic%20model%20describes%20the,have%20three%20or%20fewer%20compartments.>

Course Code	Course Title	L	T	P
23PP201008	CLINICALTOXICOLOGY	2	1	-
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course provides knowledge in the area of clinical management of different poison cases and facilitates students to learn in direct toxicological care area including Identification of toxins, pathological changes upon exposure, management practices of poison cases and preventive approaches for the public.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Apply general principles of poison management, including antidote use, supportive care, gut decontamination, and toxicokinetics for effective treatment.
- CO2.** Identify venomous snake species, understand their clinical effects, and manage snake bites, including first aid and treatment of complications.
- CO3.** Recognize and manage acute poisoning cases, including pesticides, opiates, alcohol, and caustics, with appropriate clinical interventions.
- CO4.** Diagnose and treat chronic poisoning from heavy metals such as arsenic, lead, mercury, iron, and copper.
- CO5.** Address poisoning from plants, mushrooms, and food, and manage envenomations from arthropod bites and stings.
- CO6.** Identify and treat substance abuse, including signs, symptoms, and management of dependence on CNS stimulants, depressants, hallucinogens, and tobacco.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific Outcomes			
	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO 10	PO 11	PO 12	PS O1	PS O2	PS O3	PS O4
CO1	3	2	-	-	-	-	-	-	-	-	-	-	-	2	-	-
CO2	-	-	-	-	-	2	-	-	-	-	-	-	-	2	-	-
CO3	-	-	-	-	-	2	-	-	-	3	-	-	-	2	-	-
CO4	-	-	-	-	-	2	-	-	-	3	-	-	-	2	-	-
CO5	-	-	-	-	-	3	-	-	-	-	-	-	-	2	-	-
CO6	2	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-
Course Correlation Mapping	2.5	2	-	-	-	2.3	-	-	-	3	-	-	-	2	-	-

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1: PRINCIPLES OF POISON MANAGEMENT (13 Periods)

- a) General principles involved in the management of poisoning.
- b) Antidotes and the clinical applications.
- c) Supportive care in clinical Toxicology.
- d) Gut Decontamination and Elimination Enhancement.
- e) Toxicokinetics.

Module 2: VENOMOUS SNAKE BITES (07 Periods)

- a) Families of venomous snakes.
- b) Clinical effects of venoms.
- c) General management as first aid, early manifestations, complications and snake bite injuries.

Module 3: ACUTE POISONING (14 Periods)

Clinical symptoms and management of acute poisoning with the following agents–

- a) Pesticide poisoning: organophosphorus compounds, carbamates, organochlorines, pyrethroids.
- b) Opiates overdose, Antidepressants, Barbiturates and benzodiazepines.
- c) Alcohol: ethanol and methanol.
- d) Paracetamol and salicylates, Non-steroidal anti-inflammatory drugs.
- e) Hydrocarbons: Petroleum products and PEG.
- f) Caustics: inorganic acids and alkali, Radiation poisoning.

Module 4: CHRONIC POISONING (06 Periods)

Clinical symptoms and management of chronic poisoning with the Heavy metals–

- a) Arsenic
- b) Lead
- c) Mercury
- d) Iron
- e) Copper.

Module 5: PLANT, FOOD & ENVENOMATIONS (08 Periods)

- a) Plants poisoning.
- b) Mushrooms and Mycotoxins.
- c) Food poisonings.
- d) Envenomations – Arthropod bites and stings.

Module 6: SUBSTANCE ABUSE (12 Periods)

- a) Signs and symptoms of substance abuse and treatment of dependence.
- b) CNS stimulants: amphetamine, Opioids, CNS depressants, Hallucinogens: LSD, Cannabis group, Tobacco.

Total Periods: 60

RESOURCES

TEXT BOOKS:

1. Text book Of Forensic Medicine & Toxicology by Nagesh kumar G Rao, Jaypee Brothers Medical Pub (P) Ltd
2. V V Pillay. Handbook of Forensic Medicine and Toxicology. Thirteenth edition 2003 Paras Publication, Hyderabad
3. Textbook of Forensic Medicine and Toxicology by M. Manivasagam (CBSPD Edition)
4. Medical Toxicology Review: Pearls of Wisdom, Second Edition

REFERENCE BOOKS:

1. Matthew J Ellenhorn. Ellenhorns Medical Toxicology – Diagnosis and Treatment of Poisoning. Second edition. Williams and Willkins publication, London.
2. V V Pillay. Handbook of forensic medicine and toxicology. Thirteenth edition 2003 paras publication, Hyderabad

VIDEO LECTURES:

1. <https://www.youtube.com/watch?v=e34HPJ21Z2k>
2. <https://www.youtube.com/watch?v=OwADgtJOF M>
3. <https://www.youtube.com/watch?v=IIOJ-gk7aQ8>
4. <https://www.youtube.com/watch?v=P4F-G9ml9mo>

WEB RESOURCES:

1. [https://annamalaiuniversity.ac.in/studport/download/engg/pharm/resources/pharmd_4Y%20&%201Y%20\(PB\)_4.6_clinical%20toxicology.pdf](https://annamalaiuniversity.ac.in/studport/download/engg/pharm/resources/pharmd_4Y%20&%201Y%20(PB)_4.6_clinical%20toxicology.pdf)
2. https://www.cartercenter.org/resources/pdfs/health/ephti/library/lecture_notes/med_lab_tech_students/In_toxicology_final.pdf

Course Code	Course Title	L	T	P
23PP201012	PHARMACOTHERAPEUTICS – I & II	3	1	-
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course is designed to impart knowledge and skills necessary for imparting safe and effective use of medicines in patients. They also learn pharmacotherapy of diseases with etiopathogenesis, diagnostic criteria and drug therapy management practices. This also helps to understand and practice evidence-based medicine during disease management.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Understand and manage cardiovascular conditions including hypertension, heart failure, angina, and arrhythmias, and respiratory diseases like asthma and COPD.
- CO2.** Apply rational drug use principles, including guidelines for antibiotics and surgical prophylaxis, and specific prescribing considerations for pediatric, geriatric, and pregnant patients.
- CO3.** Diagnose and treat ophthalmological conditions such as glaucoma and conjunctivitis, and endocrine disorders including diabetes and thyroid diseases.
- CO4.** Identify and manage infectious diseases (e.g., tuberculosis, HIV) and musculoskeletal disorders (e.g., rheumatoid arthritis, gout).
- CO5.** Manage renal conditions including acute and chronic renal failure, and understand oncology basics, chemotherapy, and management of treatment-induced nausea.
- CO6.** Address dermatological issues such as psoriasis, scabies, eczema, and impetigo, and apply appropriate treatment protocols.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific outcomes			
	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO 10	PO 11	PO 12	PS O1	PS O2	PS O3	PS O4
CO1	3	3	-	-	-	-	-	2	-	-	-	-	-	2	-	-
CO2	3	3	3	-	-	-	-	2	-	-	-	3	-	2	-	-
CO3	3	2	-	-	-	-	-	2	-	-	-	-	-	2	-	-
CO4	3	2	-	-	-	-	-	2	-	-	-	-	-	2	-	-
CO5	2	2	-	-	-	-	-	2	-	-	-	-	-	2	-	-
CO6	2	3	-	-	-	-	-	2	-	2	-	-	-	2	-	-
Course Correlation Mapping	2.7	2.5	3	-	-	-	-	2	-	2	-	3	-	2	-	-

Correlation Levels: 3: High; 2: Medium; 1: Low

RESOURCES

TEXT BOOKS:

1. Pharmacology and Pharmacotherapeutics by R. S. Satoskar, Nirmala Rege, and S. D. Bhandarkar
2. Goodman & Gilman's The Pharmacological Basis of Therapeutics
3. DiPiro's Pharmacotherapy: A Pathophysiologic Approach, *12th Edition*

REFERENCES:

1. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
2. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda -Kimble MA
3. Harrison's Principles of Internal Medicine, Twentieth Edition (Vol.1 & Vol.2) 20th Edition: - Volume I & Volume II
4. API Textbook of Medicine (2 Volumes)

VIDEO LECTURES:

1. https://www.youtube.com/watch?v=3_CnBMpE8hk
2. <https://www.youtube.com/watch?v=szyAAtPe0hs>
3. https://www.youtube.com/watch?v=AzA_yGjaAg8
4. <https://www.youtube.com/watch?v=ZsU8WuOqI9Y>

WEB RESOURCES:

1. <https://app.pulsenotes.com/medicine/cardiology/notes>
2. <https://app.pulsenotes.com/medicine/dermatology/notes>
3. <https://app.pulsenotes.com/medicine/infectious-diseases/notes>
4. <https://app.pulsenotes.com/medicine/oncology/notes>

Course Code	Course Title	L	T	P
23PP205003	PHARMACOTHERAPEUTICS – III Practical	-	-	3
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course is designed to impart knowledge and skills in developing therapeutic plan and provide pharmaceutical care to the patients using SOAP notes.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Demonstrate the treatment goals to the patient;
- CO2.** Analyze patient outcome in selection, monitoring and initiation of drug therapies;
- CO3.** Provide feedback to clinicians regarding drug related needs.
- CO4.** Work independently and in teams to solve problems with effective communications

CO-PO-PSO Mapping Table:

Course Outcome	Program Outcomes												Program Specific outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	3	3	-	2	2	-	-	-	-	-	-	-	-	2	-	-
CO2	3	3	-	2	2	-	-	-	-	-	-	-	-	2	-	-
CO3	-	-	-	-	-	-	-	-	3	3	-	-	-	2	-	-
CO4	-	-	-	-	-	-	-	-	3	3	-	-	-	-	-	-
Course Correlation Mapping	3	3	-	2	2	-	-	-	3	3	-	-	-	2	-	-

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

EXPERIENTIAL LEARNING

LIST OF EXPERIMENTS:

Hospital postings for a period of at least 50 Periods is 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 Assessment of drug interactions in the given prescriptions

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 [1500–2000words] should be submitted for evaluation.

Format of the assignment:

- i. Minimum & Maximum number of pages
- ii. Reference(s) shall be included at the end.
- iii. Assignment can be a combined presentation at the end of the academic year
- iv. It shall be computer draft copy
- v. Name and signature of the student
- vi. Time allocated for presentation may be 8+2 Min.

RESOURCES

TEXT BOOKS:

1. Pharmacotherapy Casebook: A Patient-Focused Approach, 11th Edition, Terry L. Schwinghammer, Julia M. Koehler, Jill S. Borchert, McGraw Hill / Medical,2020
2. Practical Psychopharmacology: Translating Findings From Evidence-Based Trials into Real-World Clinical Practice, by Joseph F. Goldberg, Stephen M. Stahl, Alan F. Schatzberg, Cambridge University Press; New edition (29 April 2021).

VIDEO LECTURES:

1. <https://www.hopkinsarthritis.org/arthritis-info/rheumatoid-arthritis/ra-treatment/>
2. <https://www.medscape.com/viewarticle/987261>
3. <https://psychopharmacologyinstitute.com/publication/pharmacotherapy-of-treatment-resistant-ocd-augmentation-strategies-2191>
4. <https://www.sydney.edu.au/medicine-health/our-research/research-centres/pain-management-research-institute.html>

WEB RESOURCES:

1. <https://www.bpsweb.org/pharmacotherapy-sample-questions/>
2. https://www.physio-pedia.com/Parkinson%27s_Disease:_A_Case_Study
3. https://www.physio-pedia.com/Panic_Disorder
4. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3002647/>

Course Code	Course Title	L	T	P
23PP205004	HOSPITAL PHARMACY PRACTICAL	-	-	3
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course provides hands-on experience on providing drug information, assessing drug interactions in prescriptions, control on inventory and manufacturing various pharmaceuticals required for patients in hospital.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Evaluate Drug interactions in prescriptions
- CO2.** Provide Unbiased information to health care professionals and patients
- CO3.** Perform various manufacturing practices in hospital
- CO4.** Appreciate the Stores Management and Inventory Control.
- CO5.** Work independently and in teams to solve problems with effective communications

CO-PO-PSO Mapping Table:

Course Outcome	Program Outcomes												Program Specific outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	3	3	-	2	2	-	-	-	-	-	-	-	-	-	-	2
CO2	3	3	-	2	2	-	-	-	-	3	-	-	-	-	-	2
CO3	3	3	-	-	2	-	-	-	-	-	-	-	-	-	-	2
CO4	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	2
CO5	-	-	-	-	-	-	-	-	3	3	-	-	-	-	-	-
Course Correlation Mapping	3	3	-	2	2	-	-	-	3	3	-	-	-	-	-	2

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

EXPERIENTIAL LEARNING

LIST OF EXPERIMENTS:

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.

RESOURCES

TEXT BOOKS:

- 1 Parthasarathi G, Karin Nyfort-Hansen, Milap C. Nahata.A Textbook of Clinical Pharmacy Practice: Essential Concepts and Skills.Universities Press, 2nd Edition.
- 2 Suresh B, Ramasamy S.Hospital and Clinical Pharmacy.Vallabh Prakashan, Latest Edition.

REFERENCES:

1. <https://jru.edu.in/studentcorner/lab-manual/dpharm/2nd-year/Hospital%20&%20Clinical%20Pharmacy.pdf>
2. https://content.kopykitab.com/ebooks/2018/08/21068/sample/sample_21068.pdf
3. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
4. Martin Stephens, Hospital Pharmacy, Second Edition, Pharmaceutical press, 2011.

VIDEO LECTURES:

1. <https://www.youtube.com/watch?v=CMw0i3VzBpE>
2. <https://www.youtube.com/watch?v=aFK90DOOyGU>
3. <https://www.youtube.com/watch?v=WN7O5QIeqNY>
4. <https://www.youtube.com/watch?v=kasOF2YmxEU>

WEB RESOURCES:

1. <https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/preceptor-toolkit/sicp-busy-day-systematic-approach-answering-drug-info-requests.pdf>
2. <https://www.phrmafoundation.org/case-study-clinically-drug-interactions/>
3. https://www.iptsalipur.org/wp-content/uploads/2020/08/BP703T_PP_V.pdf
4. <https://www.teachmint.com/tfile/studymaterial/sydpharm/hcp/hcpchapter5hospitalmanufacturingpdf/d8d8c6f8-19ff-430b-92cf-11f9820c4e8f>

Course Code	Course Title	L	T	P
23PP205005	CLINICAL PHARMACY PRACTICAL	-	-	3
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course provides hands-on experience on providing drug information, Interpretation of Laboratory data, Medication History Retrieval and Patient counselling practices required for patients in hospital.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Provide drug information services to health care professionals and patients
- CO2.** Perform patient medication reconciliation and counselling as part of pharmaceutical care practice
- CO3.** Interpret clinical laboratory findings and their significance in disease management
- CO4.** Work independently and in teams to solve problems with effective communications

CO-PO-PSO Mapping Table:

Course Outcome	Program Outcomes												Program Specific outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	3	3	-	-	2	-	-	-	-	3	-	-	-	-	-	2
CO2	3	3	-	-	2	-	-	-	-	-	-	-	-	-	-	2
CO3	3	3	-	-	2	-	-	-	-	-	-	-	-	-	-	2
CO4	3	3	-	-	2	-	-	-	-	-	-	-	-	-	-	2
Course Correlation Mapping	3	3	-	-	2	-	-	-	-	3	-	-	-	-	-	2

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Experiential Learning

LIST OF EXPERIMENTS: (Minimum 15 experiments shall be conducted)

1. Answering drug information questions (4 Nos).
2. Patient medication counselling (4 Nos).
3. Case studies related to laboratory investigations (4 Nos).
4. Patient medication history interview (3 Nos)

LIST OF 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:

- i. Minimum & Maximum number of pages.
- ii. Reference(s) shall be included at the end.
- iii. Assignment can be a combined presentation at the end of the academic year.
- iv. It shall be computer draft copy.
- v. Time allocated for presentation may be 8+2 Min.

RESOURCES

TEXT BOOKS:

1. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
2. Rhonda M Jones Patient assessment in Pharmacy Practice, Lippincott Williams & Wilkins, 3rd edition, 2016.
3. Susan M Stein Boh's Pharmacy Practice Manual: A Guide to the Clinical Experience, Wolters Kluwers, 4e, 2013.
4. Sherif Hanafy Mahmoud Patient Assessment in Clinical Pharmacy: A Comprehensive Guide, Springer, 2019.

REFERENCE BOOKS:

1. <https://www.slideshare.net/anamsohail29/clinical-pharmacy-manual>
2. Jeff Huges, Clinical Pharmacy a Practical Approach, The society of Hospital Pharmacists of Australia, 2001.

VIDEO LECTURES:

1. <https://www.youtube.com/watch?v=JSGDHJbN8xs>
2. https://www.youtube.com/watch?v=w99qnRj_ZkY
3. <https://www.youtube.com/watch?v=1LKA7EpfruE>
4. <https://www.youtube.com/watch?v=Na7NAk-9tu0>

WEB RESOURCES:

1. <https://courseware.cutm.ac.in/wp-content/uploads/2020/06/Patient-Counselling.pdf>
2. https://faculty.ksu.edu.sa/sites/default/files/phone_request._Nora_K.pdf
3. <https://www.aacc.org/science-and-research/clinical-chemistry/clinical-case-studies>
4. <http://thehub.utoronto.ca/geriatrics/wp-content/uploads/2021/08/medication-history-Medications-4.pdf>

Course Code	Course Title	L	T	P
23PH205006	BIOPHARMACEUTICS AND PHARMACOKINETICS PRACTICAL	-	-	3
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course provides various skills to carry out, design and apply the concepts like compartmental modeling, noncompartmental modeling, and other methods to study the processes of drug absorption, drug distribution, drug metabolism, drug elimination.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Acquire skills to carryout Invitro dissolution studies.
- CO2.** Design& apply skills to know the protein binding of drugs bioavailability of drugs.
- CO3.** Apply appropriate formula to determine& interpret various pharmacokinetic parameters.
- CO4.** Apply in-vitro and ex-vivo methods to estimate the absorption of drugs.
- CO5.** Work independently & communicate effectively in oral and written forms.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	3	1	2	-	-	-	-	-	-	-	-	-	3	-	-	-
CO2	3	-	2	-	-	-	-	-	-	-	-	-	3	-	-	-
CO3	3	2	2	-	-	-	-	-	-	-	-	-	3	-	-	-
CO4	3	-	3	-	-	-	-	-	-	-	-	-	3	-	-	-
CO5	-	-	-	-	-	-	-	-	3	3	-	-	3	-	-	-
Course Correlation Mapping	3	2	3	-	-	-	-	-	3	3	-	-	3	-	-	-

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

EXPERIENTIAL LEARNING

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. (eg) Tetracycline, Sulphamethoxazole, 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

RESOURCES

TEXT BOOKS:

1. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercey Dekker Inc.
2. Bio pharmaceuticals and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
3. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inn, New York and Basel, 1987.

REFERENCE BOOKS:

1. Encyclopaedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.
2. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
3. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.

VIDEO LECTURES:

1. <https://youtu.be/WuFy5r7B1pQ>
2. <https://youtu.be/x3dYISmnk5U>
3. <https://youtu.be/3S20pvn28ys>

WEB RESOURCES:

1. https://books.google.com/books/about/Biopharmaceutics_and_Pharmacokinetics.html?id=LLpLxAEACAAJ
2. <https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/absorption-distribution-metabolism-excretion-study>
3. <https://www.sciencedirect.com/topics/engineering/pharmacokinetic-model#:~:text=A%20pharmacokinetic%20model%20describes%20the,have%20three%20or%20fewer%20compartments.>

Course Code	Course Title	L	T	P
23PP205006	PHARMACOTHERAPEUTICS – I & II PRACTICAL	-	-	3
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: This course is designed to impart knowledge and skills in developing therapeutic plan and provide pharmaceutical care to the patients using SOAP notes.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Demonstrate the treatment goals to the patient;
- CO2.** Analyze patient outcome in selection, monitoring and initiation of drug therapies;
- CO3.** Provide feedback to clinicians regarding drug related needs.
- CO4.** Work independently and in teams to solve problems with effective communications

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	3	3	-	2	2	-	-	-	-	-	-	-	-	2	-	-
CO2	3	3	-	2	2	-	-	-	-	-	-	-	-	2	-	-
CO3	3	3	-	-	-	-	-	-	-	3	-	-	-	2	-	-
CO4	-	-	-	-	-	-	-	-	3	3	-	-	-	-	-	-
Course Correlation Mapping	3	3	-	2	2	-	-	-	3	3	-	-	-	2	-	-

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

EXPERIENTIAL LEARNING

LIST OF EXPERIMENTS:

Hospital postings for a period of at least 50 Periods is 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 Assessment of drug interactions in the given prescriptions

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 [1500–2000words] 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. Time allocated for presentation may be 8+2 Min.

RESOURCES

TEXT BOOKS:

- 1 DiPiro JT, Talbert RL, Yee GC, et al.
Pharmacotherapy: A Pathophysiologic Approach. *McGraw-Hill Education, Latest Edition*
- 2 Goodman & Gilman's The Pharmacological Basis of Therapeutics.
McGraw-Hill, Latest Edition

REFERENCES:

1. Pharmacotherapy Casebook: A Patient-Focused Approach, 11th Edition, Terry L. Schwinghammer, Julia M. Koehler, Jill S. Borchert, McGraw Hill / Medical, 2020
2. <https://www.pharmaceuticalpress.com/product/drugs-in-use-case-studies-for-pharmacists-and-prescribers-sixth-edition/>
3. [https://www.alghad.edu.ly/control_panel/books/pharmacy-case-studies-2009\(1\).pdf](https://www.alghad.edu.ly/control_panel/books/pharmacy-case-studies-2009(1).pdf)

VIDEO LECTURES:

1. https://www.youtube.com/watch?v=NIETfCa_Lrk
2. <https://www.youtube.com/watch?v=8RJFrLHW-Wk>
3. https://www.youtube.com/watch?v=ZwZigB_LmTg
4. https://www.youtube.com/watch?v=1IUO_m3-Sv8

WEB RESOURCES:

1. <https://www.pharmacytimes.com/view/2009-04-10236>
2. <https://diabetesjournals.org/spectrum/article/16/1/41/638/Case-Study-A-Patient-With-Type-2-Diabetes-Working>

SECOND YEAR

Course Code	Course Title	L	T	P
23PP201009	CLINICAL RESEARCH	3	1	-
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: Upon completion of this course the student should be able to understand Drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to impart knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Understand drug development processes, including pharmacological and toxicological approaches, IND application, drug characterization, and dosage form formulation.
- CO2.** Apply ethical guidelines in clinical research, addressing challenges, and understanding IRB/IEC composition, responsibilities, and procedures effectively.
- CO3.** Conduct and manage clinical trials, including phases, post-marketing surveillance, IND submissions, ICH-GCP, and CDSCO guidelines compliance.
- CO4.** Define roles and responsibilities of clinical trial personnel including sponsors, investigators, associates, auditors, coordinators, and regulatory authorities according to ICH GCP.
- CO5.** Navigate regulatory environments across the USA, Europe, and India, understanding key regulatory requirements and compliance issues for clinical trials.
- CO6.** Design clinical study documents, manage informed consent processes, handle data management, and monitor safety effectively throughout clinical trials.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	-	-	3	-	-	-	-	-	-	-	-	-	-	-	2	-
CO2	-	-	2	-	-	-	-	3	-	-	-	-	-	-	2	-
CO3	-	-	3	-	-	-	-	2	-	-	-	-	-	-	2	-
CO4	-	-	3	2	-	-	-	3	2	-	-	-	-	-	2	-
CO5	-	-	2	2	-	-	-	-	3	-	-	3	-	-	2	-
CO6	-	-	2	2	-	-	-	-	-	-	2	-	-	-	2	-
Course Correlation Mapping	-	-	2.1	2	-	-	-	2.7	2.5	-	2	3	-	-	2	-

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1 DRUG DEVELOPMENT PROCESS (15 Periods)

Introduction, Various Approaches to drug discovery - 1. Pharmacological 2. Toxicological 3. IND Application 4. Drug characterization 5. Dosage form

Module 2 ETHICAL GUIDELINES IN CLINICAL RESEARCH (10 Periods)

Challenges in the implementation of guidelines, Ethical guidelines in Clinical Research, Composition, responsibilities, procedures of IRB / IEC

Module 3 CLINICAL TRIALS AND ITS PROCEDURES (15 Periods)

Introduction to Clinical trials, Various phases of clinical trial, Methods of post marketing surveillance, Abbreviated New Drug Application submission, Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines

Module 4 ROLE AND RESPONSIBILITIES OF CLINICAL TRIAL PERSONNEL (10 Periods)

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

Module 5 REGULATORY REQUIREMENTS (08 Periods)

Overview of regulatory environment in USA, Europe and India

Module 6 CLINICAL DATA MANAGEMENT (17 Periods)

Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment), Informed consent Process, Data management and its components, Safety monitoring in clinical trials.

Total : 75 Periods

RESOURCES

REFERENCES:

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on 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.

VIDEO LECTURES:

1. <https://www.youtube.com/watch?v=dTIDYIonyo4>
2. https://www.youtube.com/watch?v=fHm6uCJ_zP4
3. https://www.youtube.com/watch?v=MDg8E7-V8_Q
4. <https://www.youtube.com/watch?v=kkEIB0iDbZU>

WEB RESOURCES:

1. <https://cdsco.gov.in/opencms/opencms/en/Home/>
2. <https://clinicaltrials.gov/>
3. <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process>

Course Code	Course Title	L	T	P
23PP201010	PHARMACOEPIDEMOLOGY AND PHARMACOECONOMICS	3	1	-
Pre-Requisite	-			
Anti-Requisite	-			
Co-Requisite	-			

COURSE DESCRIPTION: Upon completion of this course the student should be able to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Understand the scope of pharmacoepidemiology, including outcome measures, drug use metrics, and adherence, for assessing prevalence, incidence, and rates of drug use.
- CO2.** Assess and measure risk in pharmacoepidemiology, including concepts of attributable and relative risk, time-risk relationships, and odds ratios for accurate risk evaluation.
- CO3.** Apply pharmacoepidemiological methods through theoretical understanding and practical case studies, including drug utilization reviews, cross-sectional studies, and meta-analyses.
- CO4.** Utilize data sources and special applications in pharmacoepidemiological studies, including automated systems, vaccine safety, hospital settings, and risk management of drug-induced birth defects.
- CO5.** Evaluate pharmacoeconomics, including historical context, role in formulary management, and various methods such as cost-minimization, cost-benefit, cost-effectiveness, and cost-utility analysis.
- CO6.** Implement pharmacoeconomic applications using software and case studies to analyze and apply economic evaluations for decision-making in healthcare and formulary management.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	2	2	-	-	-	-	-	-	-	-	-	-	-	-	2	-
CO2	2	2	3	-	-	-	-	-	-	-	-	-	-	-	2	-
CO3	3	2	3	-	-	-	-	-	-	-	-	-	-	-	2	-
CO4	2	-	-	-	-	2	-	-	-	2	-	-	-	-	2	-
CO5	3	2	-	-	-	-	-	-	-	-	3	-	-	-	2	-
CO6	3	-	-	-	-	-	-	-	-	-	-	2	-	-	2	-
Course Correlation	2.5	2	3	-	-	2	-	-	-	2	3	2	-	-	2	-

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1 INTRODUCTION TO PHARMACOEPIDEMIOLOGY (18 Periods)

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

Module 2 PHARMACOEPIDEMIOLOGICAL RISK ASSESSMENT (07 Periods)

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

Module 3 PHARMACOEPIDEMIOLOGICAL METHODS (15 Periods)

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.

Module 4 PHARMACOEPIDEMIOLOGICAL STUDIES (10 Periods)

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.

Module 5 PHARMACOECONOMICS (18 Periods)

Definition, history, needs of pharmaco-economic evaluations, Role in formulary management decisions, Pharmaco-economic 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 and cost utility analysis.

Module 6 APPLICATIONS OF PHARMACOECONOMICS (07 Periods)

Software and case studies

Total: 75 Periods

RESOURCES

REFERENCES:

1. Arnold, R.J.G. Pharmacoeconomics: From Theory to Practice (1st Edition). CRC Press.
2. Hartzema, A.G., Tilson, H.H., & Chan, K.A. Pharmacoepidemiology And Therapeutic Risk Management (1st Edition). Harvey Whitney Books.
3. Rascati, K.L. Essentials of Pharmacoeconomics (First edition). Wolters Kluwer India Pvt. Ltd.
4. Revikumar, K.G. Pharmacoepidemiology and Pharmacoeconomics: Concepts and Practice. Pharma Med Press.
5. Strom, B.L., Kimmel, S.E., & Hennessy, S. Textbook of Pharmacoepidemiology (2nd Edition). Wiley Blackwell Publications.

VIDEO LECTURES:

1. <https://www.youtube.com/watch?v=BwuCSHRseiI>
2. <https://www.youtube.com/watch?v=juG-Vyw8U5I>
3. <https://www.youtube.com/watch?v=x8x448vQP7w>
4. <https://www.youtube.com/watch?v=3AFTQW8mBh4>
5. <https://www.youtube.com/watch?v=yb8ZiKXgtzg>

WEB RESOURCES:

1. <https://pharmareview.files.wordpress.com/2011/10/pharmacoepidemiology.pdf>
2. <https://www.ikev.org/haber/farmakovijilans/Joerg%20Hasford2.pdf>
3. <https://pharmacy.tiu.edu.iq/wp-content/uploads/2019/02/Pharmacoeconomics-lecture-note.pdf>

Course Code	Course Title	L	T	P
23PP201011	CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING	2	1	-

Pre-Requisite	-
Anti-Requisite	-
Co-Requisite	-

COURSE DESCRIPTION: Upon completion of this course the student should be able to understand principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma Drug concentration profile in altered pharmacokinetics, Drug interactions and in therapeutic Drug monitoring processes to optimize the Drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

COURSE OUTCOMES: After successful completion of the course, students will be able to:

- CO1.** Apply clinical pharmacokinetics principles to design dosage regimens, including converting between intravenous and oral dosing and adjusting for elderly, pediatric, and obese patients.
- CO2.** Analyze and manage pharmacokinetic drug interactions, focusing on the inhibition and induction of drug metabolism and the impact on biliary excretion.
- CO3.** Adjust drug dosages for renal and hepatic diseases by considering pharmacokinetic changes, measuring filtration rates, and accounting for extracorporeal drug removal.
- CO4.** Utilize Bayesian theory and adaptive methods to analyze population pharmacokinetic data and improve dosing strategies based on population-level insights.
- CO5.** Implement therapeutic drug monitoring protocols, focusing on individualizing dosage regimens, assessing variability, and correlating pharmacokinetics with pharmacodynamics for various disease conditions.
- CO6.** Explore pharmacogenetics to understand genetic polymorphisms in drug metabolism and transport, and apply these considerations to pharmacokinetics and pharmacodynamics.

CO-PO-PSO Mapping Table:

Course Outcomes	Program Outcomes												Program Specific Outcomes			
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3	PSO4
CO1	3	2	-	2	-	-	-	-	-	-	-	-	-	-	2	-
CO2	3	2	-	-	-	-	-	-	-	-	-	-	-	-	2	-
CO3	3	3	3	-	-	-	-	-	-	-	-	-	-	-	2	-
CO4	2	-	3	-	-	-	-	-	-	-	-	-	-	-	2	-
CO5	3	-	-	-	-	-	-	-	-	3	-	-	-	-	2	-
CO6	2	-	-	-	-	2	-	-	-	2	-	3	-	-	2	-
Course Correlation mapping	2.7	2.1	3	2	-	2	-	-	-	2.5	-	3	-	-	2	-

Correlation Levels: 3: High; 2: Medium; 1: Low

COURSE CONTENT

Module 1 CLINICAL PHARMACOKINETICS AND (12 Periods) **DESIGN OF DOSAGE REGIMENS**

Introduction and applications of clinical pharmacokinetics
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

Module 2 PHARMACOKINETICS OF DRUG (08 Periods) **INTERACTION**

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

Module 3 DOSAGE ADJUSTMENT IN RENAL AND (11 Periods) **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

Module 4 POPULATION PHARMACOKINETICS (09 Periods)

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

Module 5 THERAPEUTIC DRUG MONITORING (13 Periods)

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

Module 6 PHARMACOGENETICS (07 Periods)

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

Total: 60 Periods

RESOURCES

REFERENCES:

1. Concepts in Clinical Pharmacokinetics by Joseph T. Dipiro. 5th Edition
2. Biopharmaceutics and Clinical Pharmacokinetics: An Introduction, Fourth Edition, by Robert T. Notari, Marcel Deckker
3. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications by Malcolm Rowland, Thomas N. Tozer, Wolters Kluwer Health/Lippincott William & Wilkins

VIDEO LECTURES:

1. <https://www.youtube.com/watch?v=8Ylgh--Ypwo>
2. <https://videocast.nih.gov/watch=32073>
3. <https://videocast.nih.gov/watch=32075>
4. <https://videocast.nih.gov/watch=31863>
5. https://www.youtube.com/watch?v=gb2AyT0_uNs
6. <https://www.youtube.com/watch?v=7I08IjcDV8E>

WEB RESOURCES:

1. https://uomustansiriyah.edu.iq/media/lectures/4/4_2019_02_23!03_40_49_PM.pdf
2. <https://dergipark.org.tr/tr/download/article-file/490151>
3. <https://courseware.cutm.ac.in/wp-content/uploads/2020/06/THERAPEUTIC-DRUG-MONITORING-2.pdf>
4. https://www.blackwellpublishing.com/content/BPL/Images/Content_store/Sample_Chapter/9781405150460/9781405150460_4_001.pdf
5. <https://pharmacy.moh.gov.my/sites/default/files/document-upload/clinical-pharmacokinetics-pharmacy-handbook-ccph-2nd-edition-rev-2.0.pdf>
6. https://edisciplinas.usp.br/pluginfile.php/5576014/mod_resource/content/1/Dipiro%20Concepts%20In%20Clinical%20Pharmacokinetics.pdf