AMRITA VISHWA VIDYAPEETHAM
DEEMED TO BE UNIVERSITY
School of Pharmacy

Academic Regulations of Pharm. D Programme
(July 2025)

PROGRAM LEARNING OUTCOMES (PLOs)

KNOWLEDGE

K1. Recall the fundamental biomedical concepts (from human anatomy, physiology, biochemistry, microbiology, and pathophysiology) that form the basis of drug action and therapeutic use.

K2. Demonstrate knowledge of clinical laboratory diagnostics and interpretation relevant to pharmacotherapy.

K3. Recognize national and international regulatory frameworks including drug laws, ethics, and clinical trial governance.

K4. Compare the functional role of phytopharmaceuticals and nutraceuticals in managing and preventing chronic diseases.

K5. Illustrate the formulation and biopharmaceutical principles of drug dosage forms and delivery systems.

K6. Interpret guidelines and evidence-based literature for rational drug use and therapeutic decisions.

K7. Apply medicinal chemistry concepts in understanding drug structure-activity relationships and metabolic pathways.

SKILL

S1. Interpret clinical and laboratory data to monitor therapeutic outcomes and recommend modifications to ensure safe and effective treatment.

S2. Apply pharmacokinetic principles for performing relevant calculations to individualize drug dosing and optimize therapeutic outcomes.

S3. Operate digital health tools and clinical software to access patient records, drug databases, and decision-support systems in routine practice

S4. Provide patient-centered pharmaceutical care by assessing medication needs, counseling, and promoting adherence across various healthcare settings.

S5. Analyze formulation components and process parameters to ensure the development of effective and patient-acceptable pharmaceutical products.

S6. Manage pharmaceutical processes by following standard procedures and utilizing digital technologies.

S7. Apply medicinal chemistry principles to analyze structure–activity relationships (SAR) and predict the mechanisms of drug action.

S8. Correlate instrument output data with pharmacopeia acceptance criteria to make informed quality decisions.

S9. Assess adverse drug reactions, drug-drug interactions, and contraindications using both theoretical knowledge and clinical observations.
S10. Assess drug-related problems through critical analysis of prescriptions and patient-specific clinical information.

ATTITUDE

A1. Demonstrate professionalism, integrity, and accountability in all patient care and academic activities.
A2. Uphold patient confidentiality, informed consent, and ethical standards in clinical decision-making.
A3. Exhibit empathy and respect toward patients and their families in diverse healthcare settings.
A4. Show commitment to continuous learning and self-improvement in clinical knowledge and skills.
A5. Display leadership and initiative in managing clinical responsibilities and improving patient care.
A6. Collaborate effectively with physicians, nurses, and other healthcare providers to enhance patient outcomes.
A7. Participate actively in professional organizations, seminars, and clinical audits to promote the pharmacy profession

PHARM. D & PHARM.D (PB) REGULATIONS

1. Short title extent and commencements

These regulations shall be called Academic Regulations 2025 of Amrita Vishwa Vidyapeetham for the Doctor of Pharmacy Program, which shall come into force from the academic session 2025-2026 for PharmD regular and 2028-29 for PharmD PB.

2. Minimum qualification for admission: -

2.1 Pharm.D. Regular – Candidate shall have passed any of the following examinations

(1) 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the followingsubjects: Mathematics or Biology.

(2) A pass in D. Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

(3) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

(4) Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

(5) Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes, and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

2.2 Pharm.D. (Post Baccalaureate) -

Candidate shall have passed B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes, and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

3. Duration of program: -

a) Pharm.D: The duration of the program shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

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

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

b) Pharm.D. (Post Baccalaureate): The duration of the program shall be for three academic years (two yearsof study and one-year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.

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

4. **Medium of instruction and examinations**
   The medium of instruction and examination shall be English.

5. **Working days in each academic year**
   Each year shall consist of not less than 200 working days, starting from the month of July/August to May/June in every calendar year.

6. **Attendance and progress**

   100% attendance is necessary for the students; however, a candidate is required to have at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the requirements of the prescribed courses to be eligible to appear for the respective examination/s.

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

Course of Study from 1st to 6th year

Table I- First Year Pharm. D:

Category	Course Code	Name of Subject	No. of hours	No. of hours of Tutorial
PHAR	PD.101T	Human Anatomy and Physiology	3	0.5
PHAR	PD.102T	Pharmaceutics	3	
PHAR	PD.103T	Medicinal Biochemistry	3	0.5
PHAR	PD.104T	Pharmaceutical Organic Chemistry	3	0.5
PHAR	PD.105T	Pharmaceutical Inorganic Chemistry	2	0.5
SCI	PD.106T	Remedial Mathematics[$] / Biology*[#]	2	
HUM	PD.107T	Cultural Education I & II*	2	-
HUM	PD.108T	Mastery Over Mind*	1	-
PHAR	PD.109P	Human Anatomy and Physiology Practical	2	
PHAR	PD.110P	Pharmaceutics Practical	3	
PHAR	PD.111P	Medicinal Biochemistry Practical	2	
PHAR	PD.112P	Pharmaceutical Organic Chemistry Practical	3	
PHAR	PD.113P	Pharmaceutical Inorganic Chemistry Practical	2	
HUM	PD.114P	Mastery Over Mind* Practical	1	
		Total hours	**30/32**	**2 =(32/34)**

[#]Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course**.**

[$]Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course**.**

* Non University Examination (NUE)

Table II- Second Year Pharm. D:

Category	Course Code.	Name of Subject	No. of hours	No. of hours of Tutorial
PHAR	PD.201T	Pathophysiology I	3	1
PHAR	PD.202T	Pharmaceutical Microbiology	3	-
PHAR	PD.203T	Pharmacognosy & Phytopharmaceuticals	2	0.5
PHAR	PD.204T	Pharmacology-I	2	0.5
PHAR	PD.205T	Community Healthcare and Pharmacy Management	2	0.5
PHAR	PD.206T	Pharmacotherapeutics-I	2	1
PHAR	PD.207T	Pharmaceutical Jurisprudence	2	0.5
HUM	PD.208T	Cultural Education III & IV*	1	-
PHAR	PD.209P	Pharmaceutical Microbiology Practical	2	
PHAR	PD.210P	Pharmacognosy Practical	2	
PHAR	PD.211P	Pharmacotherapeutics-I Practical	3	
		Total hours	**24**	**4 = (28)**

* Non University Examination (NUE)

Table III- Third Year Pharm. D :

Category	Course Code	Name of Subject	No. of hours	No. of hours of Tutorial
PHAR	PD.301T	Pharmacology-II	3	0.5
PHAR	PD.302T	Pharmaceutical Analysis	3	0.5
PHAR	PD.303T	Pharmacotherapeutics-II	2	0.5
PHAR	PD.304T	Medicinal Chemistry	3	0.5
PHAR	PD.305T	Pharmaceutical Formulations	2	0.5
PHAR	PD.306T	Pathophysiology II	2	0.5
PHAR	PD.307P	Pharmacology-II Practical	3	
PHAR	PD.308P	Pharmaceutical Analysis Practical	2	
PHAR	PD.309P	Pharmacotherapeutics-II Practical	3	
PHAR	PD.310P	Medicinal Chemistry-Practical	2	
PHAR	PD.311P	Pharmaceutical Formulations Practical	3	
		Total hours	**28**	**3 = (31)**

Table IV- Fourth Year Pharm. D:

Category	Course Code	Name of Subject	No. of hours	No. of hours of Tutorial
PHAR	PD.401T	Pharmacotherapeutics-III	2	0.5
PHAR	PD.402T	Hospital Pharmacy	2	0.5
PHAR	PD.403T	Clinical Pharmacy	2	
PHAR	PD.404T	Biostatistics & Research Methodology	2	0.5
PHAR	PD.405T	Biopharmaceutics & Clinical Pharmacokinetics	3	0.5
PHAR	PD.406T	Clinical Toxicology	2	
HUM	PD.407T	Life Skill	3	
PHAR	PD.408W	Live in Labs*#	3	
PHAR	PD.409P	Pharmacotherapeutics-III Practical	3	
PHAR	PD.410P	Clinical Pharmacy Practical	2	
PHAR	PD.411P	Biopharmaceutics & Clinical Pharmacokinetics Practical	3	
		Total hours	**24/27#**	**2 = 26/29#**

* Non-University Examination (NUE)
# Live in Labs is an optional experiential learning initiative. Those who complete it successfully shall get a separate grade sheet/certificate.

Table V- First Year Pharm. D (PB) :

Category	Course Code	Name of Subject	No. of hours	No. of hours of Tutorial
PHAR	PDPB.101T	Pharmacotherapeutics-III	2	0.5
PHAR	PDPB.102T	Hospital Pharmacy	2	0.5
PHAR	PDPB.103T	Clinical Pharmacy	2	
PHAR	PDPB.104T	Biostatistics & Research Methodology	2	0.5
PHAR	PDPB.105T	Biopharmaceutics & Clinical Pharmacokinetics	3	0.5
PHAR	PDPB.106T	Clinical Toxicology	2	
PHAR	PDPB.107T	Pharmacotherapeutics-I & II	3	
HUM	PDPB.108T	Life Skill	3	
PHAR	PDPB.109W	Live in Labs*#	3	
PHAR	PDPB.110P	Pharmacotherapeutics-III Practical	3	
PHAR	PDPB.111P	Clinical Pharmacy Practical	2	
PHAR	PDPB.112P	Biopharmaceutics & Clinical Pharmacokinetics Practical	3	
PHAR	PDPB.113P	Pharmacotherapeutics-I & II Practical	3	
		Total hours	**30/33#**	**2= 32/35#**

* Non-University Examination (NUE)
# Live in Labs is an optional experiential learning initiative. Those who complete it successfully shall get a separate grade sheet/certificate.

Table VI- Fifth Year Pharm. D:

Category	Course Code	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hoursof Seminar
PHAR	PD.501T	Clinical Research	2	-	0.5
PHAR	PD.502T	Pharmacoepidemiology and Pharmacoeconomics	2	-	0.5
PHAR	PD.503T	Precision medicine	2		
PHAR	PD.504T	Clerkship **		20	2
PHAR	PD.505PR	Project work	-	4	-
PHAR	PD.506J	Journal club			1
		Total hours	**6**	**24**	**4= (34)**

** Attending ward rounds on daily basis.

Table VII- Second Year Pharm. D (PB) :

Category	Course Code	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hoursof Seminar
PHAR	PDPB.201T	Clinical Research	2	-	0.5
PHAR	PDPB.202T	Pharmacoepidemiology andPharmacoeconomics	2	-	0.5
PHAR	PDPB.203T	Precision Medicine	2		
PHAR	PDPB.204T	Clerkship **		20	2
PHAR	PDPB.205PR	Project work	-	4	-
PHAR	PDPB.206J	Journal club			1
		Total hours	**6**	**24**	**4= (34)**

** Attending ward rounds on daily basis.

Sixth Year Pharm. D / Third Year Pharm. D P.B:

Internship or residency training include postings in clinical departments. The clinical posting will be in general medicine and other specialty departments for a period of 12 months with rotation after every two months.

Table VIII: Year wise hour distribution for Pharm.D (Phase I)

Year	University	School level	Total
I	**28**	**4/6#**	**32/34#**
II	**27**	**1**	**28**
III	**31**	**0**	**31**
IV	**26**	**3***	**26/29***
V	**33**	**1**	**34**
Total hours for the program	**145**	**6/8#/9*/11*#**	**151/153#/154*/156*#**

#Applicable only for the students appearing for Remedial Biology (RB)/Remedial Mathematics(RM)course

*Applicable only for students opting live in labs.

Table IX: Year wise hour distribution for Pharm.D (PB) (Phase I)

Year	University	School level	Total
I	**32**	**3***	**32/35***
II	**33**	**1**	**34**
Total hours for the program (Phase I)	**65**	**1/4***	**66/69***

*Applicable only for students opting live in labs.

8. Remedial Course

There are two remedial courses; Remedial Maths/Biology. Those who have not studied biology in plus two shall study Remedial biology and those who have not studied Maths in plus two shall study Remedial Maths in the first year and those who have studied both Maths & Biology in Plus two need not study any of these Remedial Courses.

9. Self-Directed Learning (SDL)

Self-directed learning is a process in which an individual takes initiative and responsibility for their own learning, actively engages in setting goals, acquiring knowledge, and evaluating the progress. It involves activities such as diagnosing learning needs, formulating learning goals, identifying resources, choosing and implementing learning strategies, and evaluating learning outcomes. Self-directed learning aims to empower learners to become independent and critical thinkers. Incorporating self-directed learning into daily classes or timetables can greatly enhance students' learning experiences and foster their autonomy.

Scope of SDL includes:

- SDL enables individuals to develop essential life skills, such as critical thinking, problem-solving, communication, and self-reflection.
- It empowers students to explore topics beyond the curriculum and pursue knowledge according to their own interests and pace thus becoming responsible learners.
- It allows for continuous professional growth, adapting to changing job requirements and exploring new career paths.
- It helps develop an entrepreneurial mindset, fosters creativity and innovation, and equips individuals with the necessary skills to start and manage their own ventures.

- Individuals can engage in self-directed learning to acquire new skills, deepen their knowledge in areas of personal interest, and even pursue hobbies that bring them joy and fulfillment.
- It encourages individuals to continue learning throughout their lives, embracing new challenges, and adapting to an ever-changing world.

Self-directed learning (SDL) is incorporated into the timetable as it is beneficial for students, promotes autonomy, motivation, and a deeper engagement with the learning process.

10. Tutorial hours

For major courses in the Pharm D curriculum, there shall be designated tutorial hours. These hours may be utilized for various academic activities, including cycle tests, seminars, quizzes, and other subject-related exercises to enhance learning and assessment. These activities aim to provide additional support and engagement for students in the respective subjects.

11. Academic Advisory Committee

The Academic advisory committee is constituted by the Head of the Institution for each batch of Pharm.D

The composition of the Committee shall be as follows:

The Principal is the chairperson and senior faculty members of all departments (Associate Professor/Professor grade).

Terms of Reference:

i. Periodically reviewing the process of academic advising.
ii. Discuss mentoring activities with students of each batch.
iii. Interact with academic advising faculty and give suggestions for overall improvement.
iv. Ensure proper documentation of these activities.
v. The committee shall meet at least once a year.

There is a provision for Academic Advising for each batch of Pharm. D. A group of 15 students is assigned under one faculty from the 1st year onwards and the same faculty may continue till the completion of the 5th year. The faculty shall interact with each student during the assigned period regarding academic/ other matters and the same shall be documented. Faculty provide guidance and support to their students offering advice, insights, and expertise based on their experiences. They help students to navigate challenges, set goals, and develop strategies for personal and professional growth. They can guide students in selecting electives and research projects considering their academic and personal interests to meet their ultimate goals.

12. Academic and Professional Standard Committee

The Pharm. D program shall have an Academic and Professional Standard Committee constituted by the Head of the Institution and senior faculty members from each department involved in teaching Pharm. D courses.

The composition of the Committee shall be as follows:

Principal shall be the chairperson, HODs, and nominees from the departments of Assistant Professor/Associate Professor/Professor grade.

Terms of reference:

i. The committee shall meet once each year, soon after the results are published.
ii. The committee calculates the attainment based on the results of both formative and summative assessments and reviews the same.
iii. Interact with faculty in case of courses with low attainment and recommend corrective measures for improvement.
iv. Auditing the question papers of both sessional exams and summative assessments and suggesting improvements wherever required.
v. Analyze the feedback collected from the students every year.

13. Community Pharmacy Training

Scope:

The Community Pharmacy Training is designed to comprehensively prepare pharmacy students to deliver safe, effective, and patient-centered care within a community setting. This training emphasizes the development of essential competencies, including strong communication skills, a commitment to lifelong learning, and proficiency in prescription handling, patient counseling, and the use of pharmacy technologies. By engaging students in structured trainings at approved community pharmacies, the program provides experiential learning opportunities that reflect real-world practice. These placements are guided by clearly defined, competency-based objectives that foster the development of professional attitudes, ethical judgment, and critical thinking skills.

Learning Objectives

Upon completion of the community pharmacy training program, students shall be able to:

- Demonstrate an understanding of patient safety principles and effectively implement relevant policies and procedures to uphold safety standards in community pharmacy practice.
- Interpret data protection regulations, and understand the infrastructure, inventory management systems, and digital technologies essential for supporting high-quality patient care in community pharmacy settings.

- Deliver a range of pharmacy services in accordance with contractual obligations, while actively contributing to the promotion of patient health and well-being.
- Conduct patient counseling and basic health screenings using evidence-based models, communication techniques, and clinical skills to support informed decision-making and health promotion.
- Identify and address communication barriers within the pharmacy team and across the broader healthcare network to ensure effective interdisciplinary collaboration.
- Recognize gaps in clinical knowledge and demonstrate the ability to locate, evaluate, and apply appropriate resources to support ongoing professional development.
- Manage the distribution, storage, and disposal of controlled substances in compliance with legal, regulatory, and professional standards.
- Identify available workplace support systems and explore opportunities for career advancement and professional growth within the pharmacy sector.

Guidelines

As part of the mandatory practical training component for the second year of the Doctor of Pharmacy (PharmD) program, students are required to complete a one-month posting in an approved community pharmacy. This experiential training is designed to provide hands-on exposure to key aspects of community pharmacy practice, including patient counseling, prescription dispensing, and other essential pharmacy-related responsibilities. To ensure accurate monitoring of student participation, each student must submit the contact details of the supervising pharmacist at their training site. The designated head pharmacist will receive a monthly attendance sheet from the host institution and will be responsible for verifying and reporting the student's attendance. Students are expected to complete a minimum of 150 hours over the course of the month, dedicating at least six hours per day, excluding Sundays. During their postings, students are expected to achieve the following practical learning outcomes:

- Gain foundational knowledge of the structural and regulatory requirements for establishing a retail pharmacy, including insights into wholesale pharmacy operations and procedures for engaging with pharmaceutical distributors.
- Acquire a clear understanding of the legal and procedural steps involved in obtaining a license to operate a community pharmacy in accordance with national and local regulatory frameworks.
- Demonstrate the ability to accurately interpret prescriptions, dispense medications responsibly, and provide effective patient counseling in alignment with professional standards.
- Develop familiarity with the range of OTC products commonly sold in the local community and understand the regulatory and ethical considerations associated with their sale.
- Identify and monitor LASA drugs to minimize the risk of medication errors and enhance patient safety.

- Understand the prevalence of common diseases in the local population, analyze prescription trends, and become informed about government and private sector initiatives related to public health and community-based health screenings.
- Gain insight into the role and responsibilities of drug inspectors in community pharmacy practice, including the frequency and scope of their inspections.
- Learn the principles of proper drug storage, including temperature control and shelf organization, to ensure medication integrity and compliance with regulatory standards.
- Become proficient in the use of pharmacy management software systems for inventory control, billing, and patient record maintenance, and understand their role in enhancing operational efficiency.

Evaluation:

At the end of the training, students are required to get a certificate of successful completion of the training from the community pharmacy in charge and prepare a comprehensive report detailing their observations, experiences, and key learnings acquired during the placement. The certificate and report shall be submitted to the head of Institution. The report must be presented to the designated faculty members through a formal PowerPoint presentation. Student performance will be evaluated based on the quality of the report, presentation skills, and demonstrated understanding of the training objectives. Upon successful completion of the assessment, the institute shall issue a certificate to the respective candidate, acknowledging their fulfillment of the training requirements.

Sl. No.	Criteria	Score
1	Report submission and presentation	30
2	Viva voce	20
4	**Total**	50

Range of Percentage (%)	Grade	Performance
90-100	A+	Excellent
80-89	A	Very Good
70-79	B	Good
60-69	C	Average
<60	D	Poor

14.Hospital Pharmacy Training

Scope

The hospital pharmacy training program aims to provide students with practical exposure to real-world hospital pharmacy operations. It bridges the gap between classroom learning and professional practice, enabling students to:

- Gain hands-on experience in dispensing, inventory management, and patient interactions.
- Enhance their ability to communicate effectively and work collaboratively in a healthcare setting.
- Build a foundation for managing medication-related problems in a hospital environment.

Objectives

1. Proficiency in drug knowledge: Develop familiarity with generic and brand names of medications used in hospital settings.
2. Medication inventory management: Learn efficient stocking of drugs, vaccines, and record-keeping.
3. Clinical skill development: Identify and resolve medication-related issues effectively.
4. Communication enhancement: Improve patient communication and collaboration with healthcare professionals.
5. Exposure to real-world scenarios: Work in practical environments to cultivate teamwork and independence.

Guidelines

- The hospital pharmacy training is mandatory for 4th-year Pharm.D and 1st-year Pharm.D (PB) students. It shall be for not less than 150 hours within a span of 45 days in an academic year. Students must attend training under the supervision of a pharmacist for 4 hours per day. A minimum attendance of 80% is mandatory for successful completion of the posting. At the end of the posting, a hardcopy of the report must be submitted to the faculty in charge prior to the evaluation process. The evaluation will be jointly done by the Dept. of Pharmacy Practice and the Hospital Pharmacist. Students must complete the training satisfactorily and meet evaluation standards to be promoted to 5th-year Pharm.D or 2nd-year Pharm.D (PB).

Evaluation Criteria (Marks: 50)

Components	Marks
Assessment by the Hospital Pharmacist	20
Presentation	15
Viva	15
Total	50

Range of Percentage (%)	Grade	Performance
90-100	A+	Excellent
80-89	A	Very Good
70-79	B	Good
60-69	C	Average
<60	D	Poor

The grade achieved for Hospital Pharmacy training shall be included in the 4th Year PharmD/ 1st year PharmD (PB) marksheet

15.Clerkship

Scope

The Clerkship Program is designed to provide students with hands-on experience in patient care within a clinical setting. It bridges the gap between theoretical learning and real-world clinical practice, enabling students to:

- Develop essential problem-solving and decision-making skills in patient management.
- Gain practical exposure to clinical procedures, patient assessment, and diagnosis.
- Enhance their ability to communicate effectively and work collaboratively within a multidisciplinary healthcare team.
- Build a strong foundation in professionalism, ethics, and evidence-based medical practice.

Objectives

- Proficiency in Clinical Knowledge: Develop familiarity with common diseases, diagnostic approaches, and treatment protocols used in hospital settings.
- Patient Assessment and Examination: Learn history-taking, physical examination techniques, and vital sign assessment.
- Clinical Skill Development: Identify and manage common medical conditions and perform basic clinical procedures such as suturing, IV cannulation, and catheterization.
- Communication and Teamwork: Improve patient communication skills and collaborate effectively with healthcare professionals.
- Exposure to Real-World Clinical Scenarios: Work in hospital wards, outpatient clinics, and emergency departments to gain hands-on experience in patient care.
- Therapeutic Decision-Making: Develop skills in diagnosing, managing patient care, and making evidence-based treatment recommendations.

Guidelines

- Students shall be posted to various specialties and super-specialties as per the schedule prepared by the department.
- The posting shall extend for a period of not less than 600 hrs. over a span of 200 working days including clerkship presentation hours.ie 4 hrs posting during the morning session daily and 2 hrs per week of clerkship presentation.
- 80 % attendance in clerkship is mandatory
- Students shall report twice weekly to the concerned clinical preceptor for discussion.

Evaluation criteria:

The formative and summative assessments carry 50 marks each and the formative assessment has two components; the sessional exam and the preceptor evaluation. The detailed guidelines for evaluation are included under the course content of clerkship.

16. Project

Fifth-year Pharm D students shall undertake a group project aimed at developing their key research, data collection-analysis, and reporting skills. The students can opt to work in the domains of community, hospital, and clinical pharmacy under the guidance of a designated faculty as a guide and with approval from the HOD or the Head of the Institution.

Objectives for the Project:

1. Develop student's research skills covering literature review, data collection, analysis, interpretation, and successful publication of research work.
2. Develop critical assessment and problem-solving skills to address pertinent issues in the domain of pharmacy practice.
3. Foster collaboration and teamwork among students through group work and shared responsibilities.
4. Promote effective communication skills through project presentations and reports, ensuring alignment with ethical standards and professional guidelines.

Rules and Regulations:

1. Students shall work on a group project comprising of a minimum three and a maximum of four members assigned to a Faculty guide in the 4^{th} year.
2. Students shall opt to work in community, hospital, and clinical pharmacy domains.
3. Projects involving patient data collection, interaction, or intervention require Institutional Ethics Committee (IEC) approval before the commencement of the study.
4. Each group shall present the project protocol to the research committee, covering the study aim, objectives, research question, hypothesis, relevance, and anticipated timelines.
5. The research committee shall forward the project protocol and recommendations to the IEC; students shall present the project proposal to the IEC for approval.
6. Mid-thesis evaluation shall be conducted internally by the Dept. of Pharmacy Practice in the presence of the principal to assess project progress.

7. Upon completion of the project, student shall submit the raw data and the soft copy of the thesis to the faculty guide for evaluation and corrections.
8. Final evaluation is done by the committee including internal & external examiners, HOD, & Principal.
9. After evaluation, the hard copy thesis and manuscript shall be submitted as per the guidelines

Evaluation Criteria:

Mid Thesis Evaluation: This shall be conducted internally by the Dept. of Pharmacy Practice in presence of Principal, to assess the progress of the project. The students shall be assessed based on the criteria below

Research Methodology and Literature Review	10
Progress and promptness of the research work	20
Question-answer skills and team involvement	20
Total	**50 Marks**

Final Evaluation: Upon completion of the project work, the students shall submit a thesis report for final evaluation by the committee composed of internal and external examiners, the HOD, and the Principal. The candidate (s) will be evaluated individually based on the criteria listed below.

Presentation of the work	50
Quality and Clinical relevance of the project	50
Question-answer & Justification skills	50
Total	**150 Marks**

17. Internship

The Pharm D/Pharm D PB students in the 6^{th} or 3^{rd} year respectively shall undergo 1 year internship in the various clinical departments of the hospital. The internship shall have 6 rotations of 2 months each and the posting will be as per the schedule prepared by the college.

Specific Objectives:

a. To provide pharmaceutical care with clinicians, and other members of an inter-professional healthcare team based upon sound therapeutic principles and evidence-based data, considering relevant legal, ethical, social, cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.

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

b. To promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk populations, and other members of an interprofessional team of healthcare providers.

c. To demonstrate the skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive measures and promote health care services to the community.

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

e. To communicate effectively with patients and the community.

18. Condonation under exceptional cases:

If the attendance of a student falls short of 80% in any course, due to continuous absence caused by accident, prolonged illness, or unforeseen circumstances, such case may be considered by the Principal for condonation of absence based on the request of the student supported by the recommendation of the respective faculty advisor. However, in such cases, the student must have duly applied for leave in time. The overall attendance of a student in such a case shall not fall below 70%. Condonation will be considered only in the case of those students who have proved themselves to be otherwise regular, by attending at least 80% of the classes during the year, excluding the period of long leave.

At least 70% physical presence is mandatory in every course even in such exceptional cases and this provision can be exercised by a student, only once in the program. However, the student may apply for a second condonation in the final year provided he or she does not have any arrears.

Condonation cannot be claimed as a matter of right. It shall be granted at the discretion of the authorities, based on the genuineness and validity of the reasons cited for the absence. A student is not eligible for condonation if he had any unauthorized absence during the year.

19. Examinations/Assessments

The scheme for formative assessment and summative assessment is given in Table–X.

19.1. Formative assessment

The formative assessment includes sessional exams, cycle tests, PBL and assignments. There shall be three formative assessments (FA1, FA2 & FA3) and the marks of the cycle tests of FA1,FA2 and FA3 shall be submitted 10 days before the first, second, and third sessional examinations respectively. There shall be a minimum of two cycle tests per FA. The cycle test shall include Quiz/Group discussion /presentation/TBL etc. The students can be divided into groups of either 5

or 6 each and they shall submit an assignment during the academic year on specific topic listed in the syllabus, assigned by the subject in charge at the commencement of the year. The assignment topic shall be different for different groups. The average of FA1, FA2, and FA3 is to be considered as the formative assessment. In case of practical courses, 10 marks can be allotted to day-to-day assessment, based on Practical Records, Regular viva voce, etc.

19.1.1. Sessional Exams

Three Sessional exams shall be conducted for theory and two sessional exams for practical courses as per the schedule fixed by the school. In case a student misses one sessional examination due to any medical emergency, he/she can attend a re-sessional examination covering the entire syllabus of the subject conducted before the summative assessments. The scheme of question papers for theory and practical Sessional examinations is given below. The average marks of three formative assessments shall be computed for internal assessment as per the requirements given in Table -X.

The sessional exam shall be conducted for 30 marks for theory and converted to 20 marks for calculation of FA marks and the sessional exam for practical is conducted for 40 marks.

Question paper pattern for sessional exams (as per blooms taxonomy)

The pattern for the question paper is as follows. There shall be no choice of questions in the university as well as sessional exam.

Theory :

Sessional exam:

MCQ (10 questions)	=	10×1 = 10 marks
Essay question (1 question)	=	1 x 10= 10 marks
Short answer questions	=	2 x 5 = 10 marks
		Total = 30 marks

Practical :

Sessional exam

Synopsis:	=	10 marks
Experiments (Major & Minor)	=	20 marks
Viva	=	10 marks
	Total =	40 marks

19.1.2. Problem Based Learning

PBL is a teaching method where students learn by solving open-ended problems in small groups. It focuses on developing critical thinking, problem-solving, and teamwork skills.

Benefits of PBL

- Student-centered learning
- Lifelong learning skills
- Improved comprehension and self-learning
- Teamwork and communication skills
- Development of a self-motivated attitude

PBL Process for Pharm D Program

- Groups of 5-6 students formed by the class coordinator, considering diversity in academic performance, gender, and communication skills.
- Two-hour PBL sessions twice a week for two consecutive weeks (total of 4 hours per course).
- Faculty member creates a scenario or problem for each session.
- Students analyze the scenario, identify key issues, and define learning objectives in the first session.
- Students independently research the problem using library resources and prepare a write-up.
- In the second session, students discuss their findings and address the learning objectives.
- Faculty facilitator assesses student performance based on engagement and quality of work.

Guidelines

- College PBL committee oversees planning, meetings, and documentation.
- Each course has one PBL session per semester, scheduled by the class coordinator.
- Scenarios are created by faculty, approved by the department and college PBL committee, and shared with students one week before the session. Scenarios are changed annually.
- Facilitators can be faculty members or Ph.D. teaching assistants. They guide discussions but do not teach.
- Each group selects a leader and scribe/secretary for managing discussions, documentation, and presentations. These roles can rotate among group members for different courses.

19.2. Summative assessment

(1) The summative assessment for each theory and practical course through the years I to V shall be conducted by the university except for the courses with the asterisk symbol (*) in table I -VI for which examinations shall be conducted by the subject experts at the school level. The grades from school-level examinations are not included in percentage calculation but the same shall be included separately in the grade sheets of the respective year.

(2) The summative assessment may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be a supplementary examination.

(3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Table X :

T A B L E X: Scheme for Formative Assessment and Summative Assessment Year-wise

First-year examination:

Course code	Name of the course	Formative assessment									Assignment/ Seminar	PBL	Total Marks	Summative assessment		Total Marks
		FA1			FA2			FA3								
		Sessional		Cycle Test	Sessional		Cycle Test	Sessional		Cycle Test				Marks	Duration	
		Marks	Duration		Marks	Duration		Marks	Duration							
PD.101T	Human Anatomy and Physiology	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.102T	Pharmaceutics	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.103T	Medicinal Biochemistry	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.104T	Pharmaceutical Organic Chemistry	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.105T	Pharmaceutical Inorganic Chemistry	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.106T	Remedial Mathematics / Biology*#	20	1 hr	-	20	1 hr	-	20	1 hr	-	-	-	25	25	1 hr	50
PD.107T	Cultural Education I & II*	20	1 hr	-	20	1 hr	-	20	1 hr	-	-	-	25	25	1 hr	50
PD.108T	Mastery Over Mind*	20	1 hr	-	20	1 hr	-	20	1 hr	-	-	-	25	25	1 hr	50
Total		**160**	**10.5 hrs**	**50**	**160**	**10.5 hrs**	**50**	**160**	**10.5 hrs**	**50**	**25**	**75**	**325**	**325**	**13 hrs**	**650**

Course code	Name of the course	Formative assessment		Day to Day Assessment	Total Marks	Summative assessment		Total Marks
		FA1	FA2					
		Sessional	Sessional			Marks	Duration	
PD.109P	Human Anatomy and Physiology Practical	40	40	10	50	50	4 hrs	100
PD.110P	Pharmaceutics Practical	40	40	10	50	50	4 hrs	100
PD.111P	Medicinal Biochemistry Practical	40	40	10	50	50	4 hrs	100
PD.112P	Pharmaceutical Organic Chemistry Practical	40	40	10	50	50	4 hrs	100
PD.113P	Pharmaceutical Inorganic Chemistry Practical	40	40	10	50	50	4 hrs	100
Total		**200**	**200**	**50**	**250**	**250**	**20 hrs**	**500**

Applicable ONLY for the students appearing for Remedial Biology(RB)/Remedial Mathematics(RM)course.

*School level exam

Second year examination:

Course code	Name of the course	Formative assessment									Assignment/ Seminar	PBL	Total Marks	Summative assessment		Total Marks
		FA1			FA2			FA3								
		Sessional		Cycle Test	Sessional		Cycle Test	Sessional		Cycle Test				Marks	Duration	
		Marks	Duration		Marks	Duration		Marks	Duration							
PD.201T	Pathophysiology I	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.202T	Pharmaceutical Microbiology	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.203T	Pharmacognosy & Phytopharmaceuticals	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.204T	Pharmacology-I	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.205T	Community Healthcare and Pharmacy Management	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.206T	Pharmacotherapeutics-I	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.207T	Pharmaceutical Jurisprudence	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.208T	Cultural Education III& IV*	20	1 hr	-	20	1 hr	-	20	1 hr	-	-	-	25	25	1 hr	50
Total		**160**	**11.5 hrs**	**70**	**160**	**11.5 hrs**	**70**	**160**	**11.5 hrs**	**70**	**35**	**105**	**375**	**375**	**15hrs**	**750**

Course code	Name of the course	Formative assessment		Day to Day Assessment	Total Marks	Summative assessment		Total Marks
		FA1	FA2					
		Sessional	Sessional			Marks	Duration	
PD.209P	Pharmaceutical Microbiology Practical	40	40	10	50	50	4 hrs	100
PD.210P	Pharmacognosy Practical	40	40	10	50	50	4 hrs	100
PD.211P	Pharmacotherapeutics-I Practical	40	40	10	50	50	4 hrs	100
Total		**120**	**120**	**30**	**150**	**150**	**12 hrs**	**300**

*School level exam

Third-year examination:

Course code	Name of the course	Formative assessment									Assignment/ Seminar	PBL	Total Marks	Summative assessment		Total Marks
		FA1			FA2			FA3								
		Sessional		Cycle Test	Sessional		Cycle Test	Sessional		Cycle Test				Marks	Duration	
		Marks	Duration		Marks	Duration		Marks	Duration							
PD.301T	Pharmacology-II	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.302T	Pharmaceutical Analysis	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.303T	Pharmacotherapeutics-II	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.304T	Medicinal Chemistry	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.305T	Pharmaceutical Formulations	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.306T	Pathophysiology II	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
Total		**120**	**9 hrs**	**60**	**120**	**9 hrs**	**60**	**120**	**9 hrs**	**60**	**30**	**90**	**300**	**300**	**12 hrs**	**600**

Course code	Name of the course	Formative assessment		Day to Day Assessment	Total Marks	Summative assessment		Total Marks
		FA1	FA2					
		Sessional	Sessional			Marks	Duration	
PD.307P	Pharmacology-II Practical	40	40	10	50	50	4 hrs	100
PD.308P	Pharmaceutical Analysis Practical	40	40	10	50	50	4 hrs	100
PD.309P	Pharmacotherapeutics-II Practical	40	40	10	50	50	4 hrs	100
PD.310P	Medicinal Chemistry Practical	40	40	10	50	50	4 hrs	100
PD.311P	Pharmaceutical Formulations Practical	40	40	10	50	50	4 hrs	100
Total		**200**	**200**	**50**	**250**	**250**	**20 hrs**	**500**

Fourth year examination:

Course code	Name of the course	Formative assessment									Assignment/ Seminar	PBL	Total Marks	Summative assessment		Total Marks
		FA1			FA2			FA3								
		Sessional		Cycle Test	Sessional		Cycle Test	Sessional		Cycle Test				Marks	Duration	
		Marks	Duration		Marks	Duration		Marks	Duration							
PD.401T	Pharmacotherapeutics-III	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.402T	Hospital Pharmacy	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.403T	Clinical Pharmacy	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.404T	Biostatistics & Research Methodology	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.405T	Biopharmaceutics & Clinical Pharmacokinetics	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.406T	Clinical Toxicology	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.407T	Life Skill	50	1.5 hrs	-	50	1.5 hrs	-	50	1.5 hrs	-	-	-	50	50	2 hrs	100
Total		**170**	**10.5 hrs**	**60**	**170**	**10.5 hrs**	**60**	**170**	**10.5 hrs**	**60**	**30**	**90**	**350**	**350**	**14hrs**	**700**

Course code	Name of the course	Formative assessment		Day to Day Assessment	Total Marks	Summative assessment		Total Marks
		FA1	FA2					
		Sessional	Sessional			Marks	Duration	
PD.409P	Pharmacotherapeutics-III Practical	40	40	10	50	50	4 hrs	100
PD.410P	Clinical Pharmacy Practical	40	40	10	50	50	4 hrs	100
PD.411P	Biopharmaceutics & Clinical Pharmacokinetics Practical	40	40	10	50	50	4 hrs	100
Total		**120**	**120**	**30**	**150**	**150**	**12 hrs**	**300**

First year Pharm. D P B examination:

Course code	Name of the course	Formative assessment									Assignment/ Seminar	PBL	Total Marks	Summative assessment		Total Marks
		FA1			FA2			FA3								
		Sessional		Cycle Test	Sessional		Cycle Test	Sessional		Cycle Test				Marks	Duration	
		Marks	Duration		Marks	Duration		Marks	Duration							
PDPB.101T	Pharmacotherapeutics-III	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PDPB.102T	Hospital Pharmacy	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PDPB.103T	Clinical Pharmacy	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PDPB.104T	Biostatistics & Research Methodology	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PDPB.105T	Biopharmaceutics & Clinical Pharmacokinetics	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PDPB.106T	Clinical Toxicology	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PDPB.107T	Pharmacotherapeutics-I & II	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PDPB.108T	Life Skill	50	1.5 hrs	-	50	1.5 hrs	-	50	1.5 hrs	-	-	-	50	50	2 hrs	100
Total		**190**	**12 hrs**	**70**	**190**	**12 hrs**	**70**	**190**	**12 hrs**	**70**	**35**	**105**	**400**	**400**	**16hrs**	**800**

Course code	Name of the course	Formative assessment		Day to Day Assessment	Total Marks	Summative assessment		Total Marks
		FA1	FA2					
		Sessional	Sessional			Marks	Duration	
PDPB.110P	Pharmacotherapeutics-III Practical	40	40	10	50	50	4 hrs	100
PDPB.111P	Clinical Pharmacy Practical	40	40	10	50	50	4 hrs	100
PDPB.112P	Biopharmaceutics & Clinical Pharmacokinetics Practical	40	40	10	50	50	4 hrs	100
PDPB.113P	Pharmacotherapeutics-I & II Practical	40	40	10	50	50	4 hrs	100
Total		**160**	**160**	**40**	**200**	**200**	**16 hrs**	**400**

Fifth-year examination:

Course code	Name of the course	Formative assessment									Assignment/ Seminar	PBL	Total Marks	Summative assessment		Total Marks
		FA1			FA2			FA3								
		Sessional		Cycle Test	Sessional		Cycle Test	Sessional		Cycle Test				Marks	Duration	
		Marks	Duration		Marks	Duration		Marks	Duration							
PD.501T	Clinical Research	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.502T	Pharmacoepidemiology and Pharmacoeconomics	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.503T	Precision medicine	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PD.504T	Clerkship **	-	-	-	-	-	-	-	-	-	-		50	50	-	100
PD.505PR	Project work	-	-	-	-	-	-	-	-	-	-		50	150	-	200
Total		**60**	**4.5hrs**	**30**	**60**	**4.5hrs**	**30**	**60**	**4.5hrs**	**30**	**15**	**45**	**250**	**350**	**6hrs**	**600**

Second year Pharm. D P B examination:

Course code	Name of the course	Formative assessment									Assignment/ Seminar	PBL	Total Marks	Summative assessment		Total Marks
		FA1			FA2			FA3								
		Sessional		Cycle Test	Sessional		Cycle Test	Sessional		Cycle Test				Marks	Duration	
		Marks	Duration		Marks	Duration		Marks	Duration							
PDPB.201T	Clinical Research	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PDPB.202T	Pharmacoepidemiology and Pharmacoeconomics	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PDPB.203T	Precision medicine	20	1.5 hrs	10	20	1.5 hrs	10	20	1.5 hrs	10	5	15	50	50	2 hrs	100
PDPB.204T	Clerkship **	-	-	-	-	-	-	-	-	-	-	-	50	50	-	100
PDPB.205R	Project work	-	-	-	-	-	-	-	-	-	-	-	50	150	-	200
Total		**60**	**4.5hrs**	**30**	**60**	**4.5hrs**	**30**	**60**	**4.5hrs**	**30**	**15**	**45**	**250**	**350**	**6hrs**	**600**

20. Mode of examinations

1) The theory examination shall be of two hours and the practical examination shall be of four hours duration.
2) Theory and Practical of a particular course are considered as individual courses for pass criteria. A Student who fails in the theory or practical examination of a subject shall re-appear only in the failed theory or practical exam.
3) Practical examination shall also consist of a viva –voce (Oral) examination.
4) Clerkship examination – Two sessional and final examination shall be conducted for the clerkship. Students shall present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning, and knowledge of therapeutics shall be assessed.

21. Pass Criterion and award of grades.

A student shall be declared a Pass in a course of Pharm.D program if he/she secured an aggregate of 50% with a minimum of 40% marks each in formative and summative assessments. For example, to be declared as PASS, the student must secure a minimum of 20 marks in the formative assessment and 20 marks in the summative assessment of theory examinations, and a minimum of 20 marks each in the formative and summative assessment of practical examinations. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) examination shall be declared to have passed in first class. Students securing 75% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) examination shall be declared to have passed with First Class with Distinction.

22. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 21, then he/she shall reappear for the next university examination of that course. However, his/her marks of the formative Assessment shall be carried over and he/she shall be entitled to the marks obtained by him/her on passing the summative assessment examination.

23. Promotion criterion and Maximum allowable carry over

The maximum allowable carryover at any time during 1^{st} - 5^{th} year shall be two subjects from any previous year and a student shall pass all the subjects of 1^{st} year in order to be promoted to 3^{rd} year and all subjects of 1^{st} and 2^{nd} year for promotion to 4^{th} year and shall pass all the subjects of 1^{st}, 2^{nd} and 3^{rd} year for promotion to 5^{th} year. However, a student shall become eligible for internship only if he/she passes all the subjects of the 1^{st} - 5^{th} year of Pharm D.

Question paper pattern for summative theory examinations (as per blooms taxonomy)

The pattern for the question paper is as follows. There shall be no choice of questions in the university exam.

I.	Multiple Choice Questions (MCQs)	=	15x1=15marks
II.	Long Answers	=	1x10=10marks
III.	Short Answers	=	5 x 5=25marks

	Total	=	50 marks

Question paper pattern for summative assessment of practical examinations.

I.Synopsis	=	10 marks
II. Experiments(Major & Minor)	=	25 marks
III. Viva	=	15 marks
Total	=	50 marks

24. Eligibility of Examiners & Question Paper Setters

Faculty of Amrita School of Pharmacy who are handling the respective courses with a minimum of 3 years of teaching experience / Ph.D shall be appointed as examiners/Question paper setters for First year to third year examination and teachers with not less than 5 years of teaching experience / Ph.D shall be appointed as examiners/Question paper setters for the remaining years.

External faculty members of reputed universities with relevant teaching experience shall be appointed by the Addl.Controller of Examinations as observers. During the final practical examinations, such observers shall be appointed for selected courses randomly in every year who shall oversee the conduct of the practical examination, verify the practical records, theory QP etc., and submit a report in the prescribed format to the Addl. Controller of Examinations. Faculty with a minimum of 5 years of teaching experience in the concerned subject of Pharm.D shall be appointed as observers. One external faculty shall serve as an observer for exams of 2 or 3 courses of Pharm.D if scheduled on the same day or adjacent days.

25. Revaluation

A failed student shall have the right to apply for revaluation of the theory paper by filling the application form along with the required fees within the stipulated time after the publication of the result.

26. Supplementary examination of summative assessment

Supplementary examinations of summative assessment shall be conducted as "SAY" (Save An Year) exam within two months of publication of regular exam results. The exact dates of examinations shall be notified from time to time. All students with arrears are eligible for SAY.

27. Improvement of Internal marks

A student who fails in university examination in the first attempt can apply for improvement sessional exam by submitting the duly filled application form when notified by the Principal.

28. Award of Ranks

Ranks and Medals shall be awarded based on the final percentage. However, candidates who fail in one or more courses during the Pharm.D program shall not be eligible for the award of ranks. Moreover, the candidates should have completed the Pharm. D program in a minimum prescribed number of years, (Six years/ three years for Pharm D Post Baccalaureate) for the award of Ranks.

29. Publication of paper

The requirement of one publication in a Scopus indexed journal for eligibility for award of degree as mandated by Amrita Vishwa Vidyapeetham, shall be applicable to Pharm D considering the fact that itis an approved PG program.

30. Award of Degree

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

31. Additional courses for Pharm D Post Baccalaureate

Pharmacotherapeutics-I & II is an additional course for 1st year Pharm D Post Baccalaureate who join along the 4th year of Regular Pharm D This course is included to cover the Therapeutics I and Therapeutics II courses taught in the 2nd and 3rd year respectively of Pharm. D regular program. Except for this subject, all other classes will be handled together for Pharm D regular 4th year and Pharm D PB 1st year.

32. Awarding credit points for co-curricular activities

As per the requirements of Amrita Vishwa Vidyapeetham, all Pharm D students are required to publish a paper in a Scopus indexed journal in order to be eligible for the award of the degree. The award of the credit points for co-curricular activities shall be done at the end of the 5th year based on the details and documentary evidences submitted by the students and this shall appear as "Additional credits earned for co-curricular activities "in the fifth year mark list or transcript.

There shall be minimum of 2 credits and maximum of 7 credits earned from co-curricular activities (attending conferences/workshops etc).

Table- XI: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the activity	Maximum Credit points Eligible/ Activity
Participation in National/International Level Seminar/Conference/Workshop/Symposium/ Training Programs	01
**Presentation in National/International Level Seminar/Conference/Workshop/Symposium/ Training Programs	02
Academic Award/Research Award from State Level/National Agencies/ International Agencies	02
*Review Publication indexed in Scopus	01
*Research Publication indexed in Scopus	02

* Either one of these is mandatory.

**Maximum per event remains two points.

Participation and presentation maximum points 2

Participation, presentation and award maximum points 4

33. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration (twelve academic years) of the program and the students must pass within the said period, otherwise they have to get fresh Registration. There shall not be any supplementary batch for any year.

34. Re-admission after break of study

A candidate who seeks readmission to the program after a break of study shall get approval from the principal by making a written request. Readmission will not be permitted for the candidate who has more than 2 years of breakup period.

Note:

Point No 24 which describes the eligibility of the examiners and question paper setters shall be applicable to all the current batches of Pharm.D w.e.f AY 2025-26 and as per it, faculty of Amrita School of Pharmacy who are handling the respective minimum of 3 years of teaching experience / Ph.D shall be appointed as examiners/Question paper setters for First year to third year examination and teachers with not less than 5 years of teaching experience / Ph.D shall be appointed as examiners/Question paper setters for the remaining years.

Also, as per point no. 26, the supplementary exams shall be conducted as SAY Exam for all the batches of PharmD w.e.f AY 2025-26

COURSE CONTENTS

FIRST YEAR

Course Title	L	T	P	Total Hrs.	Year	Course Code
Human Anatomy & Physiology (T)	**3**	**0.5**	**0**	**75**	**I**	**PD.101T**
Human Anatomy & Physiology (P)	**0**	**0**	**2**	**50**	**I**	**PD.109P**

SCOPE:

This course is designed to impart fundamental knowledge on the structure and functions of the human body. The course will be helpful to operate the basic instruments and apparatus for studying human anatomy and physiology, and acknowledge healthy habits and lifestyle.

The course is primarily focused on understanding the gross and internal anatomy of various organs and their functions, and how the different bodily systems work together to maintain homeostasis. By understanding the interconnected mechanisms involved in homeostasis, students can appreciate how various processes are controlled and balanced within the body. The course will also be helpful to distinguish between various disorders and conditions affecting different organ systems of the human body. Thus, it provides the foundation necessary to comprehend pathophysiology and pharmacology.

Since a medicament is produced and used by the pharmacist to manage specific indication by correcting the deviations in human body, the course lays the foundation to understand how the drugs act on the various body systems in correcting the disease state of the organs. Knowledge in the course will help the students to develop the skills to determine various body parameters that provide insights into an individual's health status. This includes evaluation and interpretation of vital signs, body functions and haematological parameters. These skills are important for healthcare professionals to diagnose, monitor, and treat patients effectively. Furthermore, a solid understanding of this course empowers individuals to acknowledge healthy habits and lifestyle, support the healthcare system and educate the general public about various aspects of health.

COURSE LEARNING OUTCOMES:

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

KNOWLEDGE

K1: Define the medical terminology related to human anatomy and physiology.

K2: Describe the gross and internal anatomy of various organs of the human body.

K3: Explain the functions of various organs and systems of the human body

K4: Illustrate the various homeostatic mechanisms, imbalances and their regulation.

K5: Demonstrate the coordinated working pattern of different organs and systems.

K6: Distinguish between various disorders and conditions affecting different organ systems of the human body.

SKILL

S1: Operate the basic instruments and apparatus for studying human anatomy and physiology.

S2: Identify the organs of the different systems of the human body.

S3: Recognize the the histological specimens of the human body.

S4: Demonstrate the evaluation of vital signs and body functions.

S5: Execute the evaluation of haematological parameters.

S6: Interpret the human laboratory values.

ATTITUDE

A1: Acknowledge healthy habits and lifestyle.

A2: Demonstrate professionalism in all the activities.

A3: Appreciate the accuracy, reliability, integrity, and completeness of the data.

A4: Communicate effectively the results.

A5: Provide clinical knowledge as required.

A6: Embrace science and scientific advancements.

LECTURE WISE CONTENTS: **75 hours**

UNIT I Introduction to human anatomy and physiology **2 hours**

- Scope of anatomy and physiology, Basic terminologies (1 hr)
- Feedback system (1 hr)

UNIT II Haemopoetic System **7 hours**

- Composition and functions of blood (1 hr)
- Hemopoesis (1 hr)
- Structure and functions of RBC, WBC and platelets (1 hr)
- Blood groups and blood types, Transfusion (1 hr)
- Hemostasis and Clotting factors (2 hrs)
- Definition: Venipuncture, Venesection, Phlebotomy, Hemorrhage, Anemia, Aplastic anemia, Sideroblastic anemia, Iron deficiency anemia, Megaloblastic anemia, Pernicious anemia, Sickle cell disease, Thalassemia, Erythocytosis, Polycythemia, Leukopenia, Leukocytosis, Leukemia, Thrombocytopenia, Thrombocytosis, Agranulocytosis, Septicemia, Hemophilia- A, B and C, Von Willebrand disease, Hemolytic disease of the newborn (1 hr)

UNIT III Lymph **4 hours**

- Functions of lymphatic system, Lymphatic vessels and lymph circulation, Lymphatic organs and tissues (1 hr)
- Structure and functions of Spleen, Thymus and Lymph node (2 hrs)
- Definition: Tonsillitis, AIDS, Allergy, Autoimmune disease, Infectious mononucleosis, Lymphomas, SLE, SCID (1 hr)

UNIT IV Cardiovascular system **12 hours**

- Anatomy of the heart (2 hrs)
- Circulation of blood - Pulmonary, coronary and systemic, Histology of cardiac muscle tissue (1 hr)
- Cardiac conduction pathway and action potential (1 hr)
- Electrocardiogram (1 hr)
- Cardiac cycle (1 hr)
- Cardiac output- its maintenance and regulation (1 hr)
- Hemodynamics: factors affecting blood flow (1 hr)
- Blood pressure – its maintenance and regulation (2 hrs)
- Heart sounds and Pulse (1 hr)
- Definition: Pericarditis, Myocarditis, Endocarditis, Stenosis, Rheumatic fever, Arteriosclerosis, Atherosclerosis, Coronary artery disease, Myocardial ischemia, Hypoxia, Angina pectoris, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias, Bradycardia, Tachycardia, Fibrillation, Hypertension, Hypotension (1 hr)

UNIT V Respiratory system **6 hours**

- Anatomy of respiratory system (2 hrs)
- Physiology of respiration- exchange and transport of oxygen and carbon dioxide (2 hrs)
- Lung volumes and capacities (1 hr)
- Definition: Asphyxia, Aspiration, Dyspnea, Epistaxis, Carbon monoxide poisoning, Cyanosis, Rhintis, Rhinoplasty, Laryngitis, Pnemuothorax and hemothorax, Coryza, Seasonal Influenza, H1N1 Influenza, Severe acute respiratory syndrome, Respiratory distress syndrome, Asthma, Chronic obstructive Pumonary disease, Pneumonia, Tuberculosis, Pulmonary edema, Sudden infant death syndrome, Tracheotomy and intubation, Mechanical ventilation (1 hr)

UNIT VI Digestive system **10 hours**

- Organization and Histology of GIT (1 hr)
- Anatomy and physiology of GIT – stomach, small intestine, large intestine (4 hrs)
- Functions of accessory glands of GIT – salivary glands, liver, pancreas, gall bladder (1 hr)
- Digestion of food in GIT (2 hrs)
- Absorption of food in GIT (1 hr)
- Definition: Mumps, Peptic ulcer, Gastroesophageal reflux disease, Colorectal cancer, Hepatitis, Jaundice, Pancreatitis, Gallstones, Appendictis, Polyps, Canker sore, Cirrhosis, Colitis, Dysphagia, Flatus, Food poisoning, Gastroenteritis, Heartburn, Hemorrhoids, Hernia, Inflammatory bowel disease, Irritable bowel syndrome, Nausea, Vomiting (1 hr)

UNIT VII Nervous system **14 hours**

- Histology of nervous tissue- Neuron and Neuroglia (1 hr)
- Organization of the nervous system and functions, Generation and propagation of action potential (1 hr)
- Signal transmission at synapses, Neurotransmitters (1 hr)
- Meninges, Cerebrospinal fluid (1 hr)
- Parts of the brain, Anatomy of cerebrum, functional areas of cerebrum (2 hrs)
- Anatomy and physiology of diencephalon – Thalamus, Hypothalamus (1 hr)
- Anatomy and physiology of brain stem- Midbrain, Pons, Medulla oblongata (1 hr)
- Anatomy and physiology of cerebellum, Significance of Reticular formation, Limbic System, Basal Nuclei (1 hr)
- Cranial nerves – names and functions (1 hr)
- ANS – Anatomy and functions of sympathetic & parasympathetic nervous system (2 hrs)
- Anatomy and physiology of Spinal cord (1 hr)
- Reflex – definition and types, reflex arc, patellar reflex, plantar reflex (1 hr)

UNIT VIII Urinary system **6 hours**

- Anatomy of urinary system with emphasis on kidney and nephron (2 hrs)
- Overview of renal physiology (1 hr)
- Glomerular filtration and its regulation (1 hr)
- Tubular reabsorption and secretion, and their regulation (1 hr)
- Evaluation of kidney function- Characteristics of normal urine, Summary of abnormal constituents in urine, blood tests, renal plasma clearance (1 hr)

UNIT IX Endocrine system **6 hours**

- Pituitary gland- Relationship between the hypothalamus and pituitary gland; Hormones and functions of the anterior and posterior pituitary (2 hrs)
- Adrenal gland (1 hr)
- Thyroid and Parathyroid glands (1 hr)
- Pancreas (1 hr)
- Definition: Pituitary dwarfism, Gigantism, Acromegaly, Diabetes insipidus, Diabetes mellitus, Myxedema, Graves disease, Goiter, Hypoparathyroidism, Hyperparathyroidism, Cushing's syndrome, Addison's disease, Pheochromocytomas, Gynecomastia, Hirsuitism (1 hr)

UNIT X Reproductive system **8 hours**

- Anatomy of male reproductive system (2 hrs)
- Spermatogenesis, Hormonal control of testes (1 hr)
- Anatomy of female reproductive system (2 hrs)
- Female reproductive cycle- Phases, Hormonal regulation (2 hrs)
- Oogenesis, Labor (1 hr)

LIST OF PRACTICAL EXPERIMENTS:

1. Study of compound microscope
2. Study of tissues

    a. Microscopic study of epithelial tissue
    b. Microscopic study of connective tissue
    c. Microscopic study of muscular tissue
    d. Microscopic study of nervous tissue
3. Determination of bleeding time
4. Determination of clotting time
5. Estimation of haemoglobin content
6. Determination of blood group
7. Study of haemocytometer
8. Enumeration of total red blood corpuscles (RBC) count
9. Enumeration of white blood corpuscles (WBC) count
10. Determination of body temperature
11. Determination of heart rate and pulse rate
12. Recording of systemic arterial blood pressure
13. Study of skeletal system
    a. Identification of axial bones
    b. Identification of appendicular bones
14. Study of the structure (gross and histology) using cadaver demonstration, medical museum visit, models and sections of:
    a. Cardiovascular system
    b. Nervous system
    c. Endocrine system
    d. Respiratory system
    e. Digestive system
    f. Reproductive system
    g. Urinary system
15. Study of different family planning appliances.
16. Testing of pregnancy diagnosis.
17. Determination of the body mass index (BMI)
18. Determination of blood glucose level using one touch glucometer
19. Determination of tidal volume and vital capacity using the spirometer
20. Determination of blood oxygen level using a pulse oximeter

21. Performing cardiopulmonary resuscitation (CPR) on adults and infants
22. Performing basic first aid in case of
    a. Fainting
    b. Drowning
    c. Burns
    d. Electric Shock
    e. Snake Bite
    f. Bee Sting
    g. Dog Bite
    h. Vomiting
    i. Diarrhea
    j. Accident
    k. Cardiac arrest
    l. Stroke

SEMINAR/ASSIGNMENTS:

1. Cell- components and functions
2. Skin- structure and functions, related disorders
3. Joints- classification, types of movements and disorders
4. Nose- Olfactory pathway, physiology of olfaction, related disorders
5. Tongue- Anatomy of taste buds and papillae, physiology of gustation, related disorders
6. Eye- Anatomy of the eyeball, physiology of vision, related disorders
7. Ear- Anatomy of the ear, physiology of hearing, related disorders
8. Skeletal muscles- Histology, physiology of muscle contraction and related disorders
9. Biological effects of exercise, pranayama, and meditation
10. Biological effects of fasting, dietary supplementation and drug abuse

TEXT BOOKS:

1. Tortora GJ, Derrickson BH. Principles of Anatomy and Physiology, 16th edn. Wiley; 2020.
2. Waugh A, Grant A. Ross & Wilson Anatomy and physiology in health and illness, 14th edn. Elsevier; 2022.
3. Goyal RK, Patel NM, editors, Practical Anatomy and Physiology, 17th edn. B S Shah Prakashan; 2020.
4. Deshpande SA, Shirole DS, Amale PN, Vyawahare NS. Practical Book of Human Anatomy and Physiology, 4th edn. Nirali Prakashan; 2020.

REFERENCE BOOKS:

1. Hall JE, Hall ME. Guyton and Hall textbook of medical physiology, 14th edition. Elsevier; 2020.

2. Standring S, editor. Gray's anatomy: the anatomical basis of clinical practice, 42nd edition. Elsevier; 2021.
3. John NA. CC Chatterjee's Human Physiology, Vol. 1 & 2. 14th edition. CBS Publishers & Distributors; 2022.

Course Title	L	T	P	Total Hrs.	Year	Course Code
Pharmaceutics (T)	**2**	**0**	**0**	**50**	**I**	**PD.102T**
Pharmaceutics (P)	**0**	**0**	**3**	**75**	**I**	**PD.110P**

SCOPE:

This course is designed to impart fundamental knowledge on the art and science of handling prescriptions and dispensing medications correctly, considering different dose requirements based on various factors. It is essential for students to understand the history of the pharmacy profession and pharmaceutical industry in India and appreciate their current status. To learn about different dosage forms and their preparations, an understanding of the untoward interactions between chemicals in pharmaceutical preparations arising due to incompatibility is crucial, along with methods to overcome these issues and essential pharmaceutical calculations. It also introduces and emphasizes the applications of Artificial Intelligence (AI) in formulation design and optimization, enabling more efficient and targeted drug development.

This course will enable students to differentiate between various liquid, semisolid, and powder dosage forms based on their formulation, preparation, and uses. Additionally, students will gain insights into the interfacial properties of suspended particles, factors influencing settling in suspensions, and the theories of emulsification, which are critical for ensuring the stability and efficacy of biphasic liquid dosage forms. It also covers the evolution and significance of official books of standards (Pharmacopoeias). Furthermore, this course aims to cultivate a professional attitude in students, highlighting the significance of adhering to good laboratory practices in the preparation of various dosage forms.

COURSE LEARNING OUTCOMES:

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

KNOWLEDGE

K1: Outline the historical background, development, and current status of the profession of pharmacy, pharma industry as well as various pharmacopeias (Remembering).

K2 : Describe the different parts of prescription and the various factors affecting doses of drugs (Understanding).

K3 : Classify the different types of dosage forms and incompatibilities between ingredients (Understanding).

K4: Interpret the English meaning of the Latin terms commonly used in prescriptions (Understanding).

K5 : Distinguish between the monophasic and biphasic liquid dosage forms in terms of the types, preparation, formulation etc. (Analysis)

K6: Summarize the powders and the semisolid dosage forms considering their advantages, disadvantages, preparation, excipients used etc. (Evaluation)

SKILL

S1: Utilize different weighing and measuring techniques required for dispensing prescriptions

S2: Demonstrate the preparation of different solid powder dosage forms

S3: Perform the preparation, packing, and labelling of various semisolid dosage forms

S4: Apply various methods for altering the strength and adjusting the tonicity of solutions.

S5: Calculate the amount of drug required to prepare solutions of required strength

S6: Formulate suitable liquid dosage form for the given drug.

ATTITUDE

A1: Accept good laboratory practices while performing the preparation of various dosage forms

A2: Follow appropriate measures to correctly dispense the given prescription

A3: Cooperate with fellow students for mutual well being

A4: Praise the efforts of faculty and supporting staff who facilitate your learning

A5: Display sincerity, punctuality, and integrity

A6: Demonstrate interest, motivation, and self-evaluation for learning beyond Classroom

LECTURE WISE CONTENTS:

UNITI - Historical background and development of profession of pharmacy 2 hours

- History of professionof Pharmacy in India in relation to pharmacy education
- Industry and organization, its current status
- Pharmacy as a career
- Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia

UNIT II- Dosage forms: 3 hours

- Introduction to dosage forms, classification, Applications of AI in Formulation

UNIT III - Prescription 5 hours

- Definition
- Parts of prescription,
- Handling of Prescription and Errors in prescription
- Introduction to commonly used latin terms.

UNIT IV - Posology 4 hours

- Definition,
- Factors affecting posology.
- Pediatric dose calculations based on age, body weight, and body surface area.

UNIT V-Pharmaceutical calculations 5 hours

- Weights and measures
- Imperial & Metric system
- Calculations involving percentage solutions
- Allegation
- Proof spirit and isotonic solutions based on freezing point and molecular weight.

UNIT VI- Powders 4 hours

- Definition
- Classification, advantages and disadvantages
- Classification of powders - Powders for internal use, Powders for external use, Special powders

UNIT VII - Liquid Dosage Forms 1 hour

- Advantages and disadvantages of liquid dosage forms
- Excipients used in formulation of liquid dosage forms.

- **Monophasic liquids** **2 hours**
  - Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniment, and Lotions.

- **Biphasicliquids**
  - **Suspensions** **5 hours**
  - Definition, advantages and disadvantages,
  - Classifications
  - Formulation and Preparation of suspensions
  - Flocculated and Deflocculated suspension stability problems and methods to overcome.
  - Interfacial properties of suspended particles, settling in suspensions

  - **Emulsions** **4 hours**
  - Definition, classification
  - Types of Emulsifying agent
  - Test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.
  - Theories of emulsification

UNIT VIII- Suppositories **3 hours**

- Definition
- Types, advantages and disadvantages
- Types of bases, and methods of preparation.
- Displacement value & its calculations

UNIT IX-Pharmaceutical-Incompatibilities **4 hours**

- Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIT X- Semisolid dosage forms **5 hours**

- Definitions, classification
- Preparation of ointments, pastes, creams, and gels. Excipients used in semi solid dosage forms.

UNIT-XI **3 hours**

Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures, and medicated bandages.

Text books:

1. Jain N K. A text book of professional pharmacy. 4th ed. Delhi: Vallabha Prakashan; c1998.
2. Carter SJ. Cooper and Gunn's Dispensing for Pharmaceutical Students. 12thed.New Delhi: CBS; c2008.
3.
4. Seth AK. A text book of pharmaceutics. 2nded. Jalandhar: S Vikas & Co.; c2017.

Reference books:

1. Ansel H C. Pharmaceutical calculations. 13thed. New Delhi:LPPWW.;c2010.
2. Singh H, Schroff M L. The making of modern Pharmacy. Delhi:Vallabha Prakashan.;c2009.
3. Carter SJ. Cooper and Gunn's Tutorial Pharmacy. 6thed.Delhi:CBS; c2009.
4. Khar R K. Lachman/Liberman's Theory and Practice of Industrial Pharmacy. 4th ed. New Delhi:CBS; c2013

**Latest edition of text books and reference books can be referred*

PHARMACEUTICS (PRACTICAL)

LIST OFEXPERIMENTS:

1. **Syrups**
   a. Simple Syrup I.P
   b. Syrup of ferrous Phosphate IP
2. **Elixir**
   a. Piperizine citrate elixir BP
   b. Paracetamol elixir BPC
3. **Linctus**
   a. Simple Linctus BPC
   b. Pediatric simple Linctus BPC

4. Solutions

a. Solution of Cresol with soap IP

b. Aqueous iodine solution IP

c. Strong solution of ammonium acetate IP

5. Liniments

c. Liniment of turpentine IP

d. Liniment of camphor IP

6. Suspensions

e. Calamine lotion

f. Magnesium Hydroxide mixture BP

7. Emulsions

g. Castor oil emulsion

h. Cod liveroil emulsion

i. Liquid paraffin emulsion

8. Powders

j. Eutectic powder

k. Dusting powder

l. Divided powder

9. Semi-solid dosage forms

a. Suppositories

i. Boric acid suppository

ii. Zinc oxide suppository

b. Ointments

i.Simple ointment

ii.Sulphur ointment

iii.Non-staining iodine ointment

10. Incompatibilities

Mixtures with Physical, chemical, and therapeutic incompatibilities

RecommendedBooks:

1. Gaud,RS. Practical Pharmaceutics. 1st ed; CBS publishers .; 2831-2835.

2. Seth,A K. Practical Pharmaceutics:Systematic Approach. S Vikas& Co.;5061.

Seminar/Assignments:

1. Procure two prescriptions, carefully analyze their details, and subsequently generate a report discussing their level of correctness.
2. "Evolution and Advancement of the Pharmaceutical Industry in India: A Historical Perspective on Growth"
3. "Analysing the Present State and Envisioning the Future Outlook of the Indian Pharma Sector."
4. Write the Composition, Properties, and Applications of various Powders available in the market.
5. Write the formulation, Characteristics, and Pharmaceutical application of various monophasic liquid dosage forms (internal use) available in the market.
6. Write the formulation, Characteristics, and Pharmaceutical application of various monophasic liquid dosage forms (external use) available in the market.
7. Analyse the Aqueous -Oil Phases and Emulsifying Agents in Emulsion Products Available in the Market (at least 10).
8. Write the composition of different suspensions available in the market (at least 10).
9. Calculating Paediatric Doses for the Following Drugs:

   A) Levipil

   B) Valparin

   C) Acyclovir

   D) Clobium

   E) Ceftriaxone

Course Title	L	T	P	Total Hrs.	Year	Course Code
MEDICINAL BIOCHEMISTRY (T)	**3**	**0.5**	**0**	**75**	**I**	**PD.103T**
MEDICINAL BIOCHEMISTRY (P)	**0**	**0**	**2**	**50**	**I**	**PD.111P**

SCOPE:

Medicinal Biochemistry is designed to provide a comprehensive molecular-level understanding of the chemical processes associated with living cells in both normal and diseased states. The subject covers various mechanisms involved in biological oxidation, enzyme kinetics, inhibition, regulation, and clinical applications. It also explores the classification and functions of biomolecules, concepts of bioenergetics, and the metabolic pathways of carbohydrates, lipids, amino acids, and nucleic acids under physiological and pathological conditions.

Clinical biochemistry focuses on the chemical basis of human health and disease, emphasizing laboratory methods for diagnosis, treatment monitoring, and disease prevention. The course integrates theoretical knowledge with practical clinical applications, preparing students for advanced roles in diagnostics and research.

In alignment with **Sustainable Development Goal 3: Good Health and Well-being**, this course fosters deeper insights into disease mechanisms and supports evidence-based diagnostic and therapeutic strategies. It also supports **SDG 4: Quality Education** by promoting skill-based, interdisciplinary learning and research-oriented thinking. Through the study of enzyme applications and innovations in biochemical diagnostics, it contributes to **SDG 9: Industry, Innovation, and Infrastructure**.

COURSE LEARNING OUTCOMES

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

KNOWLEDGE

K1: Recall the classification of carbohydrates, lipids, proteins, and nucleic acids, along with examples and subtypes.

K2: Discuss the metabolic cycles associated with the metabolism of various biomolecules.
K3: Analyze errors in biomolecule metabolism that lead to disorders such as diabetes mellitus, PKU, AKU, jaundice, and atherosclerosis.
K4: Determine the clinical significance of organ function tests (liver, kidney, and lipid profile) and biochemical blood tests.

K5: Interpret the regulation of metabolic pathways (e.g., carbohydrate, lipid, amino acid, and nucleic acid metabolism) in normal and disease conditions.

K6: Assess enzyme actions and inhibition (reversible, irreversible, and allosteric) in clinical and therapeutic contexts.

SKILL

S1: Identify the presence of various biomolecules in the sample.
S2: Detect the presence of normal and abnormal constituents present in the given urine sample. (
S3: Estimate the concentration of biomolecules from the given sample using analytical methods.
S4: Identify normal reference ranges for each laboratory test to understand their significance in diagnosing and monitoring various health conditions.
S5: Interpret normal and abnormal values in laboratory tests on lipid profiles, and kidney and liver function tests.
S6: Interpret laboratory tests with the help of case studies that stimulate worldwide scenarios.

ATTITUDE

A1: Appreciate the knowledge of biochemistry in relating the significance of various enzymes in different pathological conditions.
A2: Follow professionalism in the working environment
A3: Participate in group discussions to plan effectively in performing experiments.
A4: Exhibit good communication skills to emerge as compassionate pharmacy professionals.
A5: Demonstrate leadership quality in planning and executing experiments.
A6: Cooperate with other students within the team in laboratory practices.

LECTURE WISE COTENTS:

UNIT I - Introduction to Biochemistry **5 hours**

Structure and function of biomolecules (1hr)
Biological membranes and their significance (1hr), Energy rich compounds; ATP(1hr),

Cyclic AMP and their biological significance. (1hr).

Principles of green and sustainable chemistry in biochemical research and diagnostics (1hr**)**

UNIT II – Enzymes **9 hours**

Definition (1hr) Nomenclature(1hr) IUB classification(1hr) Factor affecting enzyme activity.(1hr)

Enzyme action(1hr) Enzyme inhibition: Types-Reversible, Irreversible, and Allosteric.(2hr)

Isoenzymes and their therapeutic and diagnostic applications.(1hr)

Coenzymes and their biochemical role and deficiency diseases.(1hr)

UNIT III – Biological oxidation **4 hours**

Coenzyme system involved in Biological oxidation. (1hr)

Electron transport chain (its mechanism in energy capture;

regulation and inhibition) (1hr).

Uncouplers of ETC(1hr),

Oxidative phosphorylation(1hr)

UNIT IV – Metabolism of Biomolecules **34 hours**

- **Carbohydrate metabolism** (9 hours)
  Glycolysis (1hr)
  Citric acid cycle (TCA cycle) (1hr)
  HMP shunt(1hr)
  Glycogenolysis (1hr)
  Gluconeogenesis (1hr)
  Glycogenesis. (1hr)
  Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases) (1hr)
  Glucose, Galactose tolerance test and their significance(1hr)
  Hormonal regulation of carbohydrate metabolism. (1hr)
- **Lipid metabolism**(10 hours)
  Oxidation of saturated (β-oxidation) (1hr)
  Ketogenesis and ketolysis (2hrs)
  Biosynthesis of fatty acids (2hrs)
  Lipids; metabolism of cholesterol (2hrs)
  Hormonal regulation of lipid metabolism(1hr)
  Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolemia). (2hrs)
- **Protein and amino acid metabolism** (8 hours**)**
  Protein turnover(1hr)
  Nitrogen balance(1hr)
  Catabolism of Amino acids (Transamination, deamination & decarboxylation). (2hrs)
  Urea cycle and its metabolic disorders (1hr)
  Porphyria, jaundice. (1hr)
  Metabolic disorder of Amino acids: PKU, AKU, Albinism, Tyrosinemia (2hrs)
- **Nucleic acid metabolism** (7 hours)
  Metabolism of purine and pyrimidine nucleotides(4hrs)
  Protein synthesis, Genetic code, Inhibition of protein synthesis(1hr)
  Mutation and repair mechanism(1hr)
  DNA replication (semiconservative /onion peel models) and DNA repair mechanism. (1hr)

UNIT V – Clinical Biochemistry (18 hours)

Introduction to AI application in clinical biochemistry and diagnostics (1 hr)

Kidney function tests (5 hours)

a) Urine analysis (physical and chemical characteristics) (1hr)

b) Test for non-protein nitrogen constituents. (Creatinine and urea clearance) (1hr)

c) Urine concentration test, dilution test, urinary acidification test, cryoglobulinemia (2 hrs)

d) Urinary tract calculi (stones). (1hr)

Liver function tests (6 hours)

a) Tests based on synthetic function of liver-albumin, globulin, prothrombin time, alpha fetoprotein, Ceruloplasmin, transthyretin, Alpha-1-antitrypsin, haptoglobin (2hrs)

b) Tests based on serum enzymes- AST,ALT, ALP, GGT

c) Tests for metabolic capacity for liver- Blood ammonia (1 hr)

d) Test for hepatic function test- Bilirubin and steps in bile pigments formation/metabolism, urine bile salts, serum bile acids and urine urobilinogen.(2 hrs)

e) Dye test of excretory function- Bromosulphthalein Tests (1hr)

Lipid profile tests (2 hours)

Lipid profile tests- Determination of serum lipids and its normal ranges. (2hrs)

Immunochemical techniques (4 hours)

Radio immuno assay (RIA)- technique, advantages and disadvantages (2hrs)

Enzyme Linked Immunosorbent Assay (ELISA)- antibody detection, and antigen detection techniques(2hrs)

UNIT VI – **Electrolytes** (5 hours)

Biochemical definition and regulation of electrolytes (role of ion channels, co-transporters and exchangers, intracellular organelles and biochemical influence of hormones) (2hrs)

Electrolyte Imbalances: Determination of serum electrolytes- sodium, calcium, potassium, chlorides and bicarbonates in the body fluids (3hrs)

MEDICINAL BIOCHEMISTRY PRACTICALS

LIST OF EXPERIMENTS:

1. Qualitative analysis of carbohydrates (Sample 1: Glucose)
2. Qualitative analysis of carbohydrates (Sample 2: Fructose)
3. Qualitative analysis of carbohydrates (Sample 3: Lactose)
4. Qualitative analysis of carbohydrates (Sample 4: Maltose)
5. Qualitative analysis of amino acids (Sample 1: Histidine)
6. Qualitative analysis of amino acids (Sample 2: Tryptophan)
7. Qualitative analysis of amino acids (Sample 3: Arginine)
8. Qualitative analysis of amino acids (Sample 4: Tyrosine)
9. Qualitative analysis of abnormal constituents in urine (Albumin, bile salts, ketone bodies, glucose)
10. Estimation of liver function test using the semi-auto analyser
11. Estimation of kidney function test using the semi-auto analyser
12. Estimation of blood urea nitrogen using the semi-auto analyser
13. Estimation of various lipid profiles using the semi-auto analyser
14. Estimation of total protein using the semi-auto analyser

SEMINAR/ASSIGNMENTS:

1. Analysis of Normal Urine Parameters: Students can analyze a dataset of urine analysis results from hospital patients with normal kidney function. They can calculate and interpret

parameters such as pH, specific gravity, protein, glucose, ketones, bilirubin, and microscopic examination findings.

2. Interpretation of Lipid Profile Results: Students can examine lipid profile data from a group of patients and interpret the levels of total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides.
3. Students can analyze kidney function test results, including serum creatinine, blood urea nitrogen (BUN), and estimated glomerular filtration rate (eGFR), from a dataset of patients. They can discuss the interpretation of these results and their relevance in assessing kidney function.
4. Students can analyze liver function test data, including serum levels of enzymes such as alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and bilirubin.

TEXTBOOKS:

1. Rodwell VW, Bender D A, Botham K M, Kennelly P J, Weil PA. Harper's Illustrated Biochemistry. 31st edition, New York: McGraw Hill, 2022.
2. Vasudevan DM , Sreekumari S, Vaidyanathan K. Textbook of Biochemistry For Medical Students.9th edition, New Delhi: Jaypee Brothers Medical Publishers, 2019.
3. Satyanarayana U, Chakrapani U. Biochemistry. 6th edition, Elsevier, 2021
4. Sukrutha S.K, Soumya BA. Text Book of Biochemistry. 1st edition, Bengaluru: EMMESS Medical Publishers, 2021.

REFERENCE BOOKS:

1. Nelson DL, Cox MM. Lehninger Principles of Biochemistry. 8th edition, New York: W. H. Freeman and Company, 2021.
2. Plummer DT. An introduction to practical Biochemistry.3rd edition, India: McGraw Hill, 2017.
3. Gowenlock AH.Varleys Practical Clinical Biochemistry. 6th edition, India: CBS Publishers, 2006.
4. Pattabhiraman TN. Laboratory Manual & Practical Biochemistry, 4th edition, All India Publishers & Distributors, 2015.

**Latest edition of the text books & reference books can be referred.*

Course Title	L	T	P	Total Hrs.	Year	Course Code
Pharmaceutical Organic Chemistry (T)	**3**	**0.5**	**0**	**75**	**I**	**PD.104T**
Pharmaceutical Organic Chemistry (P)	**0**	**0**	**3**	**75**	**I**	**PD.112P**

SCOPE:

This course is designed to impart a very good knowledge about the classification and nomenclature of simple organic compounds, structural and stereo isomerism, intermediates forming in reactions, important physical properties, reactions and their basic reaction mechanisms. This also covers the important name reactions and their applications. It includes the nomenclature, chemistry and aromaticity of important heterocyclic compounds.

The syllabus emphasizes mechanisms and orientation of reactions such as electrophilic addition, free radical addition, nucleophilic aliphatic substitution (SN1 & SN2), nucleophilic addition & elimination (E1 & E2), electrophilic aromatic substitution, and heterocyclic chemistry. This syllabus also includes the synthesis, qualitative tests, identifying the preliminary test, and detection of elements of some organic compounds. They also include the physical property evaluation such as boiling point and melting point determination of organic compounds. This course cultivates a professional mindset by emphasizing the importance of good laboratory practices in the synthesis and analysis of organic compounds in pharmaceuticals.

LEARNING OUTCOMES:

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

KNOWLEDGE

K1: Outline the classification of organic compounds. (Remembering)
K2: Interpret the structure, IUPAC name of the organic compounds (Understanding)
K3: Interpret the structure & types of isomerism (structural and stereo) of organic compounds (Understanding)
K4: Explain the general principles of different mechanism of organic reactions. (Understanding)
K5: Describe the basic concepts of alkane, alkene and conjugated dienes. (Understanding)
K6: Articulate the basic knowledge regarding alkyl halides, alcohols, carbonyls, carboxylic acids, and aliphatic amines. (Applying)

SKILL

S1: Prepare organic compounds. (Preparation of different organic compounds)
S2: Determination of melting point and boiling point of organic compounds.
S3: Identify the preliminary test and detection of elements.
S4: Identify the group of organic compound to which it belongs to (based on solubility of compounds in different solvents)

S5: Classify various organic compounds based on their functional groups.
S6: Analyse the physico-chemical properties of various organic compounds.

ATTITUDE

A1: Appreciate the basic knowledge of subject.
A2: Follow professional and standard procedures.
A3: Participate in group discussion.
A4: Follow the SOPs when using lab equipment and instruments.
A5: Assist fellow students and others in executing the experiments.
A6: Take responsibility for self and group outcomes.

LECTURE WISE COTENTS:

UNIT I - Structures and Physical properties 4 hours

- Structure of organic compounds, hybridization, protic and aprotic solvents, and Inter molecular forces. (1hr)
- Acids and bases, Lowry Bronsted and Lewis theories (1hr)
- Oxidation and reduction reaction. (2hrs)

UNIT II - Classification, Nomenclature and Isomerism of organic compounds 18 hours

- Classification of Organic Compounds. (1 hr)
- Common and IUPAC systems of nomenclature of organic compounds, alkane and complex substituents. (1 hr)
- IUPAC nomenclature of alkene, alkyne, and cycloalkane (1 hr)
- IUPAC nomenclature of functional groups like alcohol, aldehyde, and ketone (1 hr)
- IUPAC nomenclature of terminal functional groups like carboxylic acid, acid halide, acid amide, ester, cyanide, amine and ether (1 hr)
- IUPAC nomenclature of Polyfunctional groups (1 hr)
- Electron displacements in organic chemistry (such as inductive effect, resonance, hyperconjugation). (2 hrs)
- Reaction intermediates (such as free radicals, carbocations, carbanions, carbenes and nitrenes). (4 hrs)
- Types of reagents - electrophilic & nucleophilic (1hr)
- Structural and stereo isomerism in organic compounds. D &L system of nomenclature of optical isomers, sequence rules, R&S system of nomenclature of optical isomers (5 hrs)

UNIT III – Organic reactions and mechanisms

- **Nucleophilic aliphatic substitution (SN2 & SN1) 4hours**
  - Nucleophiles and leaving groups - reaction, mechanism
  - Kinetics of second and first order reaction
  - Stereochemistry and steric hindrance

- Carbocation and their stability
- Rearrangement of carbocation
- Solvolysis
- Role of solvent in substitution
- SN2 versus SN1**.**

- **Elimination (E2 & E1) 4 hours**
  - Reaction, mechanism**,** kinetics, evidence, orientation, and reactivity
  - Role of carbocation, 1,2 eliminations
  - Absence of rearrangement isotope effect
  - Absence hydrogen exchange
  - Elimination versus substitution **4 hours**
- **Electrophilic addition in alkene**
  - Electrophilic addition reaction
  - Orientation and reactivity of Markownikoff rule
  - Addition of hydrogen halides
  - Addition of halogen and halohydrin formation
  - Heat of hydrogenation and stability of alkenes **4 hours**
- **Free radical addition in alkene**
  - Reaction, mechanism, orientation, peroxide effect (Anti- Markownikoff rule)
  - Mechanism of peroxide-initiated addition of hydrogen bromide,
  - Additions of carbene to alkene,
  - Comparison of free radical substitution with free radical addition,
  - Allylic rearrangements.
- **Conjugated dienes 3 hours**
  - Conjugated dienes – stability and resonance, stability of allyl radical, hyperconjugation, reactions of conjugated dienes
- **Electrophilic aromatic substitution (reaction of benzene) 10 hours**
  - Nitration, sulphonation, halogenation, Friedel-craft alkylation (2 hrs)
  - Friedel-craft acylation mechanism, reactivity and orientation (1 hr)
  - Effect of substituent groups on reactivity and orientation of benzene (1 hr)
  - Activating and deactivating O, P, & M directing groups - reactivity and orientation (1 hr)
  - Effect of halogen on electrophilic aromatic substitution in alkyl benzene (1 hr)
  - Basicity of amines and Acidity of phenols (1 hr)
  - Diazotisation, Mechanism and applications (1 hr)
  - Hoffman rearrangement and Reimer Tiemann reaction (1 hr)
  - Sandmeyer's reaction, Williamson synthesis (1 hr)
- **Nucleophilic addition reaction 8 hours**
  - General principle, Addition of HCN, Addition of alcohol, and addition of Grignard reagent. (2 hrs)
  - Aldol condensation and crossed aldol condensation (1 hr)
  - Cannizzaro reaction and crossed Cannizzaro reaction (1 hr)
  - Claisen condensation, Benzoin condensation (1 hr)
  - Perkin condensation, Knoevenagel reaction (1 hr)

- Reformatsky reaction, Wittig reaction (1 hr)
- Michael addition, Kolbe reaction (1 hr)

- **Nucleophilic aromatic substitution 2 hours**
  - reaction, mechanisms**,** orientation
  - comparison of aliphatic nucleophilic substitution with that of aromatic.

Unit IV- Alkane & cycloalkane 4 hours

- Free radicals chain reactions of alkane; mechanism, relative reactivity. (2 hrs)
- Cycloalkane (alicyclic compounds); preparations of cycloalkanes, Bayer strain theory and orbital picture of angle strain. (2 hrs)

Unit V- Carboxylic acids 5 hours

- Ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, role of carboxyl group. (2 hrs)
- Effect of substituent on acidity. (1 hr)
- Nucleophilic acyl substitution reaction, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution. (1 hr)
- Conversion of acid-to-acid chloride, esters, amide and anhydride. (1 hr)

Unit VI- Introduction of Heterocyclic rings 5 hours

- Classification, and nomenclature of Heterocyclic compounds (3 hrs)
- Aromatic character of different class of Heterocyclic compounds (five-membered, six-membered, and Fused) (2 hrs)

LIST OF EXPERIMENTS:

1. Preparation of Benzanilide by Schotten-Baumann reaction
2. Preparation of Salicylic acid from methyl salicylate by hydrolysis
3. Preparation of Aspirin by acetylation of salicylic acid
4. Preparation of Dibenzal acetone by a cross-aldol condensation reaction, or Claisen-Schmidt reaction
5. Preparation of Meta Dinitrobenzene by nitration of nitrobenzene
6. Preparation of 1-Phenyl Azo-2-naphthol by diazotization and coupling reaction
7. Determination of Melting Point and Boiling Point
8. Detection of elements (Nitrogen & sulphur) present in the sample
9. Systematic qualitative analysis of unknown organic sample (Resorcinol)
10. Systematic qualitative analysis of unknown organic sample (Urea)
11. Systematic qualitative analysis of unknown organic sample (Thiourea)
12. Systematic qualitative analysis of unknown organic sample (Amines)
13. Systematic qualitative analysis of unknown organic sample (Cinnamic Acid)
14. Systematic qualitative analysis of unknown organic sample (Benzaldehyde)
15. Systematic qualitative analysis of unknown organic sample (Methyl salicylate)

SEMINAR/ASSIGNMENTS

1. Principle of confirmatory test for various organic functional groups such as carboxylic acid, alcohol, phenol, aldehydes, ketones, amines, amides.
2. Various synthetic applications of name reactions like aldol condensation, Hoffman rearrangement
3. Basic principle of addition, substitution, elimination reactions.
4. Medicinal uses of some important organic compounds.
5. General principle for purification of organic synthetic products.

TEXT BOOKS:

1. Morrison, R. T., & Boyd, R. N and Bhattacharjee. Organic chemistry. 7th ed. Pearson Education India; 2010.
2. Arun Bahl and B.S. Bahl. A textbook of organic chemistry. 22nd ed. S. Chand; 2016.
3. P.L. Soni & H. M. Chawla. Textbook of organic chemistry. 29th edn. Sultan Chand & son: India; 2012.
4. O.P. Agarwal. Organic chemistry: reactions and reagents. 56th edn. Goel Publishing House. 2018

REFERENCE BOOKS:

1. Mann F.G & Saunders B C. Practical organic chemistry. 4th edn. Pearson Education India; 2009
2. Bruice P. Y. Organic Chemistry. 8thedn.Upper Saddle River, NJ: Pearson Education; 2015.
3. Brian S. F, Antony J.H, Peter W.G.S & Austin R.T. Vogel's textbook of Practical Organic Chemistry. 5th edn. Pearson Education India; 2003.
4. Donald L. Pavia, Gary M. Lampman, George S. Krizet al. A small-scale approach to organic laboratory techniques. U.S: Cengage Learning; 2014.

**Latest edition of the text books & reference books can be referred*

Course Title	L	T	P	Total Hrs.	Year	Course Code
Pharmaceutical Inorganic Chemistry (T)	**2**	**0.5**	**0**	**50**	**I**	**PD.105T**
Pharmaceutical Inorganic Chemistry (P)	**0**	**0**	**2**	**50**	**I**	**PD.113T**

SCOPE: The course emphasizes monographs of pharmaceutical inorganic compounds, various inorganic impurities and methods to determine them. Specification of various electrolytes and their significance in combination and replacement therapy is included. The course describes pharmaceutical inorganic compounds' preparation, properties, identification tests, storage conditions and thus incorporating the knowledge to support the development of quality, safer and effective inorganic preparations **(SDG3).** Moreover, the course covers important aspects of buffer systems involved in maintaining physiological acid-base balance. Furthermore, the course also illustrates the significance, properties, storage conditions, precautions and pharmaceutical applications of radioactive substances.

The course covers the type, source and methods to minimize errors in pharmaceutical analysis. The subject signifies an introduction of Volumetric analysis and different methods of expressing concentrations. The course also provides an understanding of the various analytical techniques and methods used to ensure the quality of drugs. It emphasizes different types of titrimetric analysis, such as acid-base titration, precipitation titration, complex metric titration, various types of redox titration, and gravimetric analysis. It introduces various AI assisted analytical techniques to determine impurities in various pharmaceutical preparations. (SDG9)

COURSE LEARNING OUTCOMES:

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

KNOWLEDGE

K1: Explain the errors encountered in pharmaceutical analysis, their type, source and methods to minimize. (Understanding)

K2: Describe the preparation, properties, identification tests, storage conditions, precautions, pharmaceutical applications of Inorganic compounds and radioactive pharmaceuticals and sustainable practices to ensure quality and safety. (Understanding)

K3: Differentiate various electrolytes and their significance in combination and replacement therapy (Understanding)
K4: Outline the role of buffer systems involved in maintaining physiological acid-base balance (Understanding)
K5: Interpret the significance of limit test in determining impurities in inorganic drugs and pharmaceuticals (Applying)
K6: Discuss the various chemical methods of quantitative analysis, their significance in determining the unknown concentration of the solution and the relevance of AI assisted techniques in detection of impurities. (Applying)

SKILL

S1: Detect the presence of Inorganic impurities in the given sample (Applying)
S2: Prepare various inorganic compounds of pharmaceutical importance (Applying)
S3: Perform the identification tests for Pharmaceutical Inorganic Compounds (Applying)
S4: Determine the concentration of the given sample (Applying)
S5: Identify the unknown inorganic anion/cation present in the sample (Applying)
S6: Analyze the percentage purity of various inorganic preparations (Analyzing))

ATTITUDE

A1: Acknowledge the value of the course regarding the properties, applications, and proper storage requirements of different inorganic preparations
A2: Follow professionalism in the working environment
A3: Participate in group discussions to plan effectively in performing experiments.
A4: Exhibit good communication skills to emerge as compassionate pharmacy professionals.
A5: Assist the fellow students in executing the experiments.
A6: Support the other students in updating knowledge in the subject.

LECTURE WISE CONTENTS:

UNIT I - Errors **3 hours**

- Sources of errors, Types, methods of minimizing errors (2 hours)
- Accuracy, precision and significant figures (1 hour)

UNIT II - Volumetric Analysis **2 hours**

- Significant Terms in volumetric analysis, Types of titration methods (1 hour)
- Methods of expressing concentration (1 hour)

Acid-base titration **3 hours**

- Theories of acid base indicators (1 hour)
- Classification of acid base titrations – Acidimetry & Alkalimetry (1 example each) & applications (2 hours)

Redox titrations **3 hours**

- Concepts of oxidation and reduction, Types of redox titrations (1 hour)
- Principles and applications of Cerimetry, Iodimetry, Iodometry (2 hours) (1 example each)

Non aqueous titration **3 hours**

- Solvents, Acidimetry and alkalimetry titration (1 example each) (2 hours)
- Estimation of Ephedrine HCl , Applications. (1 hour)

Precipitation titrations **2 hours**

- Mohr's method, Volhard's, (1 hour)
- Modified Volhard 's, Fajans method (1 example) (1 hour)

Complexometric titration **3 hours**

- Classification, metal ion indicators (1 hour)
- Masking and damasking reagents, Estimation of Calcium gluconate, Applications (2 hours)

Gravimetry **3 hours**

- Principle and steps involved in gravimetric analysis (1 hour)
- Estimation of barium sulphate. (1 hour),

Relevance of AI assisted Analytical methods to detect impurities in Pharmaceutical Preparations – An Introduction (1 hour)- SDG9

UNIT III - Limit Test **4 hours**

- Sources and types of impurities (1 hour)
- Principle & Procedure involved in the limit test
  - ✓ Chloride, Sulphate, Iron, Arsenic (1 hour)
  - ✓ Lead and Heavy metals, Modified limit test for Chloride and Sulphate (1 hour)

Sustainable practices in pharmaceutical Inorganic preparations to ensure quality and safety. (SDG-3)- 1hour

UNIT IV - Medicinal Gases **2 hours**

- Oxygen* (preparation, Assay), Carbon Dioxide, Helium (1 hour)
- Nitrous Oxide, Nitric Oxide, Nitrogen, Carbon Monoxide (1 hour) (properties, uses, storage)

UNIT V – Pharmaceutically Important Inorganic Compounds

General methods of preparation, assay for the compounds superscripted with an asterisk (*), properties, medicinal uses and storage conditions of inorganic compounds belonging to the following classes.

- **Gastro Intestinal Agents:**

Acidifiers **1 hour**

- Ammonium chloride* and Dil. HCl (1 hour)

Antacid **2 hours**

- Definition, classification, Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate* (1 hour)
- Aluminum hydroxide gel, Magnesium hydroxide mixture (1 hour)

Cathartics **1 hour**

- Mechanisms, Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite (1 hour)

- **Electrolyte Replenishers** **3 hours**

- Functions of major physiological ions (1 hour)
- Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* (1 hour)
- Oral Rehydration Salt (ORS), Physiological acid base balance (2 hours)

- **Antimicrobials** **3 hours**

- Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*(2 hours)
- Chlorinated lime*, Iodine and its preparations (1 hour)

- **Dental Products** **2 hours**

- Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents: Strontium Chloride, Zinc Chloride, ((1 hour)
- Calcium carbonate, Sodium fluoride, and Zinc eugenol cement (1 hour)

- **Miscellaneous compounds** **4 hours**

- Expectorants: Potassium iodide, Ammonium chloride*. (1 hour)
- Emetics: Copper sulphate*, Sodium potassium tartarate (1 hour)
- Haematinics: Ferrous sulphate*, Ferrous gluconate, Astringents: Zinc Sulphate, Potash Alum (1 hour)
- Poison & Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite (1 hour)

UNIT VI - Radiopharmaceuticals **4 hours**

- Radio activity, Measurement of radioactivity, Properties of α, β, γ radiations (2 hours)
- Half-life, radio isotopes (1 hour)
- Storage conditions precautions & pharmaceutical application of radioactive substances. (1 hour)

UNIT VII - Pharmaceutical aids **2 hours**

Definition, properties and uses

- Acidifiers & Alkalisers, Absorbents & Adsorbents (Aluminium Sulphate), Antioxidants & Preservatives (Sodium bisulphite, Sodium metabisulphite) (1 hour)
- Desiccants, Excipients (Magnesium stearate), Suspending agents (Bentonite), Filter aids, Colorants, Tonicity adjusting agents, Solvent & vehicles (water for injection), Flavoring & Sweetening agents. (1 hour)

PHARMACEUTICAL INORGANIC CHEMISTRY PRACTICAL

LIST OF EXPERIMENTS

1. Limit tests

- Limit test for Chloride
- Limit test for Sulphates
- Limit test for Iron
- Limit test for Arsenic

2. Assays

- Ammonium Chloride
- Ferrous Sulphate
- Copper Sulphate
- Calcium gluconate

3. Test for identity

- Magnesium Sulphate
- Ferrous Sulphate

4. Preparations

- Boric acid
- Potash alum
- Magnesium Sulphate
- Ferrous Sulphate

Assignments

- Comparative study of properties, uses and storage of various inorganic compounds as constituents in various dental products.
- Brief analysis of various official formulations of Oral Rehydration Salt and their pharmaceutical applications.
- Case study on applications of pharmaceutical inorganic compounds as antidotes.
- Medicinal importance of pharmaceutical inorganic compounds in disorders related to electrolyte imbalances
- Comparative study of properties, applications, storage of various inorganic compounds as components in various antacids and combination antacids.

Text Books

1. Vladimir Alexeyev. Quantitative Analysis.2nd ed. (illustrated, reprint). University Press of the Pacific.2000. (Theory & Practical)
2. Vogels Textbook of Quantitative Chemical Analysis. India: Pearson Education; 2006.
3. Chatwal GR. Pharmaceutical Chemistry-Inorganic. 5th ed. Himalaya Publishers. India; 2021(Theory & Practical)
4. Atherden LM. Bentley and Driver's Textbook of Pharmaceutical Chemistry. 8th ed. India: Oxford;2020 (Practical)

Reference Books

1. Indian Pharmacopoeia, 2018. Indian Pharmacopoeia Commission. The Controller of Publications, New Delhi; 2018.
2. Mohammed Ali. Textbook of Pharmaceutical Chemistry-I (Inorganic). 1st ed. CBS Publication. India:2013.
3. Jenkins GL, Knevel AM, Digangi FE. Quantitative Pharmaceutical Chemistry. 6th ed. CBS Publishers. India. 2008.

**Latest edition of the text books & reference books can be referred*

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
Remedial Biology (T)	**2**	**0**	**0**	**30**	**2**	**I**	**PD.106T**

SCOPE: This subject is designed to provide fundamental knowledge about the various organ system and functions of the human body. This course deals with the fundamental aspects of living organisms, their classification, salient features, structure, and function of cell and cell organelles, morphological and physiological process of the plants and animals.

It establishes the fundamental knowledge required to understand vital pharmacy subjects like Pharmacology and Pharmacognosy. It helps students to develop the skills to distinguish different plant tissues based on their microscopic characters. This course will enable the students to understand the concept of species and taxonomical hierarchy and five kingdom classification.

COURSE LEARNING OUTCOMES:
On successful completion of the course, the student shall be able to:

KNOWLEDGE
K1: Describe the structure, and function of cell and cell organelles**.**
K2: Discuss the classification and salient features of the five kingdoms of life.
K3: Describe the anatomy and functions of different parts of flowering plants**.**
K4: Explain the physiological process of the plant.
K5: Explain the functions associated with various organs of the human body.
K6: Explain the coordinated working pattern of different organs of each system.

SKILLS
S1: Identify the modified plant organs based on their characteristic features.
S2: Enumerate the types, functions, and location of epithelial cells.
S3: Assess the role of plant hormones in the physiological processes.
S4: Identify members different Kingdom based upon their features.
S5: Differentiate between artery and vein.
S6: Communicate effectively to convey ideas and information clearly and appropriately.

ATTITUDES
A1: Participate actively in discussions.
A2: Accept responsibility.
A3: Demonstrate regularity and punctuality in class.
A4: Cultivate critical thinking skills.
A5: Develop a commitment to continuous learning.
A6: Acquire the ability to gather, evaluate, and interpret relevant information.

COURSE CONTENTS

UNIT–I **4 Hours**

Taxonomy & Systematics

Concept of species and taxonomical hierarchy; Binomial nomenclature. (1 hr)

Salient features and classification of plants into major groups:

Algae, Bryophytes, Pteridophytes, Gymnosperm, and Angiosperm (three to five salient and distinguishing features and at least two examples of each category) (2 hrs)

Angiosperms- classification up to class, characteristic features, and examples. (1 hr)

UNIT–II **8 Hours**

Cell- The Unit of Life

Structure, Function of Plant and Animal Cell and cell organelles. (1 hr)

Cell cycle & Cell division. (1 hr)

Plant cell inclusions. (1 hr)

Structure of a human cell, Plasma membrane, and Organelles.(1 hr)

Types, functions, and location of Glandular epithelial cells (1 hr)

Structural Organization in Plants

Morphology and modifications; Tissues, types, location, and its functions; (1 hr)

Anatomy and functions of different parts of flowering plants: Root, stem, leaf, inflorescence, flower, fruit, and seed. (2 hrs)

UNIT–III **4 Hours**

Plant Physiology

Transport in plants: Movement of water, gases, and nutrients; Cell-to-cell transport– Diffusion, facilitated diffusion, active transport. (1 hr)

Plant–water relations– Imbibition, water potential, osmosis, plasmolysis; Long-distance transport of water– Absorption, apoplast, symplast, transpiration pull, root pressure, and guttation; .(2 hrs)

Transpiration– Opening and closing of stomata; Uptake and translocation of mineral nutrients– Transport of food, phloem transport, Diffusion of gases. Growth regulators–auxin, gibberellin, cytokinin, ethylene, Abscisic acid.(2 hrs)

UNIT–IV **9 Hours**

Human Physiology

Body fluids and circulation

Composition of the blood, lymph, Disorders of blood, and Structure of blood vessels.(1 hr)

Differences between artery and vein Blood vessels of vital organs, Heart sound, and Disorders of the cardiovascular system.(1 hr)

Neural control and coordination

Organization of the nervous system, Neurons, types of neurons, classification, and properties of the nerve fibre. (1 hr)

Classification of the peripheral nervous system, Structure, and functions of the sympathetic and parasympathetic nervous systems. (1 hr)

Generation and conduction of nerve impulse, Reflex action; Sensory perception. (1 hr)

Respiration

Mechanism of breathing and its regulation in humans– Exchange of gases, transport of gases and regulation of respiration. (1 hr)

Artificial respiration, Resuscitation methods. (1 hr)

Digestion and absorption

Alimentary canal and digestive glands;Role of digestive enzymes and gastrointestinal hormones; (1 hr)

Peristalsis, digestion, absorption, and assimilation of proteins, carbohydrates, and fats. (1 hr)

UNIT–V (5 hours)

Excretory products and their elimination

Modes of excretion – Ammonotelism, ureotelism, uricotelism; Human excretory system– structure and function of kidney and nephron. (1 hr)

Regulation of kidney function– Renin-angiotensin, Atrial Natriuretic Factor, ADH, and Diabetes insipidus; Role of other organs in excretion. (1 hr)

Chemical coordination and regulation

Endocrine glands and hormones; Hypothalamus, Pituitary, Pineal, Thyroid, Parathyroid, Adrenal, Pancreas, Gonads. (1 hr)

Mechanism of hormone action (Elementary Idea); Role of hormones as messengers and regulators, Hypo-and hyperactivity and related disorders (examples only). (1 hr)

Reproductive system

Genetic basis of sex determination, Primary and secondary sex organs, Role of sex hormones in reproductive development. (1 hr)

TEXT BOOKS:

1. Ghose KC, Manna B. Fundamental of Zoology. 1st edn. New Central book agency Pvt. Ltd, Kolkata, 2003.
2. Randhawa SS, Atul Kabra. 2nd edn. Remedial Biology. S Vikas and Company Pvt. Ltd., New Delhi, 2009

REFERENCE BOOKS:

1. Gokhale SB, Kokate CK, Bidarkar DS. Pharmaceutical Biology. Nirali Prakashan, Pune, 2007.
2. Dutta AC, Dutta TC. Botany for Degree Students. 6th edn. Oxford University Press, India, 2013.
3. Kokate CK, Purohit, Gokhlae. Textbook of Pharmacognosy. 37th edn. Nirali Prakashan, New Delhi, 2007.
4. Pandey PB. Botany for Degree Students. 2nd edn. S Chand & Company Pvt.Ltd., New Delhi, 2009

**Latest edition of text books and reference books can be referred*

Course Title	L	T	P	Total Hrs.	Year	Course Code
Remedial Mathematics (T)	**2**	**0**	**0**	**30**	**I**	**PD.106T**

SCOPE:

This is an introductory course in mathematics. This subject deals with the introduction to Sets, Matrices, Relations and Functions, Calculus, Sequences and Series, Mathematical Reasoning.

Calculus is a significant mathematic tool for investigating drug movement quantitatively. Differential equations are used to relate the absorptions of drugs in various body organs over time. Integrated equations are regularly used to model the cumulative therapeutic or toxic reactions of drugs in the body. Sets, relations, and functions help conduct logical and mathematical set operations on a mathematical and real-life basis. Sequence and series are used in the recognition of patterns.The series plays an important role in the differential equations and in the analysis process. Mathematical reasoning involves using logical arguments and principles to analyze and solve mathematical problems.

COURSE LEARNING OUTCOMES:

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

KNOWLEDGE

K1: Define set theory in mathematics
K2: Classify different types of matrices
K3: Illustrate relations and functions in set theory
K4: Describe the relationship between Arithmetic Mean (A.M) and Geometric Mean (G.M)
K5: Explain statements and compound statements in mathematical reasoning
K6: Describe the rules of integration.

SKILL

S1: Construct Venn diagram.
S2: Interpret matrix multiplication.
S3: Determine Cartesian products of sets.
S4: Sum of terms of special series.
S5: Construct new statements from old statements.
S6: Apply Method of substitution and Method of Partial fractions in integration.

ATTITUDE

A1: Appreciate the work of others.
A2: Share and care for good harmony and work culture.
A3: Follow the mathematical theories and rules.
A4: Participate actively in the class room activities.
A5: Support other students for mutual improvement.
A6: Demonstrate sincerity and punctuality.

COURSE CONTENTS

UNIT I **6 Hours**

Sets

Introduction, Sets and their Representations (1 hr)
The Empty Set, Finite and Infinite Sets (1 hr)
Equal Sets, Subsets (1 hr)
Power Set, Universal Set (1 hr)
Venn Diagrams, Operations on Sets (1 hr)
Complement of a Set, Practical Problems on Union and Intersection of Two Sets (1 hr)

UNIT II **6 Hours**

Matrices

Introduction matrices, Types of matrices (1 hr)
Operation on matrices (1 hr)
Transpose of a matrix (1 hr)
Matrix Multiplication (1 hr)
Properties of matrix addition and multiplication (1 hr)
Symmetric and skew-symmetric matrices, Invertible matrices (1 hr)

UNIT III **3 Hours**

Relations and Functions

Introduction, Cartesian Product of Sets (1 hr)
Relations (1 hr)
Functions (1 hr)

UNIT IV **6 Hours**

Sequences and Series

Introduction, Sequences (1 hr)
Series (1 hr)
Arithmetic Progression (A.P.) (1 hr)
Geometric Progression (G.P.) (1 hr)
Relationship between Arithmetic Mean (A.M) and Geometric Mean (G.M) (1 hr)
Sum to n terms of Special Series (1 hr)

UNIT V **3 Hours**

Mathematical Reasoning

Introduction, Statements (1 hr)

New Statements from Old, Special Words/Phrases (1 hr)

Implications, Validating Statements (1 hr)

UNIT VI **6 Hours**

Calculus

Differentiation: Introductions, Derivative of a function, Derivative of a constant (1 hr)

Derivative of a product of a constant and a function, Derivativeof the sum or difference of two functions (1 hr)

Derivative of the product of twofunctions (product formula), Derivative of the quotient of two functions (Quotient formula) – Without Proof (1 hr)

Integration: Introduction, Definition (1 hr)

Standard formulae, Rules of integration (1 hr)

Method of substitution, Method of Partial fractions (1 hr)

TEXT BOOKS:

1. Mathematics Textbook for Class 11& 12, NCERT

REFERENCE BOOKS:

1. R. D Sharma, Mathematics class XI, Volume 1, Dhanpat Rai Publication
2. R.S. Aggarwal, Mathematics Class 11, Bharti Bhavan

**Latest edition of text books and reference books can be referred.*

Course Title	L	T	P	Total Hrs.	Credits	Semester	Course Code
CULTURAL EDUCATION I & II (T)	**2**	**0**	**0**	**30**	**2**	**I**	**PD.107T**

SCOPE: To introduce students to the depths and richness of the Indian culture and knowledge traditions, and to enable them to obtain a synoptic view of the grandiose achievements of India in diverse fields. To equip students with a knowledge of their country and its eternal values.

COURSE OUTCOMES

CO1: Increase student understanding of true essence of India's cultural and spiritual heritage. Emancipating Indian histories and practices from manipulation, misunderstandings, and other ideological baggage thus, shows its contemporary relevance.

CO2: Understand the ethical and political strategic concepts to induce critical approach to various theories about India.

CO3: Familiarize students with the multidimension of man's interaction with nature, fellow beings and society in general.

CO4: Appreciate the socio-political and strategic innovations based on Indian knowledge systems. Gives an understanding of bringing Indian teaching into practical life

COURSE CONTENTS

Unit 1 – Unit 4 **6 hours**

Educational Heritage of Ancient India
Life and Happiness
Impact of Colonialism and Decolonization
A timeline of Early Indian Subcontinent

Unit- 5 – 8 **8 hours**

Pinnacle of Selflessness and ultimate freedom
Indian approach towards life
Circle of Life
Ocean of love; Indian Mahatmas.

Unit 9 – 13 **8 hours**

Man's association with Nature
Celebrating life 24/7.

Metaphors and Tropes
Become A Strategic Thinker (Games / Indic activity)
India: In the Views of Other Scholars and Travellers

Unit 14-16 **8 hours**

Personality Development Through Yoga.
Hallmark of Indian Traditions: Advaita Vedanta, Theory of oneness
Conversations on Compassion with Amma

TEXTBOOKS

Foundations of Indian Heritage

REFERENCE BOOKS

1. The beautiful tree by Dharampal
2. Peasants and Monks in British India by William Pinch
3. India, that is Bharat: Coloniality, Civilisation, Constitution by J Sai Deepak
4. Awaken Children Dialogues with Mata Amritanandamayi
5. Man and Nature by Mata Amritanandamayi Devi
6. What Becomes of the Soul After Death, Divine Life Society

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
Mastery Over Mind (MAOM) (T)	**2**	**0**	**0**	**15**	**1**	**I**	**PD.108T** **PD.114P**

SCOPE:

Mastery Over the Mind (MAOM) is an Amrita initiative to implement schemes and organize university-wide programs to enhance health and wellbeing of all students. This program as part of our efforts for sustainable stress reduction gives an introduction to immediate and long-term benefits and equips every attendee to manage stressful emotions and anxiety facilitating inner peace and harmony. The meditation technique offered by Amrita University Chancellor and world-renowned humanitarian and spiritual leader, Sri Mata Amritanandamayi Devi (Amma), is completely dedicated for guided practical meditation session and theory aspects of MAOM. The theory section comprises principle of meditation, stress management, research and science of meditation, principles of conscious communication.

This course promotes a sense of control and autonomy in the Universal Human Value System, compassion, empathy, responsibility and practicing meditation for the wholesome wellbeing of an individual. This course enhance the understanding of experiential learning based on university's mission: "Education for Life along with Education for Living", and is aimed to allow learners to realize and rediscover the infinite potential of one's true Being and the fulfilment of life's goals. During practice session students are trained through guided meditation session of different level. They experience Mind and body relaxation, get rid of energy blockage, pure unconditional love, light of consciousness, positive energy and compassion.

COURSE LEARNING OUTCOMES

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

KNOWLEDGE

K1: Discuss Principles of meditation
K2: Explain basics of stress management
K3: Summarize the role of mastery over mind in developing compassion
K4: Analyze the correlation between relationships and empathy
K5: Criticize consequences of stress.
K6: Relate the global transformation through meditation

SKILL

S1: Practice of MA-OM meditation technique that is effective in one's life
S2: Assimilate higher level of awareness and focus.
S3: Demonstrate meditation for stress and anxiety reduction.

S4: Comment on the research and science of meditation:
S5: Perform Skill fully meditation.
S6. Assess the effect of practicing meditation.

ATTITUDE

A1: Appreciate the work of others.
A2: Be sincere and devoted.
A3: Empathize and be humble
A4: Participate actively in the discussions during class.
A5: Support your team members for better outcomes.
A6: Share and care for good harmony and work culture.

COURSE CONTENTS

UNIT 1 **4 Hours**

Causes of Stress

The problem of not being relaxed. Need for meditation. Basics of stress management at home and workplace. (1 hr)
Traditions and Culture, Principles of meditation, (1hr) Promote a sense of control and autonomy in the Universal Human Value System. (1 hr)
Different stages of Meditation. Various Meditation Models. Various practices of Meditation techniques in different schools of philosophy and Indian Knowledge System. (1 hr)

UNIT II **5 Hours**

Improving work and study performance

Meditation in daily life. Cultivating compassion and good mental health with an attitude of openness and acceptance. (1hr)
Research and Science of Meditation: Significance of practicing meditation and perspectives from diverse fields like science, medicine, technology, (1hr) philosophy, culture, arts, management, sports, economics, healthcare, environment etc. (1hr)
The role of meditation for stress and anxiety reduction in one's life with insights based on recent cutting-edge technology. (1hr)
The effect of practicing meditation for the wholesome wellbeing of an individual. (1hr)

UNIT III **5 Hours**

Self communications

Principles of conscious communication. Relationships and empathy. Meditative approach in managing and maintaining better relationships in life during the interactions in the world(1hr)
Role of MAOM in developing compassion, empathy and responsibility, (1hr)
Instilling interest, and orientation to humanitarian projects as a key to harness intelligence and compassion in youth. (1hr)
Methodologies to evaluate effective awareness and relaxation gained from meditation. (1hr)
Evaluating the global transformation through meditation by instilling human values which leads to service learning and compassion driven research. (1hr)

Practice Session:
During practice sessions, students are trained through guided meditation of different levels. It starts with the relaxation of the body through step-by-step instructions. This helps them to relax physically. They are then instructed to focus on their breathing, which helps them relax and focus. Students are then instructed to keep their attention on their thoughts, followed by inhalation and exhalation with the vibration of the sound Ma-Om. This makes them experience stillness and inner expansiveness. Finally, they are instructed to practice White Flower Meditation for global peace and harmony. Through this White Flower meditation, they can connect with the universe and experience oneness.

TEXT BOOKS:

1. Mata Amritanandamayi Devi, "Cultivating Strength and vitality," published by Mata Amritanandamayi Math, Dec 2019
2. Swami Amritaswarupananda Puri ,"The Color of Rainbow " published by MAM, Amritapuri.(latest edition)

REFERENCES:

1. Craig Groeschel, "Winning the War in Your Mind: Change Your Thinking, Change Your Life" Zondervan Publishers, February 2019
2. Swami Amritaswarupananda Puri "Awaken Children Vol 1, 5 and 7 - Dialogues with Amma on Meditation", August 2019
3. Secret of Inner Peace- Swami Ramakrishnananda Puri, Amrita Books, Jan 2018.

**Latest edition of text books and reference books can be referred*

SECOND YEAR

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
PATHOPHYSIOLOGY-I (Theory)	**3**	**1**	**0**	**75**	**3**	**II**	**PD. 201T**

SCOPE:

This course provides foundational knowledge of the physiological changes and mechanisms underlying disease processes, emphasizing the understanding of cellular injury, inflammation, immune responses, and disease mechanisms. Students will gain a comprehensive understanding of how normal physiological functions are altered in various disease states, focusing on systems such as cardiovascular, renal, haematological, endocrine, and pulmonary. The course covers critical concepts such as etiology, pathogenesis, clinical manifestations, and diagnostic parameters, exploring how genetic, environmental, and lifestyle factors, along with infections and other triggers, contribute to disease initiation and progression.

In addition to theoretical knowledge, the course aims to equip students with essential skills to analyse and interpret disease processes and clinical manifestations. Students will apply pathophysiological principles to clinical scenarios, enhancing their ability to diagnose and manage disease conditions. This course also promotes a patient-centred approach, fostering sensitivity to the psychosocial aspects of disease and encouraging a holistic view of health management. Emerging digital tools such as Artificial Intelligence (AI) will also be introduced, highlighting their potential in analysing complex biological data, anticipating disease trajectories, and aiding clinical decision-making in both chronic and acute conditions. By addressing both the clinical and emotional dimensions of diseases, students will develop an empathetic and evidence-based attitude that will inform their future clinical practices.

Course Learning Objectives: Upon completion of the subject student shall be able to

KNOWLEDGE

- **K1** : Define the basic terminologies related to cell injury, inflammation and, and disease mechanisms.
- **K2** : Describe the etiology, pathogenesis, and progression of diseases at various system levels.
- **K3** : Classify diseases based on their origin, nature, and underlying mechanisms.
- **K4** : Explain the potential of Artificial Intelligence (AI) in understanding disease progression and supporting data-driven insights into complex pathophysiological conditions.
- **K5** : Interpret the clinical manifestations and complications associated with various diseases, assessing their implications on patient health.
- **K6** : Analyse the physiological changes and functional implications associated with disease progression.

SKILL

S1: Differentiate between normal and abnormal inflammatory responses and their clinical implications related to the disease conditions.

S2: Demonstrates an ability in evaluating disease conditions based on the underlying pathophysiological mechanisms.

S3: Apply critical thinking in the context of the pathophysiology of various diseases involving multiple systems.

S4 : Interpret clinical signs and symptoms of infectious diseases and correlate them with diagnostic test results for accurate diagnosis and prognosis.

S5: Analyse the impact of common health conditions on individuals and society, conducting case studies to understand the broader implications of disease.

S6 : Integrate principles of disease processes in providing patient-centred care, optimizing treatment regimens tailored to individual patient needs and specific disease conditions.

ATTITUDE:

A1 : Appreciate the diversity of patients' cultural backgrounds, beliefs, and values, considering their impact on the management of pathophysiological conditions.

A2 : Counsel patients about disorders like hypertension and diabetes, including their pathophysiology, risk factors, and management strategies.

A3 : Appreciate the role of environmental and social inequities in influencing disease progression through biological mechanisms

A4 : Promote healthy lifestyle practices, such as diet modification, physical activity, and stress management, to improve disease outcomes.

A5 : Exhibit confidence in assessing a patient's condition based on pathophysiological knowledge.

A6 : Reflect on inter professional approaches to improve health outcomes for individuals with common health conditions.

COURSE CONTENTS:

UNIT- I: Basic principles of cell injury and Adaptation **6 Hours**

- Causes, Pathogenesis and morphology of cell injury (5 Hr)
- Cellular adaptations- physiologic and pathologic adaptations (1 Hr)

UNIT- II: Inflammation **7 Hours**

- Definition, causes, signs, types of inflammation (1 Hr)
- Mechanism of acute & chronic inflammation (3 hr)
- Chemical mediators of inflammation (1 hr)
- Classification of wounds (1 hr)
- Wound healing: process and stages of wound healing, factors influencing healing of wounds (1 hr)

UNIT-III: Diseases of Immunity **8 Hours**

- Immune tolerance (1 hr)
- Hypersensitivity: type I, II, III, IV, Biological significance of hypersensitivity, Allergy due to food, chemicals and drugs (2 hr)

- Autoimmunity: Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity (2 hr)
- Transplantation rejections (types and mechanisms): allograft rejections, MHC proteins or transplantation antigens, mechanism of rejection of allograft (2 hr)
- Amyloidosis (1 hr)

Definition, Etiology, Pathogenesis, Clinical manifestations, and complications

UNIT-IV: Cardiovascular and Cerebrovascular diseases 15 hours

- Hypertension (2 hr)
- Atherosclerosis (2 hr)
- Angina Pectoris (1 hr)
- Myocardial Infarction (1 hr)
- Congestive Heart Failure (2 hr)
- Cardiac Arrhythmias (2 hr)
- Dyslipidaemia (2 hr)
- Stroke (ischemic and haemorrhage) (2 hr)

UNIT-V: Renal Disorders 3 Hours

- Acute Renal Failure (2 hr)
- Chronic Renal Failure (1 hr)

UNIT-VI: Haematological Disorders 6 Hours

- Anaemias (4 hr)
- Deep vein thrombosis (2 hr)

UNIT-VII: Endocrine Disorders 6 Hours

- Diabetes Mellitus (3 hr)
- Hypothyroidism & Hyperthyroidism (2 hr)
- Osteoporosis (1 hr)

UNIT-VIII: Pulmonary disorders 3 Hours

- Asthma (2 hr)
- Chronic Obstructive Airway Diseases (1 hr)

UNIT-XI: Infectious diseases 17 Hours

- Septicaemia (1 hr)
- Respiratory tract infections (2 hr)
- Tuberculosis (2 hr)
- Urinary tract infections (1 hr)
- Malaria (1 hr)
- Typhoid (1 hr)
- Dysentery (1 hr)

- Meningitis (1 hr)
- Endocarditis (1 hr)
- Sexually transmitted diseases (4 hr)
- Fungal infections (Candidiasis, Aspergillosis, Dermatophytosis (2 hr)

UNIT- X Environmental disorders 4 Hours

- Protein calorie malnutrition – marasmus & kwashiorkor (1 hr)
- Obesity (1 hr)
- Starvation (1 hr)
- Urban-rural inequities in disease burden: Urban stressors, climate anxiety, and their biological impact (neuro-inflammation, cortisol dysregulation) (1hr)

UNIT-XI: Application of AI in understanding disease mechanisms and predicting disease progression: Cardiovascular diseases (risk profiling for hypertension and arrhythmia), Endocrine disorders (early prediction of diabetic complications) **(1 Hour)**

ASSIGNMENTS:

1. Analyse the different types of hypersensitivity reactions (I-IV), and explain their biological significance in allergic diseases.
2. Discuss the causes and mechanisms of myocardial infarction, and evaluate the role of early intervention in improving patient outcomes.
3. Evaluate the molecular mechanisms involved in the cellular adaptation to hypoxia, and discuss their implications in pathological conditions like ischemic heart disease.
4. Explore the immunological basis of autoimmune diseases such as systemic lupus erythematosus and multiple sclerosis.
5. Investigate the relationship between chronic inflammation and cancer, focusing on how immune tolerance mechanisms contribute to tumour progression.
6. Analyse the impact of neuro inflammation in the pathogenesis of stroke, and evaluate emerging treatments targeting inflammatory pathways to improve stroke outcomes.
7. Critically assess the role of lipoprotein(a) in atherosclerotic cardiovascular diseases.
8. Investigate the genetic basis of polycystic kidney disease.
9. Analyse the pathophysiology of thromboembolic disorders, focusing on the molecular markers of risk.
10. Critically assess the relationship between metabolic syndrome and type 2 diabetes, exploring the role of insulin resistance in the development of cardiovascular complications.

TEXT BOOKS

1. Harsh Mohan. Text book of Pathology. Eighth edition. JAYPEE Brothers;2019
2. Bhende Y.M and Deodhare S.G. General Pathology & Pathology of Systems. Popular Prakashan, Mumbai;2010
3. Carol Mattson Porth. Essentials of Pathophysiology. Fourth edition. Wolters Kluwer;2015
4. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

REFERENCE BOOKS

1. Robbins and Cotran, Pathologic basis of disease. Tenth Edition. Elsevier publications; 2014

2. Mary Anne Koda-Kimble et.al. Applied Therapeutics – The Clinical Use of Drugs. Ninth Edition. Wolters Kluwer;2009

Course Title	L	T	P	Total Hrs.	Year	Course Code
PHARMACEUTICAL-MICROBIOLOGY (T)	**3**	**0**	**0**	**75**	**II**	**PD.202T**
PHARMACEUTICAL-MICROBIOLOGY (P)	**0**	**0**	**2**	**50**	**II**	**PD.209P**

SCOPE: This course deals with the fundamental aspects of microorganisms that are relevant to the field of pharmaceutical sciences, including their classification, morphology, laboratory cultivation, identification and maintenance. A detailed examination of these microorganisms enables students to recognize their roles in infections and diseases. The course includes an in-depth examination of sterilization techniques and the different methods used to control and eliminate microbial contamination in pharmaceutical manufacturing processes. Students will learn about different types of disinfectants, their modes of action, and their application in maintaining aseptic conditions in pharmaceutical facilities.

Furthermore, the course will offer insights into immunology, providing students with a deeper understanding of the body's immune response to microbial infections and the development of vaccines. The course further discusses on the fundamental aspects of immunological preparations, various diseases & transmission, its diagnosis, control and immunological tests for diagnosing these diseases.The course also focuses on clinical microbiology, microbiological assays and diagnostic tests used to detect and quantify microorganisms, aiding in pharmaceutical quality control. It also introduces students to emerging concepts such as the role of Artificial Intelligence (AI) in microbiological applications and the importance of sustainability, including clean water and sanitation, in pharmaceutical environments. Overall, this course aims to equip students with the necessary knowledge and skills to effectively understand and manage infectious diseases, apply microbiological principles to pharmaceutical practices, and contribute to the improvement of healthcare outcomes

COURSE LEARNING OUTCOMES:

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

KNOWLEDGE

K1: Explain the methods of isolation and preservation of microorganisms.

K2: Describe the various microbiological assays and microbiological standardization for pharmaceuticals, including the role of AI and sustainable practices in pharmaceutical microbiology.

K3: Identify different types of microorganisms relevant to pharmaceutical sciences.

K4: Analyse the characteristics and mechanisms of different infectious diseases and their causative agents.

K5: Illustrate the various staining methods employed for microbial identification.

K6: Develop appropriate sterilization and disinfection procedures suitable for pharmaceutical manufacturing processes.

SKILLS

S1: Identify microorganisms relevant to pharmaceutical microbiology, such as bacteria, fungi, and viruses.
S2: Apply aseptic techniques and laboratory protocols effectively in handling microorganisms.
S3: Perform microbial isolation, identification, and characterization techniques in the pharmaceutical microbiology laboratory.
S4: Acquire hands-on skills in performing microbiological tests, including microbial enumeration, and antimicrobial susceptibility testing.
S5:. Analyze laboratory results to diagnose specific infectious diseases correctly.

S6: Select appropriate techniques for microbial control and sterilization in pharmaceutical and hospital settings.

ATTITUDES

A1: Appreciate the importance of maintaining a clean and hygienic work area to prevent microbial contamination.
A2: Demonstrate ethical conduct in the use of microorganisms and adherence to safety guidelines.
A3: Cultivate a scientific curiosity and a desire for continuous learning.
A4: Display patience and attentiveness owards understanding microbial concepts.
A5: Exhibit an understanding of the impact of microbial contamination on the safety and efficacy of pharmaceutical products.
A6: Foster a sense of responsibility and professionalism while working in a laboratory environment.

LECTURE WISE CONTENTS:

UNIT I **3 Hours**

Basics of Microbiology:

- Introduction to the science of microbiology (1hr),
- Major divisions of microbial world and Relationship among them (1hr),
- Prokaryotic & eukaryotic cells (1hr) .

UNIT II **11 Hours**

Bacteria:

- Study of ultra-structure and morphological classification of bacteria (1hr),
- Nutritional requirements (1hr),

- Raw materials used for culture media, different culture medias and physical parameters for its growth (1hr),
- Bacterial growth curve, isolation, and preservation methods for pure cultures (2hrs)
- Cultivation of aerobes & anaerobes (1hr),
- Quantitative measurement of bacterial growth - total & viable counting techniques (1hr),
- Identification of bacteria using staining techniques (simple, Gram's & acid fast staining) and biochemical tests (IMViC) (2hrs).
- Artificial Intelligence applications in microbial identification (1 hr),
- Sustainable microbiological practices - Minimizing lab waste and ensuring responsible antimicrobial use, aligned with Sustainable Development Goals (SDGs) - SDG 3, 6 & 12 (1 hr).

UNIT III **10 Hours**

Fungi & viruses:

- Study of morphology(2hrs)
- Classification (2hrs),
- Reproduction/replication (3hrs),
- Pharmaceutical application (1hr),
- And cultivation of Fungi and Viruses with suitable examples (2hr).

UNIT IV **4 Hours**

Rickettsiae & Spirochetes:

- Definition , morphology, structural details (2 hrs),
- Classification of Rickettsiae and Spirochetes withexamples (2hrs).

UNIT V **7 Hours**

Sterilization:

- Principle, procedure, merits, demerits and applications of :
  Physical, chemical, gaseous sterilization (2hrs),
- Radiation and mechanical method of sterilization (1hr).
- Validation /evaluation of the efficiency of sterilization methods (1hr).
- Sterility indicators (1hr).
- Sterility testing of products including solids, liquids, ophthalmic and other sterile products, according to IP, BP and USP (2hrs).

UNIT VI **4 Hours**

Disinfectants:

- Classification and mode of action of disinfectants (1hr),
- Factors influencing disinfection, antiseptics and their evaluation (2hrs).
- Evaluation of disinfectants, preservative, bactericides & Bacteriostatics (1hr).

UNIT VII **14 Hours**

Immunology:

- Immunity, Definition, Classification (1hr),
- General principles of natural immunity (1hr),
- Phagocytosis, Acquired immunity (active and passive) (1hr),
- Local & herd immunity (1hr),
- Antigens, chemical nature of antigens structure and formation of Antibodies (1hr),
- Antigen-Antibody reactions (2hr),
- Bacterial exotoxins and endotoxins (1hr),
- Types of vaccines (1hr),
- Significance of toxoids in active immunity (1hr),
- Immunization programme & Importance of booster dose (1hr),
- Standardisation and method of preparation of vaccines and sera (2hrs),
- Different types of viral & bacterial vaccines including its storage requirements (1hr).

UNIT VIII **6 Hours**

Diagnostic tests:

- Schick's Test, Elisa test (1hr),
- Western Blot test, Southern Blot test (1hr),
- PCR Test with examples (1hr),
- Widal test, QBC (1hr),
- Mantaux test, Peripheral smear test (1hr),
- Study of malarial parasite (1hr).

UNIT IX **3 Hours**

Microbial culture sensitivity Testing:

- Principles and methods of different microbiological assay, Assessment of a new antibiotic (2hrs).
- Methods for standardization of Penicillin, Streptomycin and Vitamin B_2 and B_{12} (1hr).

UNIT X **7 Hours**

Study of infectious diseases:

- Typhoid (1hr),
- Tuberculosis (1hr),
- Malaria (1hr),
- Cholera (1hr),
- Hepatitis and Meningitis (1hr),
- HIV, Syphilis & Gonorrhea (2hrs).

UNIT XI **6 Hours**

Clinical Microbiology:

- Bacteriological examination of water, milk, food and air (2 hrs),

- Collection, processing and techniques (isolation, identification and antimicrobial susceptibility testing) for bacteriological investigations of clinical samples : Blood, urine, CSF, sputum, pus, stool, tissue etc (4 hrs).

PHARMACEUTICAL MICROBIOLOGY PRACTICAL

LIST OF EXPERIMENTS:

1. Study of apparatus used in experimental microbiology.
2. Sterilization of glass wares.
3. Preparation of culture media for bacteria and fungi.
4. Staining techniques using different microbial samples –
   a) Simple staining
   b) Gram's staining
   c) Negative staining
   d) Acid fast staining.
5. Study of motility characters of microbes.
6. Enumeration of microorganisms –

a) Total count techniques
b) Viable count techniques.

7. Study of different methods of isolation of pure cultures -

a) Spread plate technique
b) Pour plate technique
c) Streak plate techniques – simple streaking & multiple streaking

8. Biochemical testing for the identification of microorganisms.
9. Culture sensitivity testing for some microorganisms.
10. Sterility testing for sterile dosage forms.
11. Determination of minimum inhibitory concentration.
12. Microbiological assay of antibiotics by cup plate method.

SEMINAR/ASSIGNMENTS:

1. Review the significance of microbiology in pharmaceutical sciences by highlighting key contributors and major breakthroughs in drug development, vaccines, and infection control.
2. Explain the mechanisms of multi-drug resistance (MDR) and discuss its pharmaceutical challenges with relevant clinical examples.
3. Describe the structure, pathophysiology, and clinical impact of SARS-CoV-2 and its major variants, with emphasis on pharmaceutical relevance.
4. Evaluate the application of Omics technologies (Genomics, Proteomics, Metabolomics) in studying microbial metabolites and their role in pharmaceutical drug discovery.
5. Prepare a report on the current status of antibiotic resistance, assess surveillance methods, and propose strategies to combat antimicrobial resistance.

6. Discuss recent microbial diagnostic techniques, focusing on emerging infectious diseases and highlighting tools like PCR, CRISPR diagnostics, and biosensors.

TEXT BOOKS:

1. Chandrakant R. Kokare. Pharmaceutical Microbiology. 9th edition, NiraliPrakashan,Pune, 2022.
2. Ashutoshkar. Pharmaceutical Microbiology.1st edition, New Age International Ltd Publishers,New Delhi, 2019.
3. Ananthanarayan and Panicker's.Text book of Microbiology. 12th edition,Orient Longman Ltd, Chennai,2022.
4. Prescott and Dunn. Industrial Microbiology. 4th edition. CBS Publishers & Distributors, New Delhi, 2005.

REFERENCE BOOKS

1. Pelczar, Chan Kreig.Microbiology. 5th edition, Tata McGraw Hill edition, NewDelhi, 2019.
2. Prescot L.M, Jarley G.P, Klein D.A. Microbiology. 2nd edition, Mc Graw Hill Company Inc., 2005.
3. J. E Bennett , R. Dolin R (Eds): Principles and Practice of Infectious Disease. 4th edition. Churchill Livingstone, New York, 2002.
4. .Seth A.K. Pharmaceutical Microbiology (A Laboratory Hand Book).1st edition, S. Vikas & Co. Publishing House, Jalandhar , 2018.

**Latest edition of the text books & reference books can be referred*

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
PHARMACOGNOSY & PHYTOPHARMACEUTICALS (T)	**2**	**0.5**	**0**	**50**	**2**	**II**	**PD.203T**
PHARMACOGNOSY & PHYTOPHARMACEUTICALS (P)	**0**	**0**	**2**	**50**	**1**	**II**	**PD.210P**

SCOPE:

The course is designed to impart knowledge on Complementary and Alternative medicine natural Products and nutraceuticals and their impact on chronic disease prevention. It also discusses essential marketed nutraceuticals that can be appropriately used to improve health and well-being. It also covers the potential drug-drug and drug-herb-interaction and its role in regulation of components of immune system. Free radicals' impact on chronic disease and their management with antioxidants are also discussed.

The course deals with the various aspects such as extraction of Galenicals and its Extraction Process and discovery of new chemical entities of natural origin. It enables students to learn about Complementary and Alternative medicine natural Products and its safety and effecasy exemplifying with appropriate case studies. The scope extends to understanding the general concept of interactions between herbal drugs and conventional drugs, as well as interactions between herbs and food. Also, harness Artificial Intelligence (AI) tools for plant-based drug discovery and herb-drug interaction analysis, and implement eco-friendly extraction techniques to optimize sustainable phytomedicine development{*Sustainable Development Goal 3* (*SDG 3-Good Health and Well-being*)}. Further more, It explores the scope, regulatory aspects and potential of Phytopharmaceuticals, a new drug class regulated in India. This course ensures a participatory role as responsible citizens and facilitates improvement in health and well-being.

COURSE LEARNING OUTCOMES

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

KNOWLEDGE

K1: Discuss the various types of CAM Natural products

K2: Compare the various Phytopharmaceuticals and its releveance

K3: Describe the marketed nutraceuticals with their positive health outcome.

K4: List out herbs as health food and their scope in chronic disease prevention.

K5: Outline the the efficacy and safety aspects of CAM natural products

K6: Analyze the possible side effects and interactions of herbal drugs.

SKILL

S1: Use AI to study plant medicines, its drug interactions and apply green methods to extract plant compounds sustainably.

S2: Compare and contrast CAM natural products and Nutraceuticals

S3: Evaluate the chemical and biological markers in satndardized extracts

S4: Detect the limitations of marketed nutraceuticals

S5: Assess the the antioxidant potential of nutraceuticals.

S6: Apply modern methods for extraction of the herbal drugs.

ATTITUDE

A1: Upgrade technical, intellectual, and emotional skills and facilitate improvement.

A2: Develop the ability to interact effectively and respectfully with individuals.

A3: Participate autonomously in a technical and supervisory context.

A4: Accept responsibility for self and group work.

A5: Implement plans and organize work to meet deadlines.

A6: Appreciate collaborative skills to work effectively in interprofessional healthcare teams.

LECTURE WISE CONTENTS:

UNIT-I **10 Hours**

Complementary and Alternative Medicine Natural Products (CAM)

- An introduction to CAM (**1hr**).
- Define the following terms with suitable two examples of each with respect to CAM: Dietary supplements, Herbal or botanical products,Traditional medicine formulations, Folk medicines, Homeopathic remedies, Probiotics, Food-based phytochemicals (**3hrs**).
- Justify the efficacy and safety of CAM therapies based on any two available clinical studies (**3hrs**)

- Role in regulation of components of immune system (cells involved in immune response- T and B cells, macrophages, dendritic cells and natural killer cells) (**2hrs**)
- Limitations and future perspectives (**1hr**)

UNIT-II **16 Hours**

Nutraceuticals in Human Diseases

- General aspects and scope of nutraceuticals. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer and Gastrointestinal diseases. Market, growth, and types of products available in the market

  (Examples:. *Omega-3 fatty acids*: Known for their heart health benefits and cognitive support.

  Probiotics: Beneficial bacteria that support gut health and digestion.

  Curcumin (from turmeric): A powerful antioxidant with anti-inflammatory properties.

  Vitamin D: Essential for bone health and immune function.

  Green tea extract: Rich in antioxidants and associated with various health benefits (**8hrs**)
- Study of the following herbs as health food: Fenugreek, Garlic, Amla, Ginger, Ashwagandha. Spirulina (**3hrs**)
- **Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and classification. Study of the following drugs and their possible side effects and interactions: Hypericum, kava-kava, Ginkgo biloba, Ginseng, Garlic, Pepper & Ephedra. (**4hrs**)
- AI-enabled Herb-Drug Interaction Analysis: Identifying potential interactions between(**1hr**)

UNIT- III **12 Hours**

Galenicals, its extraction process and discovery of new chemical entities (NCEs) of Natural origin

- Definition of galenicals and its significance (**1hr**)
- Different extraction processes like infusion, decoction, maceration, and percolation(**1hrs**)
- Bring Sustainability into Phytomedicine Research- Use **green chemistry techniques** for extracting bioactive compounds-Modern method of herbal extraction- Supercritical fluid extraction and microwave assisted extraction (**1hr**)

- Discovery and development of anti-diabetics, antioxidants, immunomodulating agents, anti-inflammatory agents, anti-viral, antimycobacterial agents and anticancer agents with apoptotic molecular basis (**5hrs**).
- Clinically available drugs from Natural sources(BioSource, therapeutic uses and approved year): Artemisinin, Digoxin, Diosgenin, Atropine, Taxol, Vincristine and Vinblastine, Reserpine, quinine (**2hrs**).
- AI-assisted Plant-Based Drug Discovery: Mining Ayurvedic texts and databases to identify bioactive compounds with therapeutic potential(**2hrs**).

UNIT- IV **12 Hours**

Phytopharmaceuticals

- Definition, Current Trends in Phytopharmaceuticals (**1hr**)
- Development of a standardized phytopharmaceutical formulation (**2hrs**)
- Phytopharmaceuticals Regulatory requirements and licensing process (**2hrs**)
- Role of chemical and biological markers in standardization of herbal products (**1hr**)
- **Veregen® (sinecatechins):** A green tea extract approved for the treatment of genital warts. **Mytesi™ (crofelemer):** Derived from the Croton lechleri plant, approved for managing diarrhea in HIV/AIDS patients. **Filsuvez® (birch triterpenes):** Approved for the treatment of epidermolysis bullosa, a rare skin disorder. **NexoBrid® (anacaulase-bcdb):** An enzyme-rich product derived from the pineapple plant, approved for burn debridement (**4hrs**).
- Research Guidelines for Evaluating the Safety and Efficacy of Herbal products **(1hr**)

List of Assignment topics

1. The regulatory issues of Nutraceuticals and Dietary Supplements as per EU, US, and Indian guidelines. FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety.
2. Pharmacopoeia Specifications for dietary supplements and nutraceuticals.
3. Effect of processing, storage, and interactions of various environmental factors on the potential of nutraceuticals.
4. Guidelines for herbal drugs and phytopharmaceuticals (USFDA, EMA, AYUSH, WHO). Documentation, patents, and regulatory filings.
5. List of natural products /molecules under clinical trials for various disease condition

6. Plant based products -Dietary supplements / Nutraceuticals- Improving the therapeutic out come & improving the quality of life of patients
7. Drug Controller General of India (DCGI)approval process & Plant derived drugs/ Phytopharmaceuticals category.
8. Central Drugs Standard Control Organization (CDSCO)and approved plant based drugs

Text Books:

1. Evans WC. Trease and Evans Pharmacognosy. 16th edn. W.B. Sounders & Co. London; 2009.
2. Robert E.C. Wildman, Robert Wildman, Taylor C. Wallace Handbook of Nutraceuticals and Functional Foods. 3rd edn; CRC Press, United States; 2006.
3. Srilakshmi B, Dietetics. 6th edn, New Age International Publisher, New Delhi; 2017.
4. Shilpa MA, et al.,A text book of dietary supplements and nutraceuticals. 1st edn, S Vikas and Company (PV),Punjab; 2019.

Reference Books:

1. Gibson GR &William CM. Functional Foods: Concept to Product. 1stedn. London: Woodhead Publication Co.; 2000.
2. Cooper K.A. Advanced Nutritional Therapies. 1st edn.. USA Thomas Nelson Inc;1997
3. Agusti K.T., Faizal P., Role of Dietary fibers and nutraceuticals in preventing diseases.1st edn. India. BSP Books. 2019.

Additional reading Material

1. *Bone K, Mills S.* Principles and Practice of Phytotherapy: Modern Herbal Medicine. 2nd ed. London: Churchill Livingstone; 2013.

2. *Rakel D, Rindfleisch JA.* Integrative Medicine. 4th ed. Philadelphia: Elsevier; 2017.

3. Wichtl M. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis. 3rd ed. Boca Raton: Medpharm Scientific Publishers; 2004.

JOURNALS:

4. Journal of Food Science and Technology: https://www.springer.com/journal/13197
5. Food Science and Nutrition:

https://onlinelibrary.wiley.com/page/journal/20487177/homepage/publishing_with_food_science___nutrition.htm

6. Nutrients: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7352266/
7. Journal of Functional Food: https://www.sciencedirect.com/journal/journal-of-functional-foods

PHARMACOGNOSY & PHYTOPHARMACEUTICALS (Practical)

List of Experiments

1. Estimation of total Phenolic content
2. Determination of total alkaloids.
3. Estimation of total flavanoid content

4. Exercise involving isolation & detection of active principles
   i. Caffeine - from tea dust / Sennoside from Senna
   ii. Ultrasound and microwave assisted extraction
   iii. Microwave assisted extraction of curcuminoids from Curcuma longa
   iv. Glycyrhetinic acid from Liquorice
5. Preparation of three extracts using Green Technology.
6. Biological screening of herbal drugs/ Nutraceuticals/Phytopharmaceuticals
   i. *In vitro* anti-oxidant analysis
   ii. *In vitro* anti-microbial analysis
   iii. *In vitro* anti-inflammatory analysis
   iv. *In vitro* anti-diabetic analysis
   v. Hepatoprotective activity

**Latest edition of the text books & reference books can be referred*

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
PHARMACOLOGY -I (T)	**2**	**0.5**	**0**	**50**	**2.5**	**II**	**PD.204 T**

SCOPE:

The course aims to comprehend the science underlying the use of currently using therapeutic agents only and how the body reacts to them. By examining how medicines affect cells, organs, and organisms, pharmacology knowledge can aid in developing novel pharmaceuticals. Understanding the mechanisms of action of pharmaceuticals requires an understanding of signal transduction pathways, drug-receptor interactions, and the effects of medications on physiological processes.

The course provides insights into drug metabolism, including topics such as drug clearance, bioavailability, and drug-drug interactions. It provides pharmaceutical safety, detects possible side effects, and establishes the proper dose schedules to reduce adverse reactions. In addition, it provides guidance on dosage and drug selection and a better understanding of drug response variability among people, chrono pharmacology, drug interactions, rational use and disposal of drugs. It also supports academic careers, pharmacological research and knowledge expansion, and the training of future scientists and medical professionals.

COURSE LEARNING OUTCOMES

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

KNOWLEDGE

K1: Describe the scientific terms and principles of pharmacology

K2: Enumerate the different classes of clinically relevant drugs used for various diseases/disorders

K3: Illustrate the mechanistic role of drugs in modifying various diseases/disorders

K4: Describe the pharmacological actions of drugs at organ system/sub-cellular/ macromolecular levels andpharmacokineticsof medications used in the treatment of different diseases/disorders

K5: Predict the mechanism of drugs that contributeto adverse drug reactions, contraindications, and their off-label use.

K6: Correlate the knowledge in pharmacology with related medical sciences

SKILL

S1: Justify the medication choices used for the pharmacological treatment of various diseases/disorders

S2: Predict the drug interactions in a given prescription

S3: Recommend the possible alternatives to the drug therapy

S4: Identify the signs and symptoms of drug poisoning

S5: Convince the public about the need for drug therapy in a disorder/disease

S6: Educate patients about the dos and don'ts of drug therapy

ATTITUDE

A1: Appreciate the knowledge of Pharmacology for learning pharmacotherapy and toxicology.

A2: Communicate with peers and others.

A3: Support and collaborate with others.

A4: Exhibit professionalism in the working environment.

A5: Participate in healthcare initiatives.

A6: Embrace the new advancements in the healthcare system.

COURSE CONTENTS:

UNIT I: General Pharmacology 6 Hours

a. Introduction to Pharmacology

Definition and scope of pharmacology, Nature and source of drugs (1hr)

Routes of drug administration

Agonists, antagonists (competitive and non-competitive), partial agonists and inverse agonists (1hr)

b. Introduction to Pharmacokinetics

Absorption of drugs (1hr)

Distribution of drugs (1hr)

Metabolism of drugs (1hr)

Excretion of drugs (1hr)

UNIT II: Introduction to Pharmacodynamics 6 Hours

- Principles and mechanisms of drug action. (1hr)
- Classification of receptors, regulation of receptors (1hr)

- Spare receptors, dose-response relationship, therapeutic index
- Drug addiction, tolerance, dependence, drug abuse, tachyphylaxis, idiosyncrasy and allergy. (1hr)
- Enzyme induction, enzyme inhibition (1hr)
- Adverse drug reactions (1hr)
- Drug interactions (pharmacokinetic and pharmacodynamic) (1hr)
- Rational use and disposal of drugs (1 hr)

UNIT III: Drugs Acting on Peripheral Nervous System 10 Hours

Neurohumoral transmission, co-transmission, and receptors involved in the neurotransmission (2hrs)

- Adrenergics (2 hrs)
- Anti-Adrenergics (1hr)
- Cholinergics (2hrs)
- Anticholinergics (1hr)
- Neuromuscular blocking agents and skeletal muscle relaxants (1 hr)
- Local anesthetics (1hr)

UNIT IV: Cardiovascular Pharmacology 9 Hours

- Diuretics & Vasopressin analogues (2hrs)
- Anti-hypertensives (2hrs)
- Anti-anginals - emphasis on Nitrates(1hr)
- Anti-arrhythmic drugs (2hrs)
- Drugs used in congestive heart failure – emphasis on Digoxin & Dapagliflozin (1hr)
- Hypolipidemics (1hr)

UNIT-V Drugs acting on Blood and Blood Forming Agents 5 hours

- Anticoagulants (1hr)
- Thrombolytics (1hr)
- Antiplatelet agents (1 hr)
- Haemopoietic agents (1hr)
- Plasma expanders (1hr)

UNIT VI: Endocrine Pharmacology 9 Hours

- Anterior Pituitary hormones analogs and their antagonists (1hr)
- Thyroxine and anti-thyroids (1hr)
- Insulin, Oral hypoglycemics (2hrs)

- Corticosteroids (1hr)
- Androgens (1hr)
- Anabolic steroids (1hr)
- Estrogens (1hr)
- Progesterone (1hr)

UNIT VII: Miscellaneous **4 Hours**

- Antiulcer agents (1hr)
- Antihistamines (1hr)
- Anti-leucotrienes, Methyl Xanthines, Mucolytics (2hrs)

Assignments

- ❖ Illustrate the different factors influencing drug actions with a pictorial representation.
- ❖ List out the various classes of clinically used drugs based on their mechanism of action.
- ❖ Enlist the drugs that are banned from clinical use because of their potential toxicity.
- ❖ Elucidate the role of Parathormone, Calcitonin and Vitamin D in maintaining Ca homeostasis and its pharmacological relevance in various ailments
- ❖ Prepare a chart on the pharmacological aspects of Uterotonics & Tocolytics
- ❖ Illustrate the physiological functions of Corticotropins
- ❖ Prepare a chart on the pharmacological aspectsof Oral Contraceptives
- ❖ Prepare a chart on the pharmacological aspectsof nasal decongestants.
- ❖ Prepare a chart on the pharmacological aspects of Mucolytics
- ❖ Prepare a chart on the pharmacological aspects of Bronchodialators
- ❖ Prepare a chart on the pharmacological aspects of Expectorants
- ❖ Prepare a chart on the pharmacological aspects of Antitussives
- ❖ Review the pharmacology of drugs used for constipation and diarrhea
- ❖ Role of Emetics and Anti-Emetics in various disease conditions
- ❖ Prepare a chart on the physiological functions of histamines

TEXT BOOKS:

1. James R, Rod F, Graeme H, Yoon KL, David, Humphrey R. Rang & Dale's Pharmacology. 9thedn.Churchill Living Stone: Edinburgh Elsevier; 2020
2. Tripathi KD. Essentials of medical pharmacology. 8th edn. Jaypee: Delhi; 2018

3. Satoskar RS, Bhandarkar SD, Nirmala N. Pharmacology and Pharmacotherapeutics. 26th edn. Popular Prakashan; 2020.

REFERENCE BOOKS:

1. Laurence LB, Randa HD, Björn CK. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 13thedn.McGraw Hill: New York; 2017
2. Whalen K. Lippincott Illustrated Reviews: Pharmacology. 8thedn.Wolters Kluwer (India) Pvt. Ltd; 2022.
3. Gupta SK. Drug Screening Methods.3rd edn. New Delhi, India: Jaypee Brothers Medical Publishers (P) Ltd; 2016.

**Latest edition of the text books & reference books can be referred*

Course Title	Theory	Tut.	P	Total Hrs.	Year	Course Code
COMMUNITY HEALTHCARE AND PHARMACY MANAGEMENT	**2**	**0.5**	**0**	**50**	**II**	**PD.205T**

SCOPE:

The community pharmacy sector contributes to the advancement of research regarding disease incidence and prevalence as well as the evolution of pharmaceutical service policies in both the public and private sectors in India. It can also determine the right treatment regimen for the patient and put in place a sufficient system for inventory and stock control.
The Indian pharmacy landscape is evolving, and community pharmacists are required to provide a range of pharmaceutical care services. To fulfil this requirement, students will acquire a range of skills including managing inventory, distributing medications, treating minor illnesses with appropriate and safe medicine, patient counselling, and health screening services and usage of artificial intelligence (AI) based tools for better patient care in the community setting. By providing accessible, secure, and efficient medications, community pharmacists promote Sustainable Development Goal (SDG)-3, improving individuals health and well-being.

COURSE OUTCOMES:

Upon successful completion of the course, the students shall be able to;

KNOWLEDGE

K1 : Identify key legal and ethical considerations relevant to community pharmacy practice.

K2 : Understand and summarize the role of community pharmacists in medication management such as significance of drug interactions, potential adverse effects, patient counseling and healthcare screening techniques.

K3 : Evaluate the accuracy and completeness of prescription orders to prevent medication errors.

K4 : Understand the current rates and prevalence of illness in community settings, as well as the actions done by the authorities in charge of regulations to lessen the illness.

K5 : Understand the key activities taken by the Drug Regulatory bodies

K6 : Outline the various inventory control methods and associated AI tools used in community pharmacy

SKILLS

S1 : Executing the medication dispensing process in a community pharmacy.

S2 : Demonstrate an understanding of the legal and ethical considerations in pharmacy practice, such as patient confidentiality and prescription validity.

S3 : Demonstrate effective communication skills during patient counseling sessions or at medical camps, addressing patients' questions and concerns.

S4 : Analyze the prescription orders, drug interactions and potential adverse effects to identify potential medication-related problems for patients. that would enable the authorities to develop better plans of action.

S5 : Assess the safety and appropriateness of medication therapy plans for individual patients and develop strategies for improving medication adherence (including AI approaches) in patients with chronic conditions.

S6 : Implementing, preparing and analyzing the inventories

ATTITUDE

A1 : Embrace the importance of patient-centered care in community pharmacy practice.

A 2 : Integrating the concept of empathy and its role in patient counseling.

A3 : Exhibit the principles of effective communication in the context of community pharmacy and summarize the impact of patient advocacy on patient outcomes.

A4 : Apply cultural sensitivity principles to provide personalized care to patients from diverse backgrounds and utilize evidence-based practice to make patient-specific recommendations for medication therapy.

A5 : Analyze patient cases to identify potential ethical dilemmas and propose appropriate solutions that support the achievemnt of SDG.

A6 : Assess the effectiveness of patient counseling sessions through feedback and reflection and critically appraise the relevance and reliability of evidence-based resources for community pharmacy practice.

LECTURE WISE CONTENTS:

Unit I : Community Pharmacy **2 hours**

- Define community pharmacy, Outline the scope of community pharmacy 1 hour
- Describe the importance of pharmacist in community pharmacies, Explain the roles and responsibilities of community pharmacists 1 hour

Unit II : Community Pharmacy Management **3 hours**

- Select the site, space requirements and design in setting a community pharmacy, Recognize the staff requirements in community pharmacy 1 hour
- List the legal requirements to set community pharmacy, Explain the importance of maintaining various registers in community pharmacy 2 hour

Unit III : Prescriptions **2 hours**

- Define prescription, discuss about the different parts of prescription, List out the legality requirements in prescription. 1 hour
- Explain about the identification of medication related problems in prescription, Identify the errors in prescription 1 hour

Unit IV : Inventory Control in Community Pharmacy **5 hours**

- Define inventory control, List out various methods of inventory control
    - Explain ABC, VED, EOQ, Lead time. Describe the importance of safety stock 2 hour
    - Identify different types of inventories 2 hours
- Expalin the role of AI in Inventory and Supply Chain Management 1 hour

Unit V : Pharmaceutical Care **3 hours**

- Define pharmaceutical care, Describe the objectives of pharmaceutical care 1 hour
- Explain the principles of pharmaceutical care 2 hours

Unit VI : Patient Counseling **3 hours**

- Define patient counseling, List out the various outcomes of patient counseling, Discuss the various stages of patient counseling, Identify the barriers of patient counseling. 2 hours

- Describe the patient information leaflets, Outline the content and design of patient information leaflets 1 hour

Unit VII : Patient Medication Adherence **3 hours**

- Define patient medication adherence, Identify the factors affecting medication adherence 0.5 hour
- Enumerate the different techniques to overcome medication non adherence 1 hour
- Discuss the role of pharmacist in improving adherence 1 hour
- Disuss the use of AI in improving the medication adherence and reminders systems 0.5 hour

Unit VIII : Health Screening **5 hours**

- List the importance of health screening, Explain the method for screening blood pressure, Describe the method for screening blood sugar 2 hours
- Discuss the method for screening lung function 1 hour
- Outline the method for cholesterol testing 1 hour
- Govt. initiatives to setup health screening camp 0.5 hour
- Retrieving the community pharmacy screening kiosks integrated with AI to assess health risks 0.5 hours

Unit IX : OTC Medication **2 hours**

- Define OTC medicines, List various OTC medicines 1 hour
- Explain the important counseling points for OTC preparations, Enumerate the role of pharmacist in dispensing OTC medicines 1 hour

Unit X : Health Education **6 hours**

- WHO Definition of Health, Health promotion targeting SDG 3.d, Discuss the method for caring children 2 hours
- Explain the method for caring geriatric patients 1 hours
- Enumerate the method for caring pregnant & breast feeding women 2 hours

Unit XI : Communicable Diseases: causative agents, clinical presentation, prevention **(**mainly government schemes and policies targeting SDG-3.3 **6 hours**

- Tuberculosis, Leprosy 2hours
- Hepatitis 1 hours
- Typhoid, ameobiasis 1 hours
- Malaria, Dengue, Covid-19 1 hour
- STD's: Syphilis, gonorrhea, AIDS 1hour

Unit XII : Deficiency Disorders 1 hour

Define balanced diet, Discuss the treatment and prevention of deficiency disorders, Describe the role of pharmacist in prevention of deficiency disorders 1 hour

Unit XIII : Family Planning 1 hour

- Enumerate the different methods of family planning, Identify the importance of family planning, Explain the role of pharmacist and government initiatives to pronmote family planning 1 hour

Unit XIV : Responding to symptoms of minor ailments 5 hour

- List out the different types of minor ailments, pathophysiology and their treatment, Discuss in detail about pain management 1 hour
- Describe the drugs used in nausea and vomiting 1 hour
- Explain the management of dyspepsia 1 hour
- List out the drugs used in the management of diarrhea and constipation 1 hour
- Enumerate the management of pyrexia, Explain the symptoms of ophthalmology and their drug therapy 1 hour

Unit XV : Essential drug concept and rational drug therapy 2 hours

- Define essential drug, Explain essential drug list 1 hour
- Enumerate the rational use of drugs, Discuss the role of community pharmacist in promotion of rational drug therapy 1 hour

Unit XVI : Code of ethics **1 hour**

- Explain about the code of ethics for community pharmacists 0.5h
- Discuss the relationship of pharmacist with other health care providers 0.5h

Assignments

- Obtain the Essential Medicines list, analyze and deduce your suggestions on the same.
- OTC medication list
- Visit a community pharmacy/hospital pharmacy and understand the working process and submit a report
- Prepare pharmaceutical information leaflet of any preferred drug.
- General aspects to prevent spread of communicable diseases in real world (Dengue, Chikungunya etc).

TEXT BOOKS

- NS Parmar. Health Education & Community Pharmacy First Edition (2012). CBS PUBLISHERS AND DISTRIBUTORS PVT LTD
- Adepu R. Community Pharmacy Practice.1st ed. Hydrebad:Pharmamed Press; 2017.
- Parthasarathi G,Hansen NK and Nahata M. A text book of Clinical Pharmacy Practice; Essential concepts and skills. 2nd ed. New Delhi: Orient Blackswan;2012
- Revikumar KG, Miglani BD.Text book of Pharmacy Practice.2nd ed. Nashik : Career Publications; 2019.

REFERENCE BOOKS:

1. Merchant and Goyal.A text book of Hospital Pharmacy .9th ed . Ahmedabad: B.S.Shah Prakashan; 2008.

2. Walker, Roger. Clinical Pharmacy and Therapeutics. 6th ed. Edinburgh: Churchill Livingstone publication;2012

3. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins

JOURNALS AND OTHER WEB RESOURCES

- Marathe PA, Kamat SK, Tripathi RK, Raut SB, Khatri NP. Over-the-counter medicines: Global perspective and Indian scenario. J Postgrad Med. 2020 Jan-Mar;66(1):28-34. doi: 10.4103/jpgm.JPGM_381_19.
- Jimmy B, Jose J. Patient medication adherence: measures in daily practice. Oman Med J. 2011 May;26(3):155-9. doi: 10.5001/omj.2011.38.
- https://cdn.who.int/media/docs/default-source/mca-documents/child/standards-for-improving-the-quality-of-care-for-children-and-young-adolescents-in-health-facilities--policy-brief.pdf?sfvrsn=1e568644_1
- Health Screening, https://www.ncbi.nlm.nih.gov/books/NBK436014/#

Course Title	L	T	P	Total Hrs.	Year	Course Code
PHARMACOTHERAPEUTICS – I (T)	**2**	**1**	**0**	**50**	**II**	**PD.206T**
PHARMACOTHERAPEUTICS – I (P)	**0**	**0**	**3**	**75**	**II**	**PD.211P**

Scope: This course is designed to impart knowledge and skills necessary for the rational use of medicines. It provides an opportunity to learn the pharmacotherapeutic management of various diseases including recent advances, approved treatment algorithms and guidelines.It gives an insight into the basis behind the selection of drugs in disease management and the role of pharmacological and non pharmacological interventions. This course also highlights understanding, detection, assessment and prevention of various drug related problems.

Recent advancements in Pharmacotherapy and patient-specific management strategies are included and emphasized. The course emphasizes student-directed acquisition of necessary knowledge in the management of various diseases .The course emphasizes student-directed acquisition of knowledge on pathogenesis, pharmacotherapy, dose adjustment and patient counselling in the management of various diseases.

COURSE OUTCOMES:

Upon successful completion of the course students shall be able to;

KNOWLEDGE

K1: State the definitions of various disorders
K2 : Outline the etiopathogenesis and clinical manifestations of various diseases
K3 : Enumerate the reference ranges for various laboratory parameters.
K4 : Illustrate standard treatment guidelines used for various diseases/disorders
K5 : Discuss the role of pharmacological and non-pharmacological interventions in various diseases/disorders
K6: Describe the patient-specific parameters relevant in initiating and continuing drug therapy. (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects)

SKILL

S1: Justify the relevance of changes in drug therapy in the management of various disorders
S2: Interpret the variations in laboratory values
S3: Apply the pharmacological knowledge in prevention and treatment of various disorders.
S4: Demonstrate the ability to recognize and report various drug related problems
S5: Solve the various drug-related problems in the patient drug therapy
S6**:** Display proficiency in communicating clearly with a patient regarding the correct utilization of prescribed drugs.

ATTITUDE

A1: Appreciate and respect the cultural backgrounds, beliefs and values of patients.

A2: Recognise the emotional and psychological aspects of illness and demonstrate sensitivity in interactions with patients, families and caregivers.

A3: Communicate effectively with various stakeholders and exhibit professionalism in all clinical activities.

A4: Appreciate effective reporting of drug related problems among healthcare professionals.

A5: Display sincerity, punctuality and integrity in academic and nonacademic activities.

A6: Uphold the ethical values in maintaining the confidentiality of patient information.

LECTURE-WISE CONTENTS:

Introduction, Differential Diagnosis, Therapeutic goals, Pharmacological management with reference to latest guidelines and treatment algorithm &non-pharmacological approaches. Recent advancements associated with following systems/diseases

Preliminary reading topics are mentioned in brackets.

UNIT- I Cardiovascular and Cerebrovascular Systems 16 hours

- Hypertension (03 hours)
- Congestive cardiac failure (02 hours)
- Angina Pectoris (02 hours)
- Myocardial infarction (02 hours)
- Hyperlipidemias (02 hours)
- Arrhythmias (02 hours)
- Stroke (03 hours)

(*Electrophysiology of heart, Anatomy, physiology, functional areas of cerebrum and cerebellum*)

UNIT-II Renal system 08 hours

- Acute Renal Failure (02 hours)
- Chronic Renal Failure (02 hours)
- Renal Dialysis (02 hours)
- Drug induced renal disorders (02 hour)

(*Anatomy and physiology of Renal system.*)

UNIT-III Hematological System 08 hours

- Anemia- Microcytic, Macrocytic, Auto-Immune Hemolytic Anemia (03 hours)
- Coagulation Disorders -Deep Vein Thrombosis- (03 hours)

  Venous Thromboembolism & Pulmonary Embolism
- Drug induced blood disorders (02 hours)

  (*Composition and functions of blood*)

UNIT -IV Endocrine System 08 hours

- Diabetes ,Diabetic Foot and Insulin dosage adjustments (03hours)
- Thyroid diseases (03 hours)
- Osteoporosis (02 hours)

(*Oral contraceptives & Hormone replacement therapy*)

UNIT-V Respiratory System **08 hours**

- Asthma (03 hours)
- Chronic obstructive airways disease (03 hours)
- Drug induced pulmonary diseases (02 hours)

(*Physiology and regulation of respiration*)

Unit VI- Sustainability and Artificial Intelligence **02 hours**

- Ensuring Equity and Access in Essential Cardiovascular Medicines: A Public Health Sustainability Perspective (1hour)
- AI-Assisted Diagnosis and Drug Dose Adjustment in Diabetes Management. (1hour)

PHARMACOTHERAPEUTICS – I Practical

Guidelines for practical

Students are required to collect cases from various departments of AIMS hospital and five cases per academic year should be presented including both sessional practicals in SOAP format and 15 cases should be included in record covering most common diseases which is dealt in the theory syllabus.

- Student has to understand the changes in physiological functioning in the given disease condition of the patient.
- Learn the normal values of laboratory parameters applicable to each case.
- Explain the medication history and current drug therapy by direct patient interview
- Able to interpret the variations in laboratory parameters and justify the reasons for variations.
- Explain the rationale about the changes in drug therapy & clinical outcome
- Learn the PK/PD parameters of each drug in the treatment regimen and correlate it with clinical outcome of the patient.
- Compare the current treatment regimen of the patients with the approved treatment guidelines

Assignments:

1. Discuss the global impact of hypertension. How do healthcare disparities, lifestyle factors, and access to treatment contribute to the prevalence of hypertension worldwide?
2. List the strategies to minimize the risk of Drug induced renal disorders , including appropriate drug selection, dosing, and patient monitoring.
3. Prepare an assignment on the role of Gene therapy in treating genetic anemias.
4. Explain the impact of artificial intelligence and machine learning on the management of diabetes? Discuss how these technologies might improve early detection, treatment adherence, and monitoring of diabetes complications.
5. Mention the potential applications of stem cells in IVF and reproductive medicine

TEXT BOOKS:

1. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic approach. 10th edn. Mc Graw- Hill; 2017
2. Roger Walker and Cate Whittlesea. Clinical Pharmacy and Therapeutics. 5th edn. Churchill Livingstone publication; 2012
3. Robbins and Cotran. Pathologic basis of disease. 6th edn Philadelphia: Elsevier;2003
4. Laurence L. Brunton, Randa Hilal-Dandan, Björn C. Knollmann. Goodman & Gilman's: The Pharmacological Basis of Therapeutics. 13th edn. Mc Graw- Hill; 2018

REFERENCE BOOKS:

1. Kodak-Kimble, Mary Ann. Applied Therapeutics: The Clinical Use of Drugs. 11th ed. Philadelphia: LPWW;2009
2. Eric T. Herfindal. Clinical Pharmacy and Therapeutics. 5th edn. Lippincott Williams and Wilkins Publication;1992
3. Lloyd Young and Koda-Kimble. Applied Therapeutics: The clinical Use of Drugs. 10th edn. Wolters Kluwer: Lippincott Williams and Wilkins; 2013
4. Robbins and Cotran. Pathologic basis of disease. 6th edn Philadelphia: Elsevier;2003
5. Scott L. Traub. Basic skills in interpreting laboratory data. American Society of Health System Pharmacists; 1992

JOURNALS:

1. Clinical pharmacology and therapeutics. Wiley-Blackwell

2. Indian Journal of Medical Research. Med know Publications

3.American Journal of Therapeutics. Wolters Kluwer

ONLINE RESOURCES

- NICE Guidelines for HTN:https://www.nice.org.uk/guidance/ng136
- Diabetes: https://professional.diabetes.org/standards-of-care/practice-guidelines-resources

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
PHARMACEUTICAL JURISPRUDENCE (T)	**2**	**0.5**	**0**	**50**	**2**	**III**	**PD.207T**

SCOPE :

The Pharmaceutical Jurisprudence course provides students with a fundamental understanding of the essential laws and their latest amendments relevant to the pharmacy profession in India. This specialised field seamlessly integrates pharmacy principles with the legal domain. Through this course, students will gain a comprehensive understanding of the legal and regulatory frameworks governing the pharmaceutical sector. This course explores into a detailed analysis of all Acts and Rules, focusing on the latest amendments. By doing so, students will stay up-to-date with the most recent changes in the legal landscape, enhancing their ability to accurately comprehend and interpret legal requirements. Throughout the course, students will delve into key legal areas that significantly influence professional pharmacists' daily decisions.

By exploring laws in related fields, students will gain a holistic perspective on the regulatory framework that governs the pharmacy profession. Encompassing various areas of law, this course strongly emphasises empowering students to apply legal and ethical principles in their practice, ensuring optimal patient care and promoting public welfare. This comprehensive approach enables students to navigate complex legal scenarios confidently and make informed choices aligned with ethical principles. Ultimately, the Pharmaceutical Jurisprudence course lays a strong foundation for students to comprehend and apply essential laws, fostering a sense of responsibility and dedication in their professional practice as pharmacists.

COURSE LEARNING OUTCOMES:

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

KNOWLEDGE

K1. Explain key pharmaceutical laws and regulations. (Remembering)
K2. Enumerate the importance of Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals (Remembering)
K3. Review various Indian Pharmaceutical Acts and Laws (Understanding)
K4. Describe the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals (Understanding)
K5. Adapt the code of ethics during the pharmaceutical practice (Applying)
K6. Relate the various concepts of Drug policy, DPCO, Patent and Designing act (Applying)

SKILL

S1. Predict specific drug approval processes and regulatory bodies. (Understanding)
S2. Interpret legal language and terminology used in drug laws and regulations. (Understanding)
S3. Summarise ethical guidelines and principles relevant to the pharmaceutical sector (Understanding)
S4. Assess the role of regulatory agencies in ensuring drug safety and efficacy. (Applying)

S5. Adapt knowledge of pharmaceutical laws to assess compliance issues in the industry (Applying)
S6. Analyze pharmaceutical laws and regulations and their implications for various stakeholders.

ATTITUDE
A1. Identify the societal impact of pharmaceutical practices and the need for responsible engagement. (Remembering)
A2. Express a receptive attitude towards learning about the impact of laws and regulations on the pharmaceutical industry. (Understanding)
A3. Apply legal principles to resolve ethical dilemmas in the pharmacy profession. (Applying)
A4. Practice Professional ethics (Applying)
A5. Analyse the ethical and legal implications of emerging trends in the pharmaceutical industry. (Analysing)
A6. Embrace the value of lifelong learning and staying updated with legal and ethical developments in the field. (Analysing)

LECTURE WISE CONTENTS:

UNIT I **5 Hours**

Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, The Pharmacy Enquiry Committee, Hathi committee and Mudaliar committee (3 hr)
Code of Pharmaceutical Ethics Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath (2 hr)

UNIT II **18 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945
Objectives, Definitions, Legal definitions of schedules to the Act and Rules.
Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties**.** (3 hrs)

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license. (3 hrs)

Detailed study of Schedule G, H, H1, HX, J, K, L1, M, N, P, P1, T, U, V, X, Y, Sch F. Part XII B, (3 hrs)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offenses and penalties. (2 hrs)

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs, List of permitted colors used in formulations of drugs. Offenses and penalties. (2 hrs)

Objectives of Medical devices Rules 2017, Cosmetic rules 2020, The Drugs Clinical Trial rules 2019, Classification of Medical devices (2 hrs)

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities,

controlling authorities, Drugs Inspectors. Brief study of prescription and Non-prescription Products. (3 hrs)

UNIT III **15 Hours**

Pharmacy Act –1948

Objectives, Definitions. Pharmacy Council of India; Its constitution and functions, Education Regulations. State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties. Essentials of Pharmacy Practice Regulations (5hrs)

Medicinal and Toilet Preparation Act –1955

Objectives, Definitions. Licensing. Manufacture In bond and Outside bond. Export of alcoholic preparations. Manufacture of Ayurvedic Homeopathic. Patent & Proprietary Preparations. Offences and Penalties. (5 hrs)

Narcotic Drugs and Psychotropic Substances Act-1985 and Rules

Objectives,Definitions, Authorities and Officers. Constitution and Functions of narcotic & Psychotropic Consultative Committee. National Fund for Controlling the Drug Abuse. Prohibition, Control and Regulation. Opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties (5 hrs)

UNIT IV **7 Hours**

Study of Salient Features of Drugs and Magic Remedies Act and its rules

Objectives, Definitions, Prohibition of certain advertisements. Classes of Exempted advertisements. Offences and Penalties (2 hrs)

Prevention of Cruelty to animals Act-1960

Objectives, Definitions. Institutional Animal Ethics Committee. CPCSEA guidelines for Breeding and Stocking of Animals. Performance of Experiments. Transfer and acquisition of animals for experiment. Records. Power to suspend or revoke registration. Offences and Penalties (2 hrs)

National Pharmaceutical Pricing Authority

Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions. Sale prices of bulk drugs. Retail price of formulations. Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM) National Pharmaceutical Pricing Authority(NPPA) (3 hrs)

UNIT V **05 Hours**

Medical Termination of Pregnancy Act: Termination of Pregnancies, Offences& Penalties, Rules& Regulations (1 hr)

Right to Service Act (1hr)

Right to Information Act: Historical Background, Objectives, Features of the Act and its importance. Request for obtaining information, Exemptions. Designation of Public Information Officers; Constitution of Central and State Information Commissions; their Powers and Functions. Appeal and Penalties. (1 hr)

Right to Service Act (1hr)

Introduction to Intellectual Property Rights (IPR): Different forms of IPR and their protection. (1 hr)

ASSIGNMENTS:

1. Case studies relating to Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet Preparation Act, New Drug Policy, Professional Ethics, Drugs Price Control Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Diagnostic aids and appliances available in the market.

4. Collect Specimen Labels of selected drugs
5. Functioning of the Drugs control system in India
6. Important Amendments as per the current Year

TEXT BOOKS:

1. Mithal , B M. Textbook of Forensic Pharmacy. Calcutta: National; 1988.
2. Jain, NK. A Textbook of Forensic Pharmacy. Delhi: Vallabh prakashan ; 1995.
3. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
4. Eastern Book Company. The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.
5. Suresh B. A Textbook of Forensic Pharmacy. Birla Publication; 2010
6. Mehra M L. Hand book of drug law. University Book Agency;1997

REFERENCE BOOKS: (LATEST EDITION)

1. Drugs and Cosmetics Act/Rules by Govt. of India publications.
2. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
3. Narcotic drugs and psychotropic substances act by Govt. of India publications
4. Drugs and Magic Remedies act by Govt. of India publication
5. Bare Acts of the said laws published by Government.

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
CULTURAL EDUCATION III **STRATEGIC LESSONS FROM MAHABHARATA (T)**	**1**	**0**	**0**	**15**	**1**	**II**	**PD.208T**

SCOPE: The course is designed to impart knowledge about Mahabharata's depths and richness and its eternal values with respect to our Indian culture. To equip students with a knowledge of this epic and enable them to make a distinction between *dharma* and *adharma*, *right* and *wrong*, *morality* and *immorality*, and *goodness* and *badness* with an emphasis on Kaurvas (represented evil) and Pandavas (symbolized for goodness). The epic also discusses the inspirational female characters and regional tales from Mahabharata to gain a coherent understanding of its Indian values and culture. This epic also critically analyses the four goals of life: *kama* (pleasure), *artha* (wealth), *dharma* (duty) and *moksha* (liberation).

This epic also takes into consideration of Shri Krishna's strategies in Mahabharata, and lessons of dharma in Bhagavad Gita, and correlates them with present strategic management concepts. The strategic lessons from Mahabharata identify strategies and divinations that lie latent in this Ishihasa and convey them to the students for further ruminations.

COURSE LEARNING OUTCOMES

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

KNOWLEDGE

K1: Discuss the foundational concepts of Mahabharata (Understanding)

K2: Describe the characteristics of the classical Indian epic, with special reference to the Mahabharata. (Understanding)

K3: Explain the stories of Adi-Parva, Sabha-Parva, Aranyaka-Parva, Virata-Parva, Udyoga-Parva and Bhishma-Parva(Understanding)

K4: List the most important aspect of Bhishma Parva as Bhagavad Gita(Understanding)

K5: Discuss the stories of Drona-Parva, Karna-Parva, Shalya-Parva, Sauptika-parva, Stri-parva, Shanti-Parva and Anusasana-parva(Understanding)

K6: Enumerate the stories of Ashvamedhika-parva, Ashramavasika-parva, Mausala-parva, Mahaprasthanika-parva and Svargarohana-parva(Understanding)

SKILL

S1: Incorporate various strategic lessons suggested in Mahabharata in day-to-day life.

S2: Apply the principles of life skill ideas discussed in Mahabharata for materialistic life

S3: Design what Mahabharata is and what it is not, its contemporary relevance, and how it becomes part of Indians' day-to-day life

S4: Analyse inspirational female characters and regional tales from Mahabharata to gain a coherent understanding of its Indian values and culture.

S5: Assemble the imperativeness of Mahabharata in everyday life.

S6: Critically evaluate an overall idea of its contents, the multifarious lessons and possibilities of Mahabharata.

ATTITUDE

A1: Embrace the powerful influence of a good attitude on life and happiness

A2: Appreciate female characters, regional tales, traditions, and the spirit of harmonious living.

A3: Appreciate the relevance of Mahabharata for modern times.

A4: Follow the concepts of learning to live together, develop the attitude of sharing and care for a fellow being

A5: Display an attitude of honesty and sincerity and take responsibility for the societal needs

A6: Follow the principle of Mahabharata and Practicing self-compassion for others

COURSE CONTENTS

UNIT I -IV **4 Hours**

Mahābhārata - A Brief Summary (1hr)
A Preamble to the Grand Itihāsa (1hr)
The Unbroken Legacy (1hr)
Dharmic insights of a butcher (1hr)

UNIT V –VIII **4 Hours**

The Vows we take: Pratijñā (1hr)
Mahābhārata - The Encyclopaedia for Kingship and Polity Acumen (1hr)
Karna: The Maestro that Went Wide of the Mark (1hr)
Strategical Silhouette of An Extraordinary Peace Mission (1hr)

UNIT IX- XI **4 Hours**

Yajñaseni, A Woman from Fire (1hr)
Popular Regional Tales (2hr)
Death and Deathlessness (1hr)

UNIT XII- XIV **3 Hours**

Mahabharata- An All-Encompassing Text (1hr)
Mahabharatha- Whats and What Nots (1hr)
Mahābhārata in Adages (1hr)
Mahabharata

TEXT BOOK:

1. Achyutamrita Chaitanya. Strategic lessons from Mahabharata. Kollam. Amrita books. 2022.

REFERENCE BOOK:

2. Bibek Debroy. The Mahabharata. Penguin. India. 2015
3. Jayadayal Goyadka. Some Exemplary Characters of the Mahabharata. Shri Ji Books. India. 2021.
4. C. Rajagopalachari. Mahabharata. Bharatiya Vidya Bhavan.,41st edn. 2001

**Latest edition of the text books & reference books can be referred*

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
CULTURAL EDUCATION IV– LEADERSHIP LESSONS FROM RAMAYANA (T)	**1**	**0**	**0**	**15**	**1**	**II**	**PD.208T**

SCOPE: The course is designed to impart students to the depths and richness of Ramayana and its knowledge traditions. To equip students with practical knowledge learned from Ramayana and its characters for success in day-to-day life. The first chapter ***Balakanda*** deals with the origins and childhood of Rama. Sita's birth, betrothal, and marriage to Rama. The second chapter, ***Ayodhyakanda,*** includes the preparations for Rama's coronation in the city of Ayodhya, his exile into the forest, and the regency of Bharata. The third chapter **Aranya *Kanda*** contains the forest exile of Rama with Sita and Lakshmana. The kidnapping of Sita by the demon king Ravana. The fourth chapter ***Kishkinda kanda*** deals with Rama and Hanuman in Kishkindha. Chapter five ***Sundara kanda*** contains a detailed account of Hanuman's adventures, including his meeting with Sita. The sixth chapter ***Yudha Kanda*** includes the battle in Lanka between Rama and Ravana. Sita's fire ordeal. Rama's return to Ayodhya to reign over the ideal state. The seventh chapter ***Uthara kanda*** **includes** Sita's banishment. Lava and Kusha. Rama's dharma was fulfilled.

This epic also depicts vision and bringing different people together for a collective goal are unique qualities of a genuine leader like Rama and examples from Ramayana that are a source of motivation for leadership too.

COURSE LEARNING OUTCOMES

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

KNOWLEDGE

K1: Discuss general concepts of Great Itihasa (Understanding)

K2: Describe the characteristics of the classical Indian epic, with special reference to the Ramayana. (Understanding)

K3: Explain the stories of Balakanda, Ayodhya kanda, Aranya kanda and Kishkinda kanda

K4: Discuss the stories of Sundara kanda and Yudha kanda(Understanding)

K5: Describe the relevance of Ramayana and its learning aspects in modern life(Understanding)

K6: Explain the authenticity of Uttar Kanda and its attempt to explain the untold stories in the first six Kanda (Understanding)

SKILL

S1: Incorporate various strategic lessons mentioned in Ramayana for modern life.

S2: Apply the principles of life skill ideas discussed in Ramayana for materialistic life
S3: Design what Ramayana is and what it is not, its contemporary relevance, and how it becomes part of Indians' day-to-day life
S4: Analyse inspirational female characters and regional tales from Ramayana to gain a coherent understanding of it Indian values and culture.
S5: Appreciate and incorporate principles of Ramayana in everyday life.
S6: Interpret and incorporate an overall idea of its contents, the multifarious lessons and possibilities of Ramayana.

ATTITUDE

A1: Embrace the life principle of taking control of our thoughts
A2: Appreciate female characters, regional tales, traditions, and the spirit of harmonious living.
A3: Appreciate the principle of brotherhood and regular personal development in day-to-day life
A4: Follow a good attitude of compassion and love for others and practice mindfulness
A5: Appreciate life's purpose and live in alignment with our purpose
A6: Develop qualities of discipline, honesty, loyalty, and love.

COURSE CONTENTS

UNIT I - Introduction to the Great Itihasa (1hr)

UNIT II - Bala-Kāṇḍa: (Preparing for the renowned mission.(1hr)

And Ayodhya-Kāṇḍa: (Harbinger of an Entire Tradition of Nobleness**.)** (1hr)

UNIT III- Araṇya-Kāṇḍa: (Tale of the forest life) (1hr)

And Kishkindha-Kāṇḍa: (The Empire of Holy Monkeys.)(2 hrs)

UNIT IV - Sundara-Kāṇḍa: (Heart of the Ramayana)(1hr)

And Yuddha-Kāṇḍa: (The most popular part of the Ramayana)(1hr)

UNIT V - Ramayana and Modern-day learning(2 hrs)

UNIT VI - Ecological Awareness in the Ramayana(2hrs)

UNIT VII - Different Ramayana: (Epic that connects the world)(1hr)

UNIT VII- Uttara-Kāṇḍa: (An attempt to explain the untold stories)(2hr)

TEXTBOOKS:

1. C. Rajagopalachari. Ramayana. Bharatiya Vidya Bhavan., 34th edn. 2001

REFERENCE BOOK

2. Valmiki. Srimad Valmiki Ramayan English, Gita Press. Gorakhpur. 2020

**Latest edition of the text books & reference books can be referred*

THIRD YEAR

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
Pharmacology–II (T)	**3**	**0.5**	**0**	**75**	**3**	**III**	**PD.301T**
Pharmacology–II (P)	**0**	**0**	**3**	**75**	**2**	**III**	**PD.307**

SCOPE:

This subject provides an opportunity for the student to learn about different drugs used in various conditions, their classification based on their mode of action, detailed mechanism through which they act, doses and routes through which they are administered, precautions and adverse effects, contra-indications as well as the mechanism by which they interact with other drugs and the precautions to be taken while consuming the drugs. The subject emphasizes the role of antibiotics in human life and how scientists have developed various antibiotics to tackle different infections and how the specificity is maintained. It gives insights to the students regarding the rational use of antibiotics and how the irrational use is going to harm the man kind and contribute to the emergence of a post antibiotic era. Chemotherapeutic agents used in malignancy and the mechanisms and pathways involved in the management of malignancy are also included.
The subject also encompasses key aspects of cell and molecular biology, providing valuable insights into the mechanisms of chemotherapeutic agents used for various disease conditions. Various molecular biology techniques like PCR, genome sequencing and recombinant DNA technology are also covered here.

COURSE OUTCOMES:

Upon successful completion of the course, students shall be able to:

KNOWLEDGE
K1: Classify various drugs used in various conditions (Understanding)
K2: Describe the mechanisms, side effects, indications and interactions of various drugs in these classes
K3: Discuss the mechanisms by which drugs exhibit various adverse effects
K4: Comprehend the mechanisms involved in drug interactions
K5: Illustrate the importance of antibiotics and other drugs in extending the human lifespan
K6: Envisage the disaster due to antibiotic resistance
SKILL
S1: Discuss the rationale of using specific antibiotics for infection
S2: Predict the drug interaction in given prescription
S3: Implement the theoretical knowledge of drug mechanisms in practical experiments
S4: Perform various experiments following the SOPs and GLP of Lab
S5: Recognize various animal species used in animal experiments and their handling techniques
S6: Execute various in vitro and in vivo experiments
ATTITUDE
A1: Communicate effectively

A2: Collaborate and work in team
A3: Exhibit professionalism
A4: Participate in health care activities
A5: Update new advancements in health care system
A6: Exhibit responsibility towards the society

LECTURE WISE CONTENTS:

UNIT I: Neuropharmacology 10 Hours

Introduction to receptor-mediated actions of neurotransmitters like GABA, Glutamate, Glycine, serotonin, and dopamine (2 hrs)
Alcohol and disulfiram-like reactions (1hr)
General anesthetics: Stages of anesthesia, Pre-anaesthetic medications, Injectable and inhalational anesthetics (2hr)
Sedatives and hypnotics (1hr)
Anti-epileptics (2hrs)
Drugs used in Parkinson's disease and Alzheimer's disease (2 hrs)

UNIT II: Psychopharmacology 11 Hours

Antipsychotics (2hr)
Antidepressants (1hr)
Anti-anxiety agents (1hr)
Anti-maniacs- Lithium carbonate (1hr)
Endogenous opioid peptides and their receptors, Opioid analgesics and antagonists (2 hrs)
Hallucinogen, psychotropic substances (2 hrs)
Nootropics and CNS stimulants (2hrs)

UNIT-III Chemotherapy 11 hours

- General mechanism of antibiotics, antibiotic resistance (1hr)
- β lactams (1hr)
- Fluroquinolones (1hr)
- Tetracycline and Chloramphenicol (1hr)
- Macrolides, Aminoglycosides (2hrs)
- Sulfonamides and co-trimoxazole (1hr)
- Polypeptide antibiotics (1hr)
- Lincosamides (1 hr)
- Rational use of anti-biotics and proper disposal of antibiotics and other drugs (2 hrs)

UNIT-III Chemotherapy 15 hours

- Antifungal antibiotics 2 hours
- Antiviral agents 2 hours
- Anti-tuberculosis and anti-leprotic agents 3 hours
- Antimalarials 2 hours
- Anti-protozoal agents 1 hour
- Anthelmintic drugs 1 hour
- Anticancer agents 4 hours

UNIT-IV: Immunopharmacology 3 hours

- Immunosuppressants 2 hours
- Immunostimulants 1 hour

UNIT-V: Miscellaneous **5 hours**

5-HT modulators (2hrs)
Non-steroidal anti-inflammatory agents (2hrs)
Anti-gout drugs (1hr)

UNIT-VI The dynamic cell: The structures and functions of the Components of the cell (7 hrs)

- Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information. **2 hours**

- DNA replication: General bacterial and eukaryotic DNA replication. **1 hour**
- The cell cycle: Restriction point, cell cycle regulators and modifiers **1 hour**
- Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAPkinase, P38kinase, JNK, Ras and PI3-kinase pathways, biosensors**. 3 hours**

UNIT-VII The Gene: Genome structure and function **6 hours**

Gene structure: Organization and elucidation of genetic code

- Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families **3 hours**
- Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in prokaryotes and eukaryotes. **3hours**

UNIT-VIII RNA Processing: rRNA, tRNA and mRNA Processing 8 hours

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events. **2hours**

a) Altered gene functions: Mutations, deletions, amplifications, LOH, translocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.
1hour
b) The gene sequencing, mapping and cloning of human disease genes. Introduction to gene therapy and targeting. Recombinant DNA technology: principles. Processes (gene transfer technology) and applications**. 5hours**

ASSIGNMENTS:

- ❖ Drugs approved by FDA in last 5 years for treatment of various types of malignancies.
- ❖ Applications of Gene therapy in cancer treatment, recent success stories.
- ❖ Illustrate the various roles of serotonin
- ❖ New drugs approved in GI disorders. Recent updates on management of GI disorders.
- ❖ New antibiotics approved by FDA in the last 20 years and status of their clinical use.
- ❖ Antibiotic resistance and antibiotic stewardship program.

- ❖ Urinary antiseptics
- ❖ Novel antibiotics approved in last 10 years
- ❖ Polymerase chain reaction and its applications
- ❖ New generation sequencing
- ❖ CRISPR technology and its applications in disease management

TEXT BOOKS:

1) Tripathi, K. D. Essentials of medical pharmacology. 8th Ed, Jaypee, Delhi; 2018
2) R. S. Satoskar, S. D. Bhandarkar, Nirmala N. Rege. Pharmacology and Pharmacotherapeutics. 26th ed, Popular Prakashan; 2020.
3) James Ritter, Rod Flower, Graeme Henderson, Yoon Kong Loke, David MacEwan, Humphrey Rang Rang& Dale's Pharmacology. 9thed, Churchill Living stone, Edinburgh: Elsevier; 2020
4) PrasanR.Bhandari, Textbook of Pharmacology, Thieme Medical and Scientific Publishers; Noida; 2022
5) Alberts, B., Johnson, A., Lewis, J., Raff, M., Roberts, K., & Walter, P. Molecular biology of the cell. 6th Ed. New York: Garland Science: 2015
6) Cooper GM. The Cell: A Molecular Approach. 8th Ed. Sunderland (MA): Sinauer Associates; 2018
7) Ralph B and Edward D. Handbook of Cell Signaling, 2nd Ed. Elsevier/Academic Press: London:2010
8) John Dickenson, Fiona Freeman, Chris Lloyd Mills, Christian Thode, Shiva Sivasubramaniam. Molecular Pharmacology: From DNA to Drug Discovery. John Wiley & Sons; 2013.

REFERENCE BOOKS:

1. Goodman Gilman A,Rall T.W, Nies, A.I.S. and Taylor, P. Goodman and Gilman's The Pharmacological Basis of therapeutics. 13thEd, Mc Graw Hill: New York; 2017
2. Charles R Craig and Robert E Stitze. Modern Pharmacology with Clinical Application. 5th Ed , Lippincott Williams & Wilkins; London 2017
3. Katzung, B. G., Kruidering-Hall, M., & Trevor, A. J. Basic & Clinical Pharmacology, 15th Ed. McGraw-Hill Education: New York; 2019

PHARMACOLOGY–II (Practical)

LIST OF EXPERIMENTS:

1) Study of laboratory animals and their handling (a Mice, b.Rats, c.Guinea pigs, d. Rabbits).
2) Study of physiological salt solutions used in experimental pharmacology.
3) Study of laboratory appliances used in experimental pharmacology.
4) Study of use of anesthetics in laboratory animals.
5) To record the dose response curve of Ach using isolated ileum preparation.
6) To carry out bioassay of Ach using isolated ileum preparation by interpolation method.
7) Study of agonistic and antagonistic effects of drugs using isolated ileum preparation.
8) To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).

9) Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
   a) Analgesic property of drugs in analgesiometer.
   b) Anti-inflammatory effect of drugs in rat-paw edema method.
   c) Anticonvulsant activity of drugs in maximal electroshock and pentylenetetrazole methods.
   d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
   e) Locomotor activity evaluation of drugs using actophotometer and rotarod.
   f) Cardio tonic activity of drugs using isolated frog heart and mammalian heart preparations.
10) Estimation of protein by Lowry method
11) Myeloperoxidase activity in biological samples
12) Estimation of α-Amylase activity
13) Alpha-glucosidase inhibitory assay
14) Acetyl cholinesterase inhibition assay
15) Isolation and identification of DNA from various sources (banana, blood)
16) PCR and agarose gel electrophoresis

RECOMMENDED BOOKS:

1) Ghosh MN. Fundamentals of Experimental Pharmacology. 7th Ed., 2019. India: Hilton & Company
2) Kulkarni SK. Handbook of experimental pharmacology. 3rd Ed., 2021. Vallabhaprakashan
3) Arunachalam K, Sreeja PS. Bioassays in Experimental and Preclinical Pharmacology.1st ed., 2021. Springer Nature: New York USA.
4) Gupta SK. Drug Screening Methods. 2016. 3rd ed. Jaypee Brothers Medical Publishers (P) Ltd New Delhi, India.

Course Title	L	T	P	Total Hrs.	Year	Course Code
PHARMACEUTICAL ANALYSIS (T)	**3**	**0.5**	**0**	**75**	**III**	**PD.302T**
PHARMACEUTICAL ANALYSIS (P)	**0**	**0**	**2**	**50**	**III**	**PD.308P**

SCOPE:

This course focuses on comprehensively exploring the principles, techniques, and practical applications of diverse analytical techniques used in the pharmaceutical sector. The students will better understand various analytical methods employed in modern pharmaceutical laboratories for qualitative and quantitative analysis of dosage forms and biological samples. The curriculum is designed to provide students with essential knowledge concerning the principle, instrumentation, and application of spectroscopic and chromatographic techniques. Through theoretical explanations, participants will gain insight into the underlying phenomena of these analytical methods while delving into the hands-on practical aspects of operating different instruments. Moreover, this course goes beyond traditional techniques and acquaints students with **emerging analytical methods, including hyphenated techniques and their real-world applications (SDG 9)**. Such exposure to cutting-edge technologies will undoubtedly foster a deeper understanding of analytical practices within the pharmaceutical sector.

To ensure a well-rounded learning experience, the course incorporates hands-on laboratory sessions and **practical training**, allowing students to gain proficiency in instrument operation and data analysis. The students will be equipped with the necessary expertise in measuring drug concentrations in dosage forms and biological fluids, enabling healthcare professionals to monitor drug levels and adjust dosages accordingly. This practical competence contributes directly to ensuring drug **quality, safety, and efficacy**, which supports **public health initiatives and patient-centered healthcare (SDG 3).**

Furthermore, the course nurtures analytical thinking and scientific inquiry, equipping students with essential competencies to contribute meaningfully to pharmaceutical research, regulatory affairs, and clinical diagnostics. By promoting a strong foundation in pharmaceutical analysis, this program supports **equitable and inclusive education and lifelong learning opportunities (SDG 4)**, preparing graduates to address global healthcare challenges responsibly and innovatively.Upon successful completion, students will be empowered with scientifically grounded knowledge and practical expertise to ensure the quality and safety of pharmaceuticals, thereby playing a vital role in advancing healthcare standards and sustainable pharmaceutical practices.

COURSE LEARNING OUTCOMES:

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

KNOWLEDGE

K1. Define common terminologies used in instrumental analysis for a comprehensive understanding of their significance in clinical contexts. (Understanding)
K2. Discuss the interaction of matter with electromagnetic radiation and its wide-ranging applications in drug analysis (Understanding)
K3. Illustrate the fundamental principles and diverse applications of various spectroscopic and chromatographic techniques relevant to clinical research and drug development. (Applying)
K4. Apply essential practical skills using instrumental techniques, emphasizing the importance of proper sample preparations and solvent selection. (Applying)
K5. Employ appropriate instrumental techniques proficiently for both qualitative and quantitative drug analysis to make informed analytical decisions crucial for clinical diagnosis and treatment. (Analysing)
K6. Evaluate the reliability and accuracy of analytical results, identifying potential limitations and sources of error in the analysis process, particularly concerning clinical relevance and patient care. (Analysing)
Skill
S1. Compare operational techniques of UV, HPLC, fluorimeter, flame photometer, etc., focusing on their clinical applications and significance in healthcare settings. (Understanding)
S2. Develop basic practical skills using instrumental techniques relevant to clinical drug analysis and diagnostic applications. (Applying)
S3. Correlate quantitative and qualitative analysis of drugs using various analytical instruments, emphasizing their implications for patient diagnosis and treatment decisions. (Analysing)
S4. Analyze drug concentrations in the blood and other body fluids to optimize drug dosages for individual patients. (Analysing)
S5. Ensure the best possible outcomes in patient care by interpreting the data generated from analytical instruments and the significance of the results in a clinical context. (Analysing)
S6. Evaluate knowledge of interpretation of data obtained from spectra and of chromatograms (Evaluate)
Attitude

A1. Distinguish the critical role in advancing scientific knowledge and solving real-world clinical problems (Understanding)
A2. Show enthusiasm and curiosity towards exploring newer techniques and their applications. (Applying)
A3. Explore opportunities for continuous learning and staying updated with advancements. (Applying)
A4. Attain confidence in handling and operating analytical instruments effectively and safely. (Applying)
A5. Demonstrate professionalism by adhering to ethical standards and best practices in research and data handling. (Applying)

A6. Illustrate confidence in troubleshooting instrument-related issues and finding appropriate solutions. (Analysing)

COURSE CONTENTS:

UNIT-I Chromatography **30 Hours**

Principles and tecniques of Chromatography, Planar and Columnar chromatography, theories of chromatography. Choice of chromatographic condition. Concept and need for derivatization in pharmaceutical analysis (5 hrs)

Introduction to chromatographic techniques

- Paper Chromatography (1 hr)
- Thin Layer Chromatography (1 hr)
- High Performance Thin Layer Chromatography (2 hr)
- Column Chromatography: (1 hr)
- Gas Chromatography (2 hrs)
- Ion-exchange chromatography (1 hr)
- Gel filtration and affinity chromatography (1 hr)
- Chiral Chromatography(1 hr)

- **High Performance Liquid Chromatography** (10 hrs)
  Introduction, theory, instrumentation, selection of mobile phase, stationary phase, detectors, analytical and bioanalytical applications. Sample preparation of non-biological and biological samples. HPLC- method development, Data interpretation, HPLC in Bioavailability and Equivalence Studies. Hyphenation techniques, Ultra and nano-HPLC. **AI technologies used in hyphenated instruments** for data interpretation, method optimization, and decision support.

- **Electrophoresis** (5 hrs)
  Principles of separation, gel electrophoresis, SDS PAGE, Clinical and Pharmaceutical Applications. Quality control of protein-based drugs. Identifying and characterizing biomarker proteins. Studying protein-protein or DNA-protein interactions. Genomic and proteomic studies for novel drug targets.

UNIT-II Spectroscopy **21 Hours**

- **Absorption Spectroscopy:** (7 hrs) Introduction to Spectroscopy, Theory of electronic, atomic and molecular spectra, Fundamental laws of photometry, Beer-Lambert's Law, Principle and Application, Deviations and Limitations, Chromophores and Auxochromes in Biomolecules, Spectral Shifts and Solvent Effects, Instrumentation, Types of Spectrophotometers: Single-beam and double-beam spectrophotometers, Radiation Sources

and Monochromators, Detectors, Advanced Techniques like Derivative Spectroscopy, Derivatisation and Difference Spectroscopy, Applications in Pharmacy: Quality Control in Pharmaceuticals Single and Multi-Component Analysis: Spectroscopy in Biochemical and Pharmacokinetic Studies Equilibrium and Kinetics,Spectroscopic methods in Diagnosis and Monitoring glucose, cholesterol, and other critical parameters in clinical labs,

- **Fluoresence Spectroscopy** (7 hrs)

Introduction to Fluorescence Spectroscopy, Theory of Luminescence, Factors Affecting Fluorescence and Quenching, Instrumentation, Applications of Fluorescence Spectroscopy in Pharmacy and Clinical Settings, study of pharmaceutically important compounds estimated by fluorimetry. Fluorescence techniques employed for DNA/RNA quantification and enzyme activity assays. Fluorescence imaging and microscopic techniques: imaging tissues and monitoring drug absorption and distribution, deep tissue imaging with minimal damage using NIR. Application of NIR fluorophores in robotic surgery.

Inroduction to structural elucidation techniques and its clinical relevance

- Infrared Spectroscopy (3 hrs)
- NMR & ESR (2 hrs)
- X-RAY Diffraction (2 hrs)

UNIT-III SpectrometricTechniques 12 Hours

- **Mass Spectrometry**: (8 hrs)

  Basic principles of Mass Spectrometry Instrumentation: Ionization techniques: Electron ionization, Chemical ionization, Atmospheric pressure ionization (Electrospray ionization, APCI, and APPI), other sources: MALDI, ICP, etc. Mass Analyzers: Quadrupole, Time of flight, Orbitrap, High Resolution Mass Spectrometry, Hyphenated Mass Spectrometry: GC/MS, HPLC/UPLC-MS and Tandem Mass Spectrometry, Mass spectrum and applications. Over view of LCMS as an analytical technicque. A brief outline of omics study using hyphenated tandem MS including the scope of biomarkers study. **AI-driven advancements in mass spectrometry**, including machine learning models for enhancing spectral clarity, optimizing analytical methods, improving peak identification accuracy, and providing intelligent decision support in data interpretation.
- **Flame Photometry** (2 hrs)

Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques instrumentation and pharmaceutical applications.

- **Atomic Absorption Spectrometry**: (2 hrs)

Introduction, Theory, types of electrodes, instrumentation and applications.

UNIT-IV Quality Assurance 12 hours

- Concept of Quality Control and Quality assurance (2 hr)
- Total quality management, quality review and documentation. (2 hr)
- GLP, NABL, ISO 9000. (2 hrs)

- ICH- international conference for harmonisation guidelines. (4hrs)
- Qualification of equipment, validation of analytical instruments and calibration. (2 hrs)

PHARMACEUTICAL ANALYSIS PRACTICAL

LIST OF EXPERIMENTS:

1. Assay of Furosemide by absorptivity value method
2. Assay of Paracetamol tablets by UV- Spectrophotometry using calibration graph method, direct comparison method, absorbtivity value method and linear equation method
3. Assay of Chloramphenicol capsules by UV- Spectrophotometry using calibration graph method, direct comparison method and linear equation method
4. Assay of Rifampicin by colorimetry using absorbtivity value method
5. Assay of Paracetamol by colorimetry using calibration graph method, direct comparison method , absorbtivity value method and linear equation method
6. Assay of Salicylic Acid by Colorimetry
7. Determination of Isobestic Point of Bromocresol Green Solution at different pH
8. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
9. Estimation of drugs by Fluorimetric technique.
10. Quenching of quinine sulfate by fluorimetry
11. Assay of Paracetamol by HPLC
12. Assay of ranitidine by HPLC
13. Assay of Paracetamol in plasma by HPLC

SEMINAR/ASSIGNMENTS:

1. Case studies on HPLC trouble shooting
2. Protocol for the preparation of various biological samples for analysis
3. Analytical techniques for therapeutic drug monitoring (TDM)
4. SOP for method development and validation
5. Application of SDS PAGE in Proteomics
6. Analytical Softwares used like Waters' UNIFI® and MassLynx™, Agilent's MassHunter, Bruker's MetaboScape® and Compass® software

TEXT BOOKS:

1. Willard, H.H., Merritt, L.L., Dean, J.A., & Settle, F.A. Instrumental methods of analysis, 7th edition. EWP, East West Press Ltd., Delhi/Madras;1988.
2. Skoog, D.A., Heller, F.J., Nieman, T.A., Principles of Instrumental Analysis, WBSaunders;1997
3. Becket A.H. & Stenlake J.B. Practical Pharmaceutical Chemistry Vol. I and II, 4th edition, the Athlone Press of the University of London;1988.
4. Kenneth A. Connors. A Textbook Of Pharmaceutical Analysis, 3rd Edition. Wiley India Pvt. Limited; 2007.
5. Silverstein, R. M., Webster, F. X., Kiemle, D. J. Spectrometric Identification of Organic Compounds. 6th edition. Wiley India Pvt. Limited; 2006
6. Sethi, P. D. Quantitative Analysis of Drugs in Pharmaceutical Formulations. India: CBS Publishers & Distributors; 2015
7. Kemp, W. Organic Spectroscopy. United States: Palgrave Macmillan; 1991
8. Vogels Textbook Of Quantitative Chemical Analysis. India: Pearson Education; 2006.

REFERENCE BOOKS:

1. Indian Pharmacopoeia, 2018. Indian Pharmacopoeia Commission.The Controller of Publications, New Delhi; 2018.
2. BPC- Dept. of Health, U.K. for HMSO.
3. USP - Mack Publishing Co., Easton, PA.
4. The Extra Pharmacopoeia – The Pharm. Press, London.
5. Sethi, P. D. Sethi's HPLC High Performance Liquid Chromatography: Quantitative Analysis of Pharmaceutical Formulations, Volume 8. India: CBS Publishers & Distributors; 2015
6. Clarke, E. G. C. Clarke's Analysis of Drugs and Poisons: In Pharmaceuticals, Body Fluids and Postmortem Material. United Kingdom: Pharmaceutical Press; 2004
7. Remington, J. P. Remington: The Science and Practice of Pharmacy. United Kingdom: Lippincott Williams & Wilkins; 2006
8. Stahl, E. Thin-Layer Chromatography: A Laboratory Handbook. Germany: Springer Berlin Heidelberg. Higuchi. T and Hasen. E. B. Text Book of Pharm. Analysis. New York Inter Science Publishers; 2013

JOURNALS:

Biomedical Chromatography.
https://analyticalsciencejournals.onlinelibrary.wiley.com/journal/10990801

Journal of Pharmaceutical and Biomedical Analysis.
https://www.sciencedirect.com/journal/journal-of-pharmaceutical-and-biomedical-analysis

Clinical Chemistry and Laboratory Medicine (CCLM)
https://www.degruyter.com/journal/key/cclm/html#overview

Course Title	L	T	P	Total Hrs	Year	Course Code
Pharmacotherapeutics II (T)	**2**	**0.5**	**0**	**50**	**III**	**PD.303T**
Pharmacotherapeutics II (P)	**0**	**0**	**3**	**75**	**III**	**PD.309P**

SCOPE:

This course is designed to impart knowledge and skills necessary for the rational use of medicines. It provides an opportunity to learn and analyse pharmacotherapeutic management and its applications in various diseases including recent advances, approved treatment algorithms, and guidelines. It provides insight into the rationale behind medication selection for managing diseases as well as the role of pharmacological and non-pharmacological therapies to optimize patient care. Additionally, this course emphasizes understanding, identifying, evaluating, and preventing a variety of drug-related issues. Recent advances in pharmacotherapy and patient-specific management strategies are included and emphasized. The course emphasizes student-directed acquisition of necessary knowledge in the management of various diseases using AI approach.(SDG 4)

This course also, highlighting the importance of evidence-based decision-making in selecting the most effective medications for individual patients. Students will develop critical thinking skills to evaluate the risks and benefits of pharmacological treatments, ensuring that pharmacotherapy is tailored to optimize therapeutic outcomes and minimize adverse effects. By promoting safe, effective, and individualized treatment strategies, this course contributes to improving overall patient health and supports the goal of universal access to quality healthcare. (SDG 3)

COURSE LEARNING OUTCOMES:

Upon successful completion of the course, students shall be able to:

KNOWLEDGE

K1: Identify clinical manifestations and complications of specified diseases to guide pharmacotherapeutic decision-making.

K2: Describe the importance of differential diagnosis in the effective management of medical conditions

K3: Discuss the patient-specific parameters relevant to initiating and continuing drug therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response, and adverse effects)

K4: Explain non-pharmacological and pharmacological approaches for the management of various diseases

K5: Illustrate standard treatment guidelines used for various diseases/disorders

K6: Correlate the rationale behind the use of the current treatment algorithm for the management of various diseases

SKILL

S1: Compare the patient's current treatment regimen with the approved treatment algorithm for the management of various diseases

S2: Demonstrate the ability to recognize various drug-related problems

S3: Justify the rationale for changes in drug therapy and patients' clinical outcomes
S4: Demonstrate effective patient counselling skills in the clinical setting.

S5: Apply the pharmacological knowledge in the prevention and treatment of various disorders

S6: Solve the various drug-related problems in the patient drug therapy

ATTITUDE

A1: Communicate effectively with patients and other healthcare professionals

A2: Exhibit professionalism in all the clinical activities

A3: Display sincerity, punctuality, and integrity in all the academic and non-academic activities

A4: Support and collaborate with various stakeholders

A5: Follow the ethical values in maintaining the confidentiality of patient information

A6: Appreciate the effective reporting of drug-related problems among healthcare professional

LECTURE WISE CONTENTS:

Introduction to disease or disorders, Differential Diagnosis, Therapeutic goals, Non pharmacological and Pharmacological management including treatment algorithm & latest guidelines. Recent advancements associated with following diseases

UNIT- I Infectious disease 22 hrs

- Guidelines for rational use of antibiotics and surgical prophylaxis 2 hrs
- Septicaemia 2 hrs
- Respiratory Tract infections: Pneumonia, Influenza, Bronchitis 3 hrs
- Tuberculosis 2 hrs
- UTI 2 hrs
- Malaria 2 hrs
- Meningitis 2 hrs
- Endocarditis 2 hrs
- HIV&Opportunistic infections 2 hrs
- Fungal infections: Candidiasis, Aspergillosis, Dermatophytosis 3 hrs

UNIT- II Musculoskeletal disorders 10 hrs

- Rheumatoid Arthritis 2hrs
- Osteoarthritis 2hrs
- Gout 2hrs
- Systemic lupus erythematosus 2hrs
- Spondylitis 2hrs

UNIT-III Central Nervous System 7 hrs

- Alzheimer's Disease 2hrs
- Parkinson Disease 2hrs
- Epilepsy 2 hrs
- Artificial Intelligence in Neurological disorder managements 1 hr

UNIT-IV Psychiatric Disorders 11 hrs

- Schizophrenia 3hrs
- Affective Disorders 2hrs
- Anxiety Disorders 2hrs
- Sleep Disorders 2hrs
- Obsessive Compulsive Disorders 2hrs

PHARMACOTHERAPEUTICS–II PRACTICAL

Guidelines for Practical

Students are required to collect cases from various departments of AIMS hospital and a minimum of 6 cases (including sessional exam) should be presented in SOAP format and 20 should be recorded covering the most common diseases included in the theory syllabus. During the case collection, students shall be able to

- Understand the changes in physiological functioning in the given disease condition of the patient.
- Learn the normal values of laboratory parameters applicable to each case

- Able to interpret the variations in laboratory parameters and justify the reasons for variations.
- Explain the rationale for the progress of changes in drug therapy & and clinical outcome
- Learn the PK/PD parameters of each drug in the treatment regimen and correlate it with the clinical outcome of the patient.
- Compare the current treatment regimen of the patients with the approved treatment guidelines
- Learn the antibiotic policies followed in our hospital.

ASSIGNMENTS:

- Case study analysis: Drug therapy for complex condition
- Application of pharmacogenomics in optimizing drug therapy for individual patients.
- Healthcare Technology and Digital Health in Drug Therapy Management
- Current challenges in managing multi drug bacterial infections in hospitalized patients.
- Recent trends in the management of Tuberculosis in patients with chronic liver disease.
- Current management and challenges of invasive fungal infections in ICU.
- National Health schemes in India: Impact on pharmaceutical care
- Different psychiatric assessment scales used in clinical setting for assessing severity of symptoms and treatment progression

TEXT BOOKS:

- Walker, Roger. Clinical Pharmacy and Therapeutics.5th ed. Edinburgh: Churchill Living Stone publication;2012
- Dipiro JT. Pharmacotherapy: A Pathophysiologic approach. 11thed.NewYork: McGraw Hill;2017.
- HerfindalEricT.Clinical Pharmacy and Therapeutics.5th ed. Philadelphia: LPWW;1988
- Robbins and Cotran. Pathologic basis of disease. 8th ed. Philadelphia: Elsevier;2003

REFERENCE BOOKS:

- Kodak-Kimble, Mary Ann. Applied Therapeutics: The Clinical Use of Drugs. 11th ed. Philadelphia: LPWW;2009
- Porth's Essentials of Pathophysiology. 5thed, Philadelphia: LPWW;2011
- Brunton L, Lazo JS. Goodman & Gilman's The Pharmacological Basis of Therapeutics. 13th ed. New York: McGraw Hill;2006

Course Title	L	T	P	Total Hrs.	Year	Course Code
MEDICINAL CHEMISTRY (T)	**3**	**0.5**	**0**	**75**	**III**	**PD.304T**
MEDICINAL CHEMISTRY (P)	**0**	**0**	**2**	**50**	**III**	**PD.310P**

SCOPE:

This course is designed to impart fundamental knowledge, and skills to design the structure and correlate with the functions of drugs. It includes details on Chemistry, Mechanism of action, adverse effects, uses of Chemotherapeutic Agents, and the synthesis of some important drugs. The course also covers the basics of modern drug design techniques, including QSAR and combinatorial chemistry. This subject will introduce students to structure-activity relationships, which help to predict and evaluate the therapeutic effects of different drugs. In alignment with the United Nations Sustainable Development Goals (SDGs), particularly: SDG 3(Good Health and Well-being), SDG 9(Industry, Innovation, and Infrastructure), SDG 12 (Responsible Consumption and Production) SDG 13 (Climate Action) this syllabus emphasizes the design and development of safer, effective, and environmentally responsible drugs. Students will explore modern drug discovery approaches including role of AI in drug discovery, computer-aided drug design (CADD), and prodrug strategies that aim to enhance therapeutic efficacy while minimizing ecological and health risks.

The course helps to equip the students with the necessary knowledge and skills for the synthesis and analysis of new synthetic molecules. In addition to the foundational knowledge of drug design and synthesis, this course provides students with a comprehensive understanding of pharmacokinetics and pharmacodynamics, enabling them to assess how drugs interact with the body at a molecular level. The curriculum also provides a commitment to continuous learning and staying updated with advancements in the field of medicinal chemistry

COURSE OUTCOMES:

Upon successful completion of this course, students shall be able to;

KNOWLEDGE

K1: Memorize the chemistry of drugs concerning their biological activity
K2: Describe the concept of rational drug design, prodrug and different modern drug design techniques
K3: Summarize knowledge in the chemistry of different anticancer, antibiotics, and different anti-viral agents
K4: Outline the AI tools and platforms used in medicinal chemistry.
K5: Sketch the synthesis of therapeutic useful drug molecules using available synthetic pathways
K6: Illustrate the SAR of some important drug classes concerning their biological activity

SKILL

S1: Prepare compounds of medicinal interest using available synthetic and new pathways

S2: Analyse the effects of various functional groups in the therapeutic activity of drugs

S3: Calculate the percentage purity of synthesized medicinally important compounds by performing assays per pharmacopoeial procedure

S4: Estimate the amount of drug present in the synthesized compounds

S5: Apply the significance of physicochemical parameters in the therapeutic actions of drugs

S6: Employ standard operating procedures (SOPs) and Good Laboratory Practices (GLP) while performing experiments

ATTITUDE

A1: Participate in group discussions for the design of a new synthetic pathway of therapeutic agents

A2: Appreciate the relevance of Structural Activity Relationships in the biological action of drugs

A3: Explore opportunities for continuous learning and staying updated with advancements in the field of medicinal chemistry

A4: Accept the significance of Medicinal Chemistry in the healthcare system

A5: Follow a safe, green, and eco-friendly approach in developing the synthetic scheme of medicinal compounds

A6: Appreciate self-motivation and the ability to engage in self-directed learning

COURSE CONTENTS:

UNIT-1 Modern concept of rational drug design **9 Hrs**

- A brief introduction to Quantitative Structure-Activity Relationship (QSAR) (3 hrs)
- Combinatorial chemistry and computer-aided drug design(CADD) (2 hrs)
- Prodrugs: Basic concepts and application of prodrugs design. (2 hrs)
- Role of Artificial Intelligence (AI) in Modern Drug Discovery and Medicinal Chemistry (2 hrs)

A study of the development of the following classes of drugs, including Classification SAR, synthesis of important drugs (Superscripted by *), Structure not necessary (Superscripted by $^{\$}$), chemical nomenclature, uses, newly approved drugs under each category and brand names of important marketed products.

UNIT- II Anti-infective agents

Antifungal Agents **4 Hrs**

Azoles: SAR of azole antifungals, Econazole, Miconazole, Ketoconazole, Fluconazole, Clotrimazole*, Voriconazole$^{\$}$. Posaconazole$^{\$}$, Isavuconazole$^{\$}$ (2 hrs)

Antifungal Antibiotics: Amphotericin$^{\$}$, Nystatin$^{\$}$, Griseofulvin (1 hr)

Miscellaneous: Tolnaftate*, Micafungin$^{\$}$ (1 hr)

Urinary tract anti-infectives **2 Hrs**

SAR of quinolone antibacterial agents (1 hr)
Nalidixic acid, Norfloxacin, Ciprofloxacin*, Ofloxacin, Nitrofurantoin*, Methanamine, fosfomycin (1 hr)

Antitubercular agents **3 Hrs**

Synthetic anti-TB agents: Isoniazid*, Ethionamide, Pyrazinamide, Paraaminosalicylic acid*, Ethambutol (2 hrs)
Anti TB antibiotics: Rifampin[$], Capreomycin[$], Streptomycin[$]
XDR, and MDR TB (1 hr)

Antiviral agents and Anti-AIDS agents **6 Hrs**

Viral life cycle, Viral diseases
Amantadine, Rimantadine (1 hr)
Acyclovir*, Ganciclovir, Valcyclovir Iodoxuridine*, Zidovudine, Lamivudine[$], Didanosine*, Efavirenz[$], Nevirapine (4 hrs)
New Antiviral Drugs for Treatment of Viral diseases: Remdesivir[$], Nirmatrelvir[$], Ritonavir[$], Molnupiravir[$], Nitazoxanide[$], Ribavirin[$] and Ivermectin[$] (1 hr)

Antiprotozoal agents **2 Hrs**

Introduction to protozoal diseases and causative organisms (1 hr)
Metronidazole*, Diloxanide Furoate*, Dehydroemetine[$], Nifurtimox (1 hr)

Anthelmintics **2 Hrs**

Benzimidazoles: Mebendazole, Albendazole*, Piperazine, Diethyl carbamazine*.

Antimalarials **4 Hrs**

Etiology of malaria
Quinoline Antimalarials: SAR of Quinoline Antimalarials (1 hr)
Chloroquine phosphate*, Amodiaquine, Pamaquine, Primaquine*, Proguanil, Cycloguanil, Pyrimethamine (2 hrs)
Artimisine derivatives (1 hr).

UNIT-III Sulfonamides and Sulfones **4 Hrs**

Classification of sulphonamides, SAR of Sulfonamides (1 hr)
Sulfadiazine*, Sulfamethoxazole, Sulfacetamide*, Sulfasalazine (2 hrs)
Folate Reductase Inhibitors: Trimethoprim*,
Synergistic Action of Cotrimoxazole. Sulfones: Dapsone* (1 hr)

UNIT-IVAntibiotics **7 Hrs**

Classification of antibiotics, Chemistry of penicillin (1 hr)
Beta-lactam antibiotics: Penicillins. Penicillin G, Ampicillin, Amoxicillin, Cloxacillin (1 hr)
Beta-lactamase inhibitors: Clavulanic Acid[$], Thienamycin[$], Cephalosporins: Cephalexin, Cefadroxil, Cefuroxime (2 hrs)
Aminoglycosides: Neomycin[$], Amikacin[$], Gentamicin[$] (1 hr)
Tetracycline: Chemistry and SAR of tetracycline, Chlortetracycline[$], Doxycyclin[$](1 hr).

Macrolides: Erythromycin[$], Azithromycin[$]
Miscellaneous: Bacitracin, Mupirocin, Chloramphenicol*(1 hr).

UNIT-V Antineoplastic agents **7 Hrs**

Alkylating agents: Mechanism and SAR of alkylating agents, Cyclophosphamide*, Mechlorethamine*, Chlorambucil* (2 hrs).
Antimetabolites: Mercaptopurine*, Fluorouracil, (1 hr)
Methotrexate Antibiotics: Daunorubicin[$], Doxorubicin[$], Dactinomycin[$], Bleomycin[$](1 hr)
Plant products: Etoposide[$], Taxol[$], Vincristine[$] and Vinblastine[$]
Miscellaneous: Cisplatin, Interferons (1 hr).
Newer Anticancer Drugs: Lurbinectedin[$], Rituximab[$], Cetuximab[$], decitabine[$], Pemigatinib[$], Talazoparib[$], Olaparib (2 hrs)

UNIT-VI Cardiovascular agents:

a) Antianginal agents and vasodilators **2Hrs**

Nitro vasodilators: Isosorbide Dinitrate, Nitroglycerin*, Pentaerythritol tetranitrate*, Nicorandil

b) Antiarrhythmic agents: **3 Hrs**

Class I: Quinidine, Procainamide*, Phenytoin*, Lidocaine*
Class II: Beta-blockers- Propranolol*
Class III: Amiodarone, Bretylium
Class IV: Calcium Channel Blockers: Verapamil, Diltiazem

c) Antihypertensive agents: **4Hrs**

Beta-blockers- Atenolol*, Metoprolol ACE inhibitors: Captopril*, Enalapril, Fosinopril Angiotensin antagonists: Telmisartan, Losartan Calcium channel blockers: Nifedipine*, Amlodipine, Felodipine Adrenergic agents: Clonidine*, Methyldopa. Adrenergic antagonists: Prazosin, Reserpine[$]. Vasodilators: Hydralazine, Minoxidil

d)Diuretics: **3Hrs**

Carbonic anhydrase inhibitors: Acetazolamide* Thiazides: SAR of thiazide diuretics Chlorthiazide, Hydrochlorothiazide. Loop diuretics: Furosemide*, Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol.

e) Antihyperlipidemic agents: **2Hrs**

Types of hypolipoproteinaemia, Clofibrate*, Fenofibrate, Cholestyramine, Lovastatin, Simvastatin, Atorvastatin, Probucol.

UNIT-VII Anticoagulants and Antiplatelet agents: 1 Hr

Warfarin*, Dicoumarol*, Anisindione, Aspirin, Clopidogrel

UNIT-VIII Hypoglycaemic agents: 3Hrs

Sulfonylureas: Tolbutamide*, Chlorpropamide*, Glipizide Biguanides: Metformin*. Metaglinides: Nateglinide Thiazolidinediones: Pioglitazone, Rosiglitazone. Glucosidase inhibitors: Acarbose[$], Voglibose[$] Miscellaneous: Miglitol

UNIT-IX Thyroid and Antithyroid agents 2 Hrs

Bio-synthesis of Thyroid hormone (1 Hr)
L-thyroxine, L- Threonine**,** Propylthiouracil, Methylthiouracil, Methimazole*, Carbimazole (1 Hr)

UNIT- X Anticonvulsants 2Hrs

Classification of anticonvulsants: Phenytoin*, Ethosuximide*, Trimethadione, Carbamazepine, Valproic acid

UNIT-XI Hypnotics and sedatives 3 Hrs

Classification of hypnotics and sedatives: Phenobarbitone*, Diazepam, Alprazolam, Zolpidem, Chlordiazepoxide, Triclofos sodium, SAR of barbiturates, and benzodiazepines

MEDICINAL CHEMISTRY PRACTICAL

LIST OF EXPERIMENTS:

I. Synthesis of medicinally important compounds/Intermediates

1. Preparation of 2,3-Diphenylquinoxaline
2. Preparation of 7- Hydroxy 4- Methyl Coumarin
3. Microwave-assisted synthesis of Phenytoin
4. Microwave-Assisted Synthesis of Aspirin
5. Preparation of Benzocaine
6. Preparation of phenothiazine from diphenylamine
7. Preparation of benzimidazoles from OPDA

II. Assay of some medicinally important synthesized compounds

III. Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors, and acceptors for the class of drugs course content using drug design software (Swiss ADME) Drug likeliness screening (Lipinski RO5) (Demo)

SEMINAR/ASSIGNMENTS:

1. Identify ten existing therapeutic agents which are used for drug repurposing.
2. Identify the newly approved drugs under each of the following categories, mention the advantages of newly approved drugs over existing drugs and their brand names

- Antifungal Agents
- Antitubercular agents
- Antiprotozoal agents
- Anthelmintic agents
- Antimalarial agents
- Antineoplastic agents
- Antiviral agents and Anti-AIDS agents

TEXT BOOKS:

1. John MB, John HB. Wilson and Gisvold's Textbook of Organic, Medicinal and Pharmaceutical Chemistry. 12th ed. New York, Philadelphia: Wolters Kluwer, Lippincott Williams & Wilkins; 2011.
2. Victoria, Roche, David AW, Thomas LL. Foye's Principles of Medicinal Chemistry. 8th ed. New York, Philadelphia: Lippincott Williams & Wilkins, Wolters Kluwer; 2019.
3. Ilango K, Valentina P. Medicinal chemistry for Pharm D.1st ed.Keerthi Publishers;2012.
4. Patrick G. L. An Introduction to Medicinal Chemistry. 4th ed. New York: Oxford University Press; 2009.
5. Mann F.G & Saunders B C. Practical organic chemistry. 4th ed. India: Pearson Education India; 2009(Practical)
6. Vishnoi N.K. Advanced Practical organic chemistry. 3rd ed. India: S. Chand; 2010 (Practical).
7. Govt. of India. Indian Pharmacopoeia 2022 (Volume I ,II, III &IV),9th ed.. India: The Indian Pharmacopoeia Commission; 2022. (Practical)

REFERENCE BOOKS:

1. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
2. Sriram D, Yogeeswari P. Medicinal Chemistry.4th ed. Dorling Kindersley(India) Pvt Ltd;2013.
3. Welly M.E., M.E. Walffred. Burger's Medicinal Chemistry, 1 – 8. 8th ed.Newyork: Wiley Interscience Publication;2005.
4. Pandeya SN, Dimmock JR, An introduction of Drug design. 2nd ed. New Age International, 2019.
5. Brian S. F, Antony J.H, Peter W.G.S & Austin R.T. Vogel's textbook of Practical Organic Chemistry. 5th ed. India: Pearson Education India; 2003(Practical)

**Latest edition of the text books & reference books can be referred*

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
PHARMACEUTICAL FORMULATIONS (T)	**2**	**0.5**	**0**	**50**	**2**	**3**	**PD. 305T**
PHARMACEUTICAL FORMULATIONS (P)	**0**	**0**	**3**	**75**	**1.5**	**3**	**PD. 311T**

SCOPE:

This course focuses on the development, manufacturing, and delivery of active pharmaceutical ingredients into effective and safe dosage forms. Through this course, students will gain an in-depth understanding of the principles of drug formulation, manufacturing processes, and quality assurance for both novel and conventional drug delivery systems .It covers formulation concepts, including particle technology, which plays a pivotal role in preformulation and formulation studies The course emphasizes the art and science of combining APIs with excipients to develop various dosage forms, such as tablets, capsules, injections, inhalations, and more.

The curriculum explores techniques and equipment used for formulation development, small-scale preparation, and commercial production. It also highlights the importance of quality control measures to ensure finished products meet safety and efficacy and stability standards. The course fosters an attitude of meticulous attention to detail, encouraging students to apply theoretical knowledge to practical problem-solving in formulation development. Furthermore the course introduces novel drug delivery systems and their advantages and disadvantages. It explores the design and rationale behind modified-release dosage forms and advanced delivery platforms. The course addresses sustainability by exploring environmental aspects of propellant-free technologies, the advancement of digitalised DPIs, and the role of AI in enhancing pharmaceutical formulations and smart drug delivery within dry powder inhalation systems.Overall this course prepares students to approach the field of pharmaceutical development with an innovative outlook, fostering adaptability and continuous learning to meet the dynamic needs of the healthcare industry.

COURSE LEARNING OUTCOMES

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

KNOWLEDGE

K1: List different types of dosage forms and its classification

K2: Discuss the science of particle technology.

K3: Describe different techniques in preparation of various formulations

K4: Explain the quality control parameters for the formulations

K5: Distinguish conventional and novel drug delivery systems

K6. Analyse drug degradation and stability testing parameters

SKILL

S1: Prepare pharmaceutical tablets and capsules
S2: Evaluate prepared tablets
S3: Perform sealing of ampoules
S4: Prepare cold cream, lipstick and shampoo
S5: Discuss the labelling and packaging specifications of pharmaceutical formulations
S6: Determine the expiry date of a drug using stability data.

ATTITUDE

A1: Participate in group discussions
A2: Appreciate all the initiatives of the institution
A3: Follow emerging trends in the field of pharmaceutical sciences
A4: Foster Critical thinking
A5: Cultivate empathy and compassion

A6: Exhibit Professionalism

COURSE CONTENTS:

UNIT I Powder Technology **2 hours**

Particle size, Surface area, Derived properties of powder, porosity, packing arrangement. (1hrs)

Flow property and determination. (1hrs)

UNIT II Tablets **15 hours**

Definition,Advantages and disadvantages, Classification (4 hrs)
Excipients,Processing&Granulation techniques(3 hrs)
Compression and Machines, Processing problems (2 hrs)
Quality control and evaluation. (3 hrs)

Tablet coating

Advantages, Materials, Types (1hrs)
Methods,Equipments, (1hrs)
Quality control tests, Processing problems(1hrs)

UNIT III Capsules **7 hours**

Definition,Advantages and disadvantages,Types,Different sizes and shapes. (1 hrs)

Raw material for capsule shell manufacturing,Capsule shell production. (2 hrs)
Production and filling of hard gelatin capsules. (1 hrs)
Production of soft gelatin capsules (1 hrs)
Quality control tests**.** (2 hrs)

UNIT IV Inhaled formulations 8 hours

Pharmaceutical Aerosols

Definition,Advantages ,Propellants(1 hrs)
Containers, Components (1 hrs)
Types of aerosol systems, Aerosol Filling, Evaluation tests (2 hrs)

Dry powder inhalations

Formulation of DPIs. (2 hrs)
Environmental impact of inhalers (1 hr)
Digitalised DPIs and smart inhalers (1 hr)

UNIT V Sterile Dosage Forms 12hours

Parenterals

Definition, Types,Advantages and disadvantages, Large and small volume Parenterals,Official Preparations. (2 hrs)
Formulation,Vehicles and Excipents(2 hrs)
Layout , Facilities for parenteral Manufacturing area(3 hrs)
Sterilisation and Quality Control tests. (3 hrs)

Ophthalmic Preparations

Types: Eye drops, Eye Lotions,Eye ointments ,Contact lens solutions .General formulation aspects of ophthalmic formulations. (2 hrs)

UNIT VI Controlled and Novel Drug delivery Systems 4 hours

Definition, Rationale and concept of
Controlled drug delivery systems, Delayed, Extended and sustained drug delivery systems
Transdermal, Buccal, rectal , parenteral , implants ,ocular and nasal drug delivery systems. (4 hrs)

UNIT VII Satbility studies 2 hours

Physical and chemical factors affecting chemical degradation of pharmaceutical product. (1 hr)

Accelerated stability testing in expiration dating of pharmaceutical dosage forms. (1 hr)

PHARMACEUTICAL FORMULATIONS (Practicals)

LIST OF EXPERIMENTS:

1. Formulation and evaluation of Tablets

a. Determination of angle of repose and flow property of granules.
b. Ordinary compressed tablet-wet granulation
c. Tablets prepared by direct compression.
d. Soluble tablet.
e. Chewable tablet

2. Tablet coating (demonstration)

3 .Formulation and filling of hard gelatin capsules

4 Formulation of parenterals

a.Sealing of ampoules

b Dextrose and Sodium chloride infusion.

c. Formulation of eye drops/eye ointments

5. Cosmetic preparations

a. Cold cream and vanishing cream
b. Clear liquid shampoo
c. Tooth paste and tooth powders

6. Formulationof Liquid Preparation

Syrups
Antacid Suspensions

7. Determination of stability studies of aspirin by accelerated stability study

ASSIGNMENTS:

1. Discuss the importance of paediatric-specific formulations in healthcare considering the physiology, pharmacokinetics, and drug administration requirements.

2. Explore the functions of excipients in pharmaceutical formulations, including their role in stability, solubility, bioavailability, and patient acceptability.

3. Investigate various commercially available drug delivery systems, including immediate-release, controlled-release, sustained-release, and targeted delivery systems.

4. Prepare stability study protocol as per ICH guidelines.

5. Discuss the impact of 3D printing, personalized medicine, and digital drug delivery systems and other innovations in formulation technology for patient care.

6. Detail the components of a dry powder inhaler device including the mouthpiece, dose counter, drug reservoir and the importance of proper use of device for achieving optimal treatment outcomes

TEXT BOOKS:

1. Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz. Pharmaceutical dosage forms: Tablets, second edition - In Three Volumes . 8thEd .New York : Dekker, ©1989—90
2. Leon Lachman, Herbert.A.Lieberman, Joseph.L.Kanig . The theory and practice of Industrial Pharmacy, 3rd Ed. Varghese Publishing House, 1990.
3. E. A. Rawlins. Bentley's Textbook Of Pharmaceutics. 8thEd .Elsevier 1977
4. Carter S J. Cooper and Gunn's Tutorial Pharmacy. 12th edition New Delhi, India: CBS Publishers & Distributors; 2021.

REFERENCE BOOKS:

1. Loyd V. Allen .Jr .PhD, Nicholas G. Popovich, PhD, Howard C. Ansel, PhD. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems. Lippincott Williams & Wilkins, 2005
2. Michael E Aulton. Pharmaceutics: The Science of Dosage form design. 2nd ed. Edinburgh ; New York : Churchill Livingstone, 2002.
3. Joseph P Remington, Alfonso R Gennaro . Remington. The science and practice of pharmacy. 20th ed. Baltimore, Md : Lippincott Williams & Wilkins, ©2000.
4. .Britain Pharmacopoeia / Unites States Pharmacopoeia / Indian Pharmacopoeia /
5. Martin A, Bustamante P, Chun AHC. Physical Pharmacy, Physical Chemical Principles in Pharmaceutical Sciences. 4th edn, Lippincott Williams and Wilkins, Philadelphia, 2001

JOURNALS:

1. Journal of Pharmaceutical Sciences-Elsevier
2. Pharmaceutical Research-Springer
3. Drug Development and Industrial Pharmacy-Taylor & Francis
4. Pharmaceutical Development and Technology - Taylor & Francis

**Latest edition of the text books & reference books can be referred*

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
PATHOPHYSIOLOGY - II (Theory)	**2**	**0.5**	**0**	**50**	**2**	**III**	**PD.306T**

SCOPE:

This course focuses on the fundamental mechanisms underlying disease processes, with particular attention to the pathophysiology of various disorders across multiple systems. It covers a wide range of conditions affecting the central nervous system, psychiatric disorders, cancer, pain-related conditions, gastrointestinal disorders, and more. The course emphasizes the etiology, pathogenesis, clinical manifestations, and complications associated with these diseases. Students will gain an understanding of how these conditions arise, progress, and affect physiological functions. Additionally, the course will explore factors such as genetics, environmental influences, and lifestyle choices that contribute to the initiation and development of diseases.

The content also addresses the clinical implications and challenges of managing various pathologies, with a specific focus on recognizing disease patterns, understanding their biological basis, and diagnosing these conditions effectively. The course will also provide an in-depth study of systemic diseases like cancer, mental health disorders, gastrointestinal diseases, and conditions in obstetrics, gynaecology, ophthalmology, and dermatology. Students will explore how diseases manifest clinically, their progression, and their impact on the human body. The course also introduces students to the emerging role of Artificial Intelligence (AI) in predicting disease progression, enhancing diagnostic accuracy, and supporting clinical decision-making in the context of complex pathophysiological conditions. By the end of the course, students will be equipped with the knowledge to analyse the pathophysiological mechanisms and apply this understanding to clinical practice, providing optimal patient care in diverse healthcare settings.

COURSE LEARNING OBJECTIVES:

Upon completion of the subject student shall be able to

KNOWLEDGE

K1 : Define the basic terminologies related to the pathophysiology of infectious, musculoskeletal, neurological, and psychiatric disorders.

K2 : Classify tumours and differentiate between benign and malignant neoplasms.

K3 : Describe the mechanisms underlying pain and its related disorders.

K4 : Examine the emerging role of AI in understanding the complex pathological processes.

K5 : Analyse how the body reacts to eliminate the disease and the functional changes associated with the disease.

K6 : Explore the pathophysiology basis of chronic diseases and their societal impact.

SKILL

S1: Differentiate between normal and abnormal inflammatory responses related to the disease conditions.

S2: Evaluate a disease condition based on the underlying pathophysiological mechanisms.

S3: Apply critical thinking in the context of the pathophysiology of various diseases involving multiple systems.

S4 : Interpret signs and symptoms of infectious diseases and correlate them with diagnostic test results for accurate diagnosis and prognosis.

S5: Integrate knowledge of environmental risk factors to propose preventive health strategies.

S6: Exhibit competency in diagnosing and discussing cancer progression and management options.

ATTITUDE:

A1 : Appreciate the diversity of patients' cultural backgrounds, beliefs, and values in the context of pathophysiological conditions.

A2 : Counsel patients about their disorders, including its pathophysiology, risk factors, and management strategies.

A3 : Recognize the emotional and psychological aspects of illness and demonstrating sensitivity in interactions with patients, families, and caregivers

A4 : Create awareness among patients on the importance of lifestyle recommendations, such as diet modification, exercise, and stress management, to optimize overall health.

A5 : Demonstrate confidence in pathophysiology knowledge when assessing a patient’s condition.

A6 : Reflect on inter professional approaches to improve health outcomes for people with common health conditions.

LECTURE WISE CONTENTS:

Definition, Etiology, Pathogenesis, Clinical manifestations, and complications of the following diseases

UNIT- I Disorders of Central Nervous System 5 Hours

- Alzheimer's disease (2 hr)
- Parkinsonism (1 hr)
- Epilepsy (2 hr)

UNIT- II Psychiatric disorders 6 Hours

- Schizophrenia (2 hr)
- Affective disorders (1 hr)
- Anxiety disorders (1 hr)
- Sleep disorders (1 hr)
- Obsessive compulsive disorders (1 hr)

UNIT- III Cancer Pathophysiology 7 Hours

- General aspects of neoplasia and definition, terminology, Classification of tumours and differences between benign and malignant tumours (1 hr)
- General biology of tumours (1 hr)
- Etiology and pathogenesis of cancer (1 hr)
- Biological effects of radiation (1 hr)
- Spread of malignant tumours (1 hr)
- Invasions and metastasis (1 hr)
- Patterns of spread, disturbances of growth of cells and Histological diagnosis of malignancy (1 hr)

UNIT- IV Pain & related disorders 5 Hours

- Pain pathway (2 hr)
- Neuralgias (1 hr)
- Headaches (1 hr)

UNIT- V Gastrointestinal disorders 8 Hours

- Peptic ulcer disease (2 hr)
- Inflammatory bowel disease (2 hr)
- Liver cirrhosis & alcoholic liver disease (3 hr)
- Hepatitis & Jaundice (1 hr)

UNIT- X: Musculoskeletal disorders 6 Hours

- Rheumatoid arthritis (2 hr)
- Osteoarthritis (1 hr)

- Gout (1 hr)
- Systemic lupus erythematous (1 hr)
- Spondylitis (1 hr)

UNIT VII Disorders of Obstetrics & Gynaecology 3 Hours

- Dysmenorrhea (1 hr)
- Polycystic Ovarian Syndrome (1 hr)
- Infertility (1 hr)

UNIT VIII Disorders of Ophthalmology 4 Hours

- Glaucoma (2 hr)
- Viral & bacterial conjunctivitis (2 hr)

UNIT IX Disorders of Dermatology 5 Hours

- Psoriasis (2 hr)
- Eczema (1 hr)
- Impetigo (1 hr)
- Scabies (1 hr)

UNIT-XI: Application of AI in understanding disease mechanisms and predicting disease progression 1 Hour

- AI in cancer: early detection, tumour classification, and prognosis prediction to guide personalised treatment decisions

ASSIGNMENTS:

1. Discuss the molecular mechanisms underlying the progression of Alzheimer's disease, highlighting the roles of amyloid plaques, tau tangles, and neuro inflammation in disease pathogenesis.
2. Investigate the cellular and molecular mechanisms involved in cancer metastasis, highlighting the role of the epithelial-mesenchymal transition (EMT) and micro environmental factors in tumour spread.
3. Analyse the pathophysiological mechanisms of chronic pain in disorders such as neuropathy and fibromyalgia, focusing on neuroplasticity, central sensitization, and the role of pain modulators.
4. Role of immune system dysfunction, microbial dysbiosis, and environmental factors in IBD.
5. Molecular basis of hepatic fibrosis in liver cirrhosis and alcoholic liver disease, with an emphasis on signalling pathways.
6. Impact of neuro inflammation in psychiatric disorders such as schizophrenia and affective disorders, exploring the contribution of cytokines, microglia, and neurotransmitter imbalances.
7. Role of adipose tissue dysfunction, insulin resistance, and inflammatory mediators in Obesity.

8. Neurobiological and pharmacological mechanisms underlying sleep disorders, with particular attention to the regulation of the sleep-wake cycle and the role of neurotransmitters in conditions like insomnia and sleep apnoea.
9. Immune evasion mechanisms employed by pathogens in infectious diseases like TB and Malaria.
10. Role of neurotransmitter systems in schizophrenia and affective disorders.

TEXT BOOKS

1. Harsh Mohan.Text book of Pathology. Eighth edition. JAYPEE Brothers;2019
2. Bhende Y.M and DeodhareS.G.General Pathology & Pathology of Systems. Popular Prakashan, Mumbai;2010
3. Carol Mattson Porth. Essentials of Pathophysiology. Fourth edition. Wolters Kluwer;2015
4. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

REFERENCE BOOKS

1. Robbins and Cotran, Pathologic basis of disease. Tenth Edition.Elsevier publications; 2014

2. Mary Anne Koda-Kimble et.al. Applied Therapeutics – The Clinical Use of Drugs. Ninth Edition. Wolters Kluwer;2009

FOURTH YEAR

Course Title	L	T	P	Total Hrs	Year	Course Code
PHARMACOTHERAPEUTICS – III (T)	**2**	**0.5**	**0**	**50**	**Pharm. D IV** **Pharm. D P. B I**	**PD.401T** **PDPB.101T**
PHARMACOTHERAPEUTICS – III (P)	**0**	**0**	**3**		**Pharm. D IV** **Pharm. D P. B I**	**PD.409T** **PDPB.110T**

SCOPE: This course encompasses a comprehensive exploration of therapeutic modalities to various diseases and it aims to impart a solid understanding of the underlying mechanisms and pathological changes involved in various conditions, serving as a foundation for effective treatment strategies. Through a detailed examination of the rationale guiding drug selection, students will learn to consider factors such as pharmacokinetics, pharmacodynamics, and patient-specific characteristics in disease management decisions.

Furthermore, the course emphasizes the integration of pharmacological and non-pharmacological interventions to optimize patient care. Students will delve into the significance of lifestyle modifications, dietary adjustments, and other non-drug therapies alongside medication regimens. Overall, the course equips students with the knowledge and tools to autonomously navigate the complexities of pharmaceutical care, staying updated of the latest developments in pharmacotherapy and implementing evidence-based practices to ensure optimal outcomes for patients.

COURSE OUTCOMES:

KNOWLEDGE

K1: Outline the etiopathogenesis and clinical manifestations of various diseases.

K2: Discuss the pharmacological and non-pharmacological interventions in the management of various diseases.

K3: Develop an understanding of standard treatment guidelines of various diseases.

K4: Design individualised therapeutic plans based on diagnosis and resolve various DRP.

K5: Discuss controversies in drug therapy.

K6: Justify the rationale for updated treatment algorithms in disease management.

SKILLS

S1: Identify the patient specific parameters relevant in initiating and continuing drug therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

S2: Apply pharmacological and therapeutic knowledge in prevention and treatment of various disorders.

S3: Detect various drug-related problems.

S4: Elaborate on the reasoning behind the advancements in clinical outcomes and the modifications implemented in drug therapy.

S5: Audit prescriptions for accuracy and appropriateness.

S6: Educate patients on the correct use of prescribed drugs.

ATTITUDE

A1: Appreciate the cultural backgrounds, beliefs, and values of patients.

A2: Recognize the emotional and psychological aspects of illness.

A3: Communicate effectively with various stakeholders and exhibit professionalism in all clinical activities.

A4: Appreciate effective reporting of drug related problems (DRP) among healthcare professionals.

A5: Display sincerity, punctuality and integrity in academic and non-academic activities.

A6: Uphold the ethical values in maintaining the confidentiality of patient information.

LECTURE WISE CONTENTS:

Introduction to the disorders, Differential Diagnosis, Therapeutic goals, Non pharmacological and Pharmacological management including dose optimisation , treatment algorithm & latest guidelines. Recent advancements associated with following disease

UNIT- I Gastrointestinal System-II **(13 Hours)**

- Peptic Ulcer Disease **(3 hours)**
- Inflammatory bowel disease (Ulcerative Colitis & Crohn's Disease) **(4 Hour)**
- Liver disorders - Alcoholic liver disease **(3 Hour)**
- Viral hepatitis including jaundice (Hepatitis-A, B, C, D and E) **(3 Hour)**
- Drug induced liver disorders **(1 Hour)**
-

UNIT-II Oncology **8 hrs**

- •Chemotherapy of breast cancer 2hrs
- •Leukaemia 2 hrs
- •Lung Cancer 2 hrs
- •Management of chemotherapy nausea and emesis 2 hrs

UNIT-III: Dermatology **5 hours**

- Psoriasis 1hr
- Scabies 1 hr
- Eczema 1hr
- Impetigo 2 hr

UNIT- IV Ophthalmology **(4 Hours)**

- Conjunctivitis –Viral & Bacterial 2 hrs
- Glaucoma 2 hrs

UNIT –V Pain management **(7 Hours)**

- Neuralgias **(3 Hour)**
- Headaches **(3 Hour)**
- Surgical Anaesthesia **(1 Hour)**

UNIT – VI Obstetrics and Gynaecology **(8 Hours)**

- Menopausal,Peri-menopausal and Post-menopausal therapy **(4 Hour)**
- Menstruation related disorders (Dysmenorrhea, PCOD) **(2 Hour)**
- Infertility **(2 Hour)**

UNIT VII – Sustainability and Artificial Intelligence in Healthcare (2 Hours)

- Sustainable Approaches in Chronic Disease Management: Focus on Gastrointestinal, Oncological, and Dermatological Disorders **(1 Hour)**
- AI in Clinical Decision Support: Applications in Pain, Reproductive Health, and Ophthalmology **(1 Hour)**

UNIT-VII Evidence Based Medicine **(2 Hours)**

Definition, Importance, Levels of evidences and hierarchy, various Sources of Evidences, PICO Model, Systematic Review and Meta-analysis.

ASSIGNMENTS:

- Gut Microbiota and Its Role in Alcoholic Liver Disease Progression
- Checkpoint Inhibitors in Breast Cancer: Current Evidence and Future Directions
- CAR-T Cell Therapy in Leukaemia: Breakthroughs and Challenges
- Biological Therapies for Moderate-to-Severe Psoriasis: A Comparative Analysis
- Emerging Role of CGRP Inhibitors in Migraine Management
- Innovations in Assisted Reproductive Technologies (ART) for Infertility
- Incorporating Patient-Reported Outcomes in Evidence-Based Practice

TEXT BOOKS:

1. Pharmacotherapy: A Pathophysiologic approach – 11th edition. Joseph T. Dipiro et al. Appleton &Lange; 2020
2. Clinical Pharmacy and Therapeutics – 7th edition. Eric T. Herfindal, Williams and Wilkins Publication --
3. Applied Therapeutics: The clinical Use of Drugs. 10th edition. Lloyd Young and Koda-Kimble MA; 2012

REFERENCES BOOKS:

1.Clinical Pharmacy and Therapeutics- 5th edition. Roger and Walker, Churchill Livingstone publication 2012
2.Davidson's principles and practice of medicine. 21st edition. Davidson, S., Bouchier, I. and Edwards, C.E.L.B.S. and Churchill Livingstone, London.1991

JOURNALS:

1.American Journal of Therapeutics. Wolters Kluwer

2.Clinical pharmacology and therapeutics. Wiley-Blackwell

3.OMICS International
4.Indian Journal of Medical Research. Med know Publications

WEB RESOURCES FOR UPDATED GUIDELINES

- **Gastroenterology Guidelines : https://gastro.org/clinical-guidance/**
- **Oncology Guidelines : https://www.esmo.org/guidelines**
  https://ascopubs.org/jco/special/guidelines
- **Pain:https://www.who.int/who-revision-of-pain-management-guidelines**

- **Headache:https://www.aafp.org/pubs/afp/issues/2021/0900/p316.html**

PHARMACOTHERAPEUTICS (Practical)

Practical Hours**:75 Hours(3hours/week)**

Guidelines for Practical

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved through 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 shall be submitted at the end of the course for evaluation. Each student shall present at least 5 medical cases they have observed and followed in the wards.

- Students has to demonstrate ability to interpret the variations in laboratory parameters and justify the reasons for variations.
- Explain the rationale about the progress of clinical outcome and changes made in drug therapy
- Students should be able to perform audit of a given prescription and report various drug related problems.
- Demonstrate the ability to prepare discharge medication and communicate effectively with a patient on the proper use of prescribed medication.
- Evaluate, infer and propose clinical pharmacist's intervention on a given prescription.

Recommended books

- Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic approach. 11th edn. Mc Graw- Hill; 2017
- Lloyd Young and Koda-Kimble. Applied Therapeutics: The clinical Use of Drugs. 10th edn. Wolters Kluwer: Lippincott Williams and Wilkins; 2013
- Robbins and Cotran. Pathologic basis of disease. 6th edn. Philadelphia: Elsevier;2003
- Scott L. Traub. Basic skills in interpreting laboratory data. American Society of Health System Pharmacists; 1992

Journals:

1.American Journal of Therapeutics. Wolters Kluwer

2.Clinical pharmacology and therapeutics. Wiley-Blackwell

3.OMICS International

4.Indian Journal of Medical Research. Med know Publications

Course Title	L	T	P	Total Hrs	Year	Course Code
HOSPITAL PHARMACY (T)	**2**	**0.5**	**0**	**50**	**Pharm. D IV** **Pharm. D P. B I**	**PD.402T** **PDPB.102T**

SCOPE:

Hospital Pharmacy encompasses the study of Pharmaceutical care within the hospital setting, emphasizing the role of Pharmacists in patient care, thereby ensuring the safe and effective use of medications. The scope includes an in-depth exploration of hospital Organizational structure, the various functions and responsibilities of hospital Pharmacists, ranging from drug procurement, dispensing, and distribution to the involvement of Pharmacists on multiple hospital committees, which ensures effective and safe medication practices for patient well-being.(SDG 3) Students also acquire knowledge regarding the principles of Hospital formulary management and how medications are selected and approved for use in a hospital.

Students will explore the integration of technology in Hospital Pharmacy practices, such as automated dispensing systems and electronic health records which integrates innovation and digital infrastructure into hospital workflows (SDG 9) The subject covers the collaborative nature of healthcare, emphasizing effective communication and teamwork with other healthcare professionals. Ethical considerations and legal responsibilities of hospital Pharmacists, including issues related to patient confidentiality and informed consent, are essential components of the subject which prepares students for a well-rounded and ethical practice in hospital settings and also reinforces trust, justice and transparency in healthcare institutions (SDG 16)

COURSE LEARNING OUTCOMES:
Upon successful completion of the course the student shall be able to:

KNOWLEDGE

K1: Recall the structure and functions of various hospital committees involved in medication safety.

K2: Explain the classification and organizational structure of hospitals and hospital pharmacies

K3: Apply the principles of formulary development and drug inclusion/exclusion in a hospital setting

K4: Analyse the procurement and warehousing processes of pharmaceuticals including inventory control methods

K5: Evaluate the role of the pharmacist in total parenteral nutrition and radiopharmaceutical handling

K6: Design a hospital formulary model with evidence-based justification for drug listings

SKILL

S1: Identify the workflow of drug distribution methods used in hospital settings

S2: Demonstrate understanding of inventory control using ABC-VED and other relevant techniques

S3: Practice safe and effective dispensing and documentation during routine and emergency care

S4: Analyse prescription errors and suggest preventive strategies using clinical examples

S5: Evaluate the effectiveness of technology (EHR, ADM) in improving pharmacy operations

S6: Develop a training protocol for junior pharmacists on interprofessional communication

ATTITUDE

A1: Recall the ethical and legal responsibilities of hospital pharmacists

A2: Understand the importance of professional behavior and punctuality in clinical practice

A3: Apply principles of collaboration and teamwork in multidisciplinary healthcare scenarios

A4: Analyse real-life ethical dilemmas related to patient confidentiality and consent

A5: Critically appraise hospital policies and initiatives in the context of new healthcare technologies

A6: Develop a code of conduct or personal practice framework demonstrating sincerity and professional integrity

LECTURE WISE CONTENTS:

UNIT- I

- **Hospital – its Organization, functions, budget, training and Regulatory aspects (12 hours)**

- Definition, Classification of Hospital. Primary, Secondary and tertiary hospitals. Organization structure of hospital. (1 Hr)
- Hospital Pharmacy and its management. (1 Hr)
- Organizational Structure of Hospital Pharmacy, Staff requirements, Infrastructure & work load statistics, role of Pharmacist. (1 Hr)

- Management of materials and finance (1 Hr)
- Roles & responsibilities of Hospital Pharmacist
- The Budget – Classification, Preparation and implementation (2 Hrs)
- Internal and external training programme (1Hr)
- Continuing professional development programs. Role of Pharmacist in education and training program. (1Hr)
- Professional Relations and practices of Hospital Pharmacist with other healthcare professionals (2 Hrs)
- Good Pharmacy Practice (GPP) guidelines
- National Accreditation Board for Hospitals (NABH) and Joint Commission International (JCI) accreditation requirements, ISO certification (1Hour)
- Hospital Finance and Insurance – Health insurance, Reimbursement Policies, Government Schemes (Eg: Ayushman Bharat)
- Legal and Ethical aspects – Patient rights, Medical negligence laws, Hospital Ethics (1Hour)

UNIT- II Hospital drug policy **10 hours**

- Hospital Formulary -Definition, Structure, differentiation of Hospital formulary & Drug list, Preparation and revision. Guidelines for addition and deletion of drugs from hospital formulary. (2 Hrs)

  Hospital committees

- Pharmacy and Therapeutics Committee (PTC), Purpose, Composition and functions. (2 Hrs)
- Automatic stop order for dangerous drugs.(1 Hr.)

  Infection committee – Goals, composition, functions and role of Pharmacist.
  American Society of Hospital Pharmacy (ASHP) guidelines for Infection control in Hospitals (1 Hr.)
- Research and ethics committee- Objectives, composition, functions .(1 Hr.)
- Antibiotic Committee- Objectives, composition, functions, and role of Pharmacist.(1 Hr)
- Hospital pharmacy communication - Newsletter.(1 Hr)
- Emergency drug list preparation.(1 Hr)

UNIT- III Hospital Pharmacy Services **12 hours**

- Procurement & warehousing of drugs and Pharmaceuticals (1Hr)
- Inventory Control

- Definition, various methods of Inventory Control
- ABC, VED, EOQ, Lead time, Safety stock (2Hrs)
- Stock Management (FIFO, FEFO principles)

- Drug distribution in hospital (1Hr)
- Individual prescription method (1Hr)
- Floor stock method
- Unit dose drug distribution method
- Dispensing of drugs during off hours
- Distribution of narcotic and other controlled substances in a hospital (2Hrs)
- Central Sterile supply services (CSSD)- Location and layout. Role of Pharmacist in CSSD (2Hrs)
- High risk medication list of a hospital (1Hr)
- High risk medication usage in a hospital
- Look alike and Sound alike drugs. (1Hr)
- Patient education for safe usage of drugs by preventing drug –drug and drug –food interaction. (1Hr)

UNIT- IV **3 hours**

Total Parenteral Nutrition

- Total parenteral nutrition – Ingredients, Method of Preparation, Types of TPN, indications
- Administration and complications of TPN (2 Hrs)
- Monitoring and adjustment, Role of Healthcare provider
- Weaning off TPN, Ethical considerations (1 Hr)

UNIT-V **4 hours**

Ancillary substances used in hospitals

Surgical instruments used in hospitals, Different types of forceps, Airway tubes etc (1Hr)

Surgical aids: Surgical dressings, absorbable gelatine sponge, sutures, ligatures, and medicated bandages. (2 Hrs)

Needles, Syringes, Catheters, IV set, Ryle's tube, Rectal tubes , Oxygen masks, Thermometers (1Hr)

UNIT VI **7 hours**

Policy in Handling Radiopharmaceuticals, medical gases and Bio-waste management

- Radio Pharmaceuticals – Method of manufacture, Therapeutic and diagnostic uses, Handling and packaging (2Hrs)
- Policy for the usage and dispensing of radioactive drugs in a hospital (1Hr)
- Policy and procedure while using medical gases (1Hr)
- Storage and delivery of medical gases- Characteristics, storage, distribution and regulation of medical gases (2 Hrs)

- Bio waste management in Hospital –Including radioactive and drug waste handling (1Hr)

UNIT VII **2 hours**

Technology and Automation in Hospital Pharmacy

- Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry . AI-driven Decision Support Systems in Hospital Pharmacy (1hr)-
- Barcode medicine identification and Automated Dispensing of Medicines (ADM)
- Drug Information Retrieval &Storage, Electronic Medical Records (1 Hr)

ASSIGNMENTS:

- Prepare an SOP for the handling and disposal of radiopharmaceuticals and medical gases as per NABH/JCI standards.
- Collect 10 anonymized prescriptions (real or simulated) and perform an error analysis. Suggest corrective and preventive actions.
- Compare and contrast the ABC-VED method with other inventory systems like EOQ and Safety Stock.
- Evaluate the functioning and impact of the antibiotic committee in reducing antimicrobial resistance. Include pharmacist roles and contributions.
- Prepare a step-by-step plan for the procurement of high-risk medications including supplier selection, storage, and financial budgeting.
- Discuss how a hospital pharmacist applies communication strategies to coordinate with other departments during a public health emergency.
- Describe the practical application of electronic health records (EHR) and automated dispensing systems in minimizing errors.
- Deconstruct each stage of TPN preparation, administration, and monitoring to evaluate pharmacist responsibilities.

TEXT BOOKS:

1. Dr. J.S. Qadry,R.K.Goyal ,R.K. Parikh ,Ramesh K. Merchant & Qadry's A text book of Hospital Pharmacy .9th edn . B.S.Shah Prakashan 2008.
2. K.G. Revikumar. A text book of Pharmacy Practice.2nd edn. Career publications ;2012.
3. Kapur. Intoduction to surgical instruments and procedure for undergraduates. 2nd edn. Elsevier Health 2009.
4. Sharma & madhuri. Essentials for Hospital supportive services.2nd edn.Jaypee brothers.2003.
5. Shishir Bashkar. Hospital waste management: A guide for self assessment and review.2nd edn.Jaypee publications 2009.

REFERENCE BOOKS:

1. William.E. Hassan . Hospital Pharmacy.5th edn . Lea & Febiger, 1986
2. Richard J Kowalsky, Steven Falen. Radiopharmaceuticals in nuclear pharmacy and nuclear medicine. 2nd edn. Mc Graw-Hill medical 2004.
3. Francis Fish, John owen Dacoson. Surgical dressings,ligatures,and sutures (Pharmaceutical monograph) Hard cover-1. William Heinenann medical books Ltd.1967.
4. Lachman L,Lieberman HA, Kanig JL. Theory and practice of Industrial pharmacy. 3rd edn.Varghese publishing house 1991.

JOURNALS:

1. Journal of Pharmacy Practice and Research (Wiley)
2. Journal of pharmacy practice. - (SAGE Publishers)
3. American journal of health system pharmacy. (online)-(ASHP)
4. International journal of clinical Pharmacy (Springer)
5. Journal of Clinical Pharmacy and Therapeutics (Wiley)

Course Title	L	T	P	Total Hrs	Year	Course Code
CLINICAL PHARMACY (T)	**2**	**0.5**	**0**	**50**	**Pharm. D IV** **Pharm. D P. B I**	**PD.403T** **PDPB.103T**
CLINICAL PHARMACY (P)	**0**	**0**	**3**	**75**	**Pharm. D IV** **Pharm. D P. B I**	**PD410P** **PDPB.111P**

SCOPE:

This course is designed to equip students with the basic knowledge and skills necessary to become competent clinical pharmacists. Through this course, students will develop expertise in providing drug therapy monitoring, patient counselling, medication reconciliation, and in understanding the importance of pharmacovigilance and the interpretation of laboratory data in the clinical scenario. The course emphasizes evidence-based decision-making, allowing students to critically evaluate drug and poison information, participate in ward rounds, and contribute to medication safety initiatives. Additionally, students will gain proficiency in pharmaceutical care concepts, hence ensuring that they can optimize therapeutic outcomes through individualized patient care. By studying drug utilization evaluation and quality. They will develop the ability to assess and improve clinical pharmacy services within healthcare institutions by analysing the drug utilisation patterns and through quality assurance.

This course fosters essential clinical and interpersonal skills and the students will enhance their ability to communicate effectively with healthcare professionals and patients, improving medication adherence and minimizing medication errors. Exposure to pharmacovigilance principles will enable them to identify, report, and prevent adverse drug reactions, contributing to patient safety. Furthermore, critical evaluation of biomedical literature will help students integrate the latest research into clinical practice, supporting evidence-based pharmacy interventions. The course also introduces students to the emerging role of Artificial Intelligence (AI) in optimizing clinical decision-making and patient safety, as well as sustainable practices in pharmacy aimed at promoting rational medicine use and minimizing healthcare-related environmental impact. By the end of the course, students will develop a patient-centred approach, ethical responsibility, and a commitment to continuous learning, preparing them for dynamic roles in the healthcare settings.

COURSE OBJECTIVES:

Upon successful completion of this course students shall be able to:

KNOWLEDGE

K1: Define key concepts in clinical pharmacy, including drug therapy monitoring, medication reconciliation, and pharmaceutical care.

K2: Explain the importance of patient counselling in improving medication adherence and therapeutic outcomes.
K3: Identify potential medication-related risks using pharmacovigilance principles.
K4: Describe the role of Artificial Intelligence (AI) in enhancing clinical decision-making, medication-related risks, and supporting evidence-based pharmaceutical care.
K5: Analyze clinical laboratory test results to drug-induced abnormalities and optimize therapy.
K6: Evaluate the effectiveness of clinical pharmacy interventions in reducing medication errors and adverse drug reactions (ADRs).

SKILL

S1: Perform medication chart reviews and clinical assessments to monitor drug therapy.
S2: Conduct medication history interviews and patient counselling sessions effectively.
S3: Demonstrate proficiency in interpreting haematological, biochemical, and microbiological lab data.
S4: Apply structured documentation techniques like SOAP and FARM to record and analyse patient cases.
S5: Analyse real-world medication errors and ADR cases to design effective interventions.
S6: Evaluate biomedical literature for its validity, applicability, and relevance in clinical decision-making to optimize therapeutic outcomes and enhance evidence-based pharmacy practice.

ATTITUDE
A1: Acknowledge the significance of clinical pharmacy in improving patient safety and healthcare outcomes.
A2: Demonstrate ethical responsibility in clinical decision-making and patient care.
A3: Value teamwork and interprofessional collaboration in ward rounds and clinical settings.
A4: Apply professional communication and counseling skills to improve patient adherence.
A5: Demonstrate a commitment to sustainability by promoting environmentally responsible practices in medication use, waste reduction, and resource optimization in clinical pharmacy services.
A6: Implement strategies for optimizing pharmacovigilance reporting and patient safety initiatives.

LECTURE WISE CONTENTS:

UNIT -1 Introduction to Clinical Pharmacy (1 hours)

- Definitions, development and scope of clinical pharmacy (1 hr)

UNIT- II Daily activities of a clinical pharmacist (24 hours)

- **Drug therapy monitoring**: Medication chart review, Clinical review, Pharmacist interventions (2 hr)
- **Ward round participation** –Objectives and types of ward rounds (1 hr)
- **Medication history interview** –definition, objectives, components and steps of medication history interview, role of pharmacist in medication history interview (2 hr)

- **Medication reconciliation** – definition, objectives, stages at which medication reconciliation to be conducted, steps, role of pharmacist, challenges and strategies to improve the process. (2 hr)
- **Drug and poison information** - Introduction to drug information resources available, Systematic approach in answering DI queries, Critical evaluation of drug information and literature, Preparation of written and verbal reports, Establishing a Drug Information Centre, Poisons information- Members, organization & information resources (3 hr)
- **Patient counselling** - Stages of patient counselling, Verbal and non-verbal communication skills, Patient counselling techniques, Barriers of patient counselling (3 hr)
- **Medication errors-** Definition, causes of medication errors, types, strategies to reduce medication errors (2 hr)
- **HR, LASA drug list**, its detection and prevention in a hospital setting (2 hr)
- **Pharmaceutical care** – CORE, PRIME, SOAP, FARM concepts (2 hrs)
- **Drug utilisation evaluation (DUE) and review (DUR)** – Types and steps. (3 hrs)
- **Quality assurance** of clinical pharmacy services (1 hr)

UNIT- III Lab Data Interpretations (12 hours)

- Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results
  a. Haematological tests (1 hr)
  b. Liver function tests (2 hr)
  c. Renal function tests (2 hr)
  d. Thyroid function tests (1 hr)
  e. Tests associated with cardiac disorders (1 hr)
  f. Fluid and electrolyte balance tests, protocols for electrolyte corrections (2 hr)
  g. Pulmonary Function Tests (1 hr)
  h. Microbiological culture sensitivity tests (2 hr)

UNIT- IV Pharmacovigilance (10 hours)

- Scope, definition and aims of pharmacovigilance (1 hr)
- Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used] (1 hr)
- Reporting, evaluation, monitoring, preventing ADRs and role of pharmacist in ADR management (1 hr)
- Hemovigilance and Materiovigilance (2 hr)
- Vaccine safety surveillance: vaccine pharmacovigilance, vaccination failure, AEFI (1 hr)
- Pharmacovigilance Methods:
  Passive surveillance – Spontaneous reports and case series, Stimulated reporting,
  Active surveillance – Sentinel sites, drug event monitoring and registries,
  Comparative observational studies – Cross sectional study, case control study and cohort study, Targeted clinical investigations (2 hr)

- Good Pharmacovigilance Practices (GVP): Legal Framework of the Global Pharmacovigilance Program: Guidelines on GVP, Major Pharmacovigilance Processes, Product or population-specific considerations. (1 hr**)**

UNIT V Critical evaluation of biomedical literature 3 Hours

- Introduction to biomedical literature evaluation (definition, types, and role of literature in clinical pharmacy practice) (1hr)
- Study designs and critical appraisal of clinical trials in terms of validity, bias, confounding factors and interpretation of results (1 hr)
- Translating Biomedical Literature into Clinical Practice and ethical considerations and limitations of biomedical literature (1 hr)

UNIT VI Artificial Intelligence in Clinical Pharmacy 1 Hour

- Introduction to applications of AI in clinical pharmacy practice
- AI- driven tools for drug interaction alerts, adverse event prediction, and therapy optimization
- Limitations and ethical considerations of AI in patient care

UNIT VI Sustainability in Clinical pharmacy 1 Hour

- Principles of sustainability in clinical settings
- Rational drug use and its impact on minimizing pharmaceutical waste
- Sustainable approaches to drug utilization evaluation and prescription auditing

CLINICAL PHARMACY (Practical)

LIST OF EXPERIMENTS:

1. Critical Appraisal of Drug Information Requests – Analyze and respond to five complex drug information queries, incorporating evidence-based medicine and risk-benefit assessment.

2. Effective Patient Medication Counseling – Conduct five counseling sessions, focusing on patient understanding, adherence strategies, and personalized education.

3. Clinical Interpretation of Laboratory Investigations – Evaluate five patient cases, correlating lab values with pathophysiological conditions and recommending therapeutic interventions.

4. Comprehensive Medication History and Therapeutic Review – Conduct and critically assess five detailed patient medication history interviews, identifying potential drug-related problems.

5. Pharmacovigilance and ADR Risk Management – Analyze five ADR cases, assess causality using standardized tools (e.g., Naranjo scale), and propose risk mitigation strategies.

6. Medication Safety and Error Prevention Strategies – Investigate five medication error cases, determine root causes using FMEA or RCA techniques, and develop preventive measures.

7. Advanced FARM Case Analysis – Perform two in-depth FARM (Findings, Assessment, Recommendations, and Monitoring) analyses, integrating clinical judgment and therapeutic planning.

SEMINAR/ASSIGNMENTS:

1. Construct a Drug Utilization Evaluation (DUE) protocol for a high-risk medication (e.g., antibiotics, anticoagulants).
2. Recognize adverse drug reactions in a patient and apply Naranjo Causality Assessment Scale to evaluate the suspected ADR.
3. Identify at least two cases related to hemovigilance and materiovigilance.
4. Discuss the structure and functioning of the Pharmacovigilance Program of India (PvPI), its objectives, and the role of clinical pharmacists in monitoring and reporting adverse drug reactions (ADRs).
5. Apply the principles of pharmaceutical care and the FARM model to design a clinical pharmacy intervention plan for a patient with poorly controlled hypertension, incorporating patient-specific factors, medication adjustments, and monitoring strategies.
6. Apply the Principles of Medication Reconciliation to Develop a Comprehensive Medication Management Plan for a Hospitalized Patient, ensuring accuracy in

Medication History, identifying discrepancies, and proposing interventions to prevent potential Medication errors.

TEXTBOOKS:

1. Dr.G.Parthasarathi, Karin Nyfort-Hansen and Milap Nahata. A text book of Clinical Pharmacy Practice; Essential concepts and skills. 2nd edn. Orient Blackswan Pvt.Ltd;2012
2. Mary Lee. Basic Skills in Interpreting Laboratory Data, 6th edn. American Society of Health System Pharmacists; 2017
3. A J Winfield, R Michael E Richards. Pharmaceutical Practice. 3rd edn. Churchill Livingstone; 2004.

REFERENCE BOOKS

1. Scott L. Traub. Basic skills in interpreting laboratory data. American Society of Health System Pharmacists; 1992
2. Jacques Burton Wallach. Interpretation of Diagnostic Tests.7th edn. Lippincott Williams and Wilkins;2004
3. Robert J. Cipolle, Linda M. Strand, Peter C. Morley. Pharmaceutical Care Practice: The Patient-Centered Approach to Medication Management Services, 3rd edn. Mc Graw-Hill;2012

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
BIOSTATISTICS AND RESEARCH METHODOLOGY	**2**	**0.5**	**0**	**50**	**2**	**Pharm. D IV** **Pharm. D P. B I**	**PD.404T** **PDPB.104T**

SCOPE:

This course offers an essential introduction to Biostatistics and Research Methodology, with a focus on applications in biomedical and clinical research. It prepares students with the core skills needed to design, execute, and interpret studies involving health data. Key statistical principles such as descriptive statistics, probability distributions, hypothesis testing, and regression analysis are covered. The course also explores different research designs and epidemiological methods, guiding students on selecting appropriate approaches based on specific research objectives.

Beyond theoretical knowledge, students will gain hands-on experience in data handling and statistical analysis using tools like Microsoft Excel, R, and SPSS. Working with real-world datasets, they will learn to apply statistical techniques to explore relationships, evaluate hypotheses, and support evidence-based conclusions in health research. The course also highlights the significance of proper data collection, research ethics, and the confidentiality of sensitive health information.

Additionally, students will examine the interdisciplinary and collaborative aspects of research, enhancing their ability to conduct rigorous investigations. By the course's end, they will be equipped to independently carry out statistical analyses, assess research critically, and actively contribute to studies in healthcare, pharmacy, and allied fields.

COURSE OUTCOMES:

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

KNOWLEDGE

K1: State the fundamental statistical concepts and methods used in Biomedical research.

K2: Outline various study designs and their appropriate applications in different research scenarios.

K3: Discuss the different types of sampling design and identify the various steps in sampling design

K4: Distinguish between different types of data in research and various methods used for data collection

K5: Explain key components of research design and statistical analysis, including observational studies, clinical trials, and survey studies

K6: Review the application of statistical software tools in data management and analysis

SKILL

S1: Interpret statistical methods and techniques to health-related data

S2: Design study protocols, including data collection tools and study methods.

S3: Communicate research findings effectively through written reports, visualizations, and presentations

S4: Derive appropriate statistical models with suitable assessment based on various samples relevant to pharmaceutical/clinical research

S5: Interpret the data generated in biology, public health and other health sciences using modern statistical methods

S6: Use various computer software to organize, input and analyze data, output results and interpret them (M.S. Excel, SPSS, R)

ATTITUDE

A1: Express commitment to ethical conduct and adherence to research regulations and guidelines

A2: Participate in activities for continuous learning and updating knowledge and skills

A3: Respect data integrity, confidentiality, and protection of human subjects

A4: Manage effective communication skills in conveying analytical findings

A5 Appreciate the value of interdisciplinary collaboration in conducting high-quality biomedical research

A6: Assist the healthcare professionals in implementing the correct statistical methods

COURSE CONTENTS:

Unit 1-Introduction (9 Hours)

Introduction to Biostatistics: Definitions and applications, Branches of statistical Methods (1 hour)

Basic statistical concepts: Variable, Types of variables, constant, Parameter, Statistic, Rate, Ratio and proportions, Level of Measurement scale (1 hour)

Introduction to Research: Definitions and types of research, Literature review and AI tools, Types of data (2 hour)

Research protocol, Report writing and Presentation of the data: Concept, Components, Presentation of data and AI tools (tabular and graphical) (2 hour)

Sampling and Data collection methods: Important terms in sampling, Sampling design, Probability and non-probability sampling methods (Definitions, Merits and demerits) Methods of data collection (Survey, questionnaires) (3 hour)

Unit 2- Descriptive statistical Methods (8 Hours)

Measures of Central Tendency: Concept and calculation of Central tendency: Mean, Median, Mode (1 hour)

Measures of Dispersion: Mean deviation, Range, inter quartile range, Quartile deviation, Standard deviation, variance, Coefficient of Variation, Standard error of mean (2 hour)

Correlation: Scatter Diagram, Correlation coefficient and its interpretation, Correlation coefficient based on rankings. (2 hour)

Regression: Definition, Types (Simple linear regression, Multiple regression, Logistic regression), Least square method of estimation, Odds ratio, Calculation of Regression, Relationship between correlation and regression. (3 hour)

Unit-3 Statistical Inference (16 Hours)

Probability distributions: Definition of probability, Bayes theorem, Binomial distribution, Poisson distribution and Normal distribution (Definitions, properties and example). (2 hour)

Properties of normal curve: Divergence from normality (Skewness and Kurtosis), Application of Normal distribution, Concept of Standard Error (2 hour)

Statistical Hypothesis: Null and alternative hypothesis, Type I and Type II errors, Power of the test, level of significance, one tail and two tail tests, estimation of confidence interval (2 hour)

Testing the statistical significance of a hypothesis: Steps in testing the statistical hypothesis, Tests of statistical significance (2 hour)

Parametric test: One sample t test, Paired and unpaired t test, F test and Analysis of Variance (ANOVA) with its Purpose, Designs and Examples. Post hoc tests: criteria for the selection and its interpretation. (4 hour)

Non parametric test: Test of significance (Chi square, Fishers exact test), Wilcoxon rank sum test, Wilcoxon signed rank test, Kruskal Wallis one-way analysis of variance, Friedman's two-

way analysis of variance Post hoc tests: criteria for the selection and its interpretation. (4 hour)

Unit-4: Study designs, measuring the burden of disease (10 Hours)

Types of Study designs: observational studies (cohort studies, case-control studies, cross sectional studies), experimental studies (randomized controlled trials) (Definition, Advantages and disadvantages) (3 hour)

Diagnostic tests: Sensitivity and Specificity, ROC and AUC curves (1 hour)

I**ndices of disease**: Prevalence, Incidence, Relative risk, attributable risk, Crude and Specific rates, Direct Vs Indirect standardization (1 hour)

Sample size estimation: Importance of sample size in research design, Methods for calculation (Estimation of Mean, two means, Proportion, two proportion), G*power (3 hour)

Introduction to systematic review and meta-analysis. (2 hour)

Unit-5 Introduction to SPSS, Excel and R (7 Hours)

Getting Started: Interface, Menus, Data Entry, Data Editing (2 hour)

Basic Analysis & Graphical Tools in Excel, SPSS and R (5 hour)

ASSIGNMENTS

1. Compare and contrast probability vs non-probability sampling using real-life examples from published health research.
2. Construct and interpret a dataset (10–15 entries) using graphical and tabular methods.
3. Perform a **paired and unpaired t-test** using sample data and interpret results.
4. Create a table of **sensitivity, specificity, PPV, NPV**, and construct a simple **ROC curve** using dummy data.
5. Import an Excel sheet to SPSS, perform **basic descriptive analysis**, and submit the output.

TEXT BOOKS:

1. K. R. Sundaram, S.N. Dwivedi, V. Sreenivas; **Medical Statistics: Principles and Practice**, 2nd Edition, Wolters Kluwer, Lippincott Williams and Wilkins, 2014
2. Manju Pandey; **Biostatistics: Basic and Advanced**, 1st Edition, Viva Books,2015.
3. Wayne W. Daniel, Chad L. Cross **Biostatistics: Basic Concepts and Methodology for the Health Sciences,** 10th edition, Wiley India Pvt. Ltd,2014
4. Agarwal, B. L: Basic Statistics – Third edition: New Age International (P) Ltd.Publishers, New Delhi.

REFERENCE BOOKS:

1. S. C. Gupta, Fundamentals of Statistics: 7th Edition, Himalaya Publishing House: 2017
2. Douglas C. Montgomery, Design and Analysis of Experiments 10th Edition, Wiley India: 2019
3. Cronk, B. C. 2017. How to use SPSS: a step-by-step guide to analysis and interpretation. 9th Edition. Routledge, New York, USA

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
BIOPHARMACEUTICS AND CLINICAL PHARMACOKINETICS (T)	**3**	**0**	**0**	**75**	**3**	**Pharm. D IV** **Pharm. D P. B I**	**PD.405T** **PDPB.105T**
BIOPHARMACEUTICS AND CLINICAL PHARMACOKINETICS (P)	**0**	**0**	**3**	**50**	**1.5**	**Pharm. D IV** **Pharm. D P. B I**	**PD411P** **PDPB.112P**

SCOPE: This subject is designed to impart knowledge and skills of biopharmaceutics and pharmacokinetics and their applications in clinical practice, design of dose and dosage regimen and in solving the problems arised therein.

Biopharmaceutics is the study of the relationship between the physicochemical properties of a drug, its formulation and route of drug administration on the behaviour of drug in the body. The principles underlying drug absorption, distribution, metabolism, excretion as well as factors influencing these processes are highlighted including use of AI. The course introduces Pharmacokinetics that deal with the quantitative study of drug movement within the body, by the understanding of pharmacokinetic parameters which aids in optimizing drug dosing and therapeutic efficacy. Dose calculation in special population such as obese, geriatrics, paediatric patients, pregnant and lactating mothers is also dealt in the course. The course also highlights the causes of pharmacokinetic variability in diseased conditions. The course enhances analytical and problem-solving abilities to interpret pharmacokinetic data. It also develops a patient-centered approach, encouraging critical thinking, problem solving and ethical practices in optimizing drug therapy and reducing adverse effects.

COURSE LEARNING OUTCOMES

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

KNOWLEDGE

K1: Differentiate between biopharmaceutics, pharmacokinetics and pharmacodynamics

K2: Outline the basic principles of biopharmaceutics and the use of AI to predict ADME

K3: Describe the pharmacokinetics of drugs and its role in improving therapeutic outcomes

K4: Explain bioavailability and bioequivalence and the design of BA/BE protocols.

K5: Calculate various pharmacokinetic parameters using compartment models in normal and diseased conditions.

K6: Employ the factors to be considered in dose calculation for Geriatrics, Paediatrics and obese population

SKILL

S1: Determine the order of reaction of the drug movement in the body using the given data
S2: Estimate fraction of the administered dose (relative and absolute bioavailability) that enters systemic circulation
S3: Illustrate Compartment models (one and two) to give visual representation of drug disposition and rate process associated with it.
S4: Calculate pharmacokinetic parameters using the plasma concentration time profile
S5: Demonstrate metric measures conversions, milli-equivalent to milligram and vice versa
S6: Calculate drug dosing in hepatic and renal failure

ATTITUDE

A1: Cooperate and work effectively in groups.
A2: Communicate effectively through presentations.
A3: Follow emerging trends in the field of pharmaceutical sciences
A4: Appreciate all the efforts to improve the knowledge
A5: Cultivate empathy and compassion.
A6: Embrace lifelong learning during professional development

1. Biopharmaceutics
1. **Introduction to Biopharmaceutics (9 Hr.)**

a. ***Absorption****:* Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes,

b. ***Distribution:*** Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

c. ***Elimination:*** Drug metabolism and basic understanding of metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs.

- Pharmacokinetic drug interactions
- Inhibition and Induction of Drug Metabolism.
- Inhibition of Biliary Excretion**.**

d. ***AI for predicting ADME properties***

2. Introduction to Pharmacokinetics and compartment models. (13 Hr.)

Definition and introduction to Pharmacokinetics,
One Compartment model (a) Intravenous Injection (Bolus) (b) Intravenous infusion and (c) Extravascular administrations. Pharmacokinetics parameters - K_e, $t_{1/2}$,V_d, AUC,K_a, Clt, Clt_{hep} and CL_R- Extraction ratio definitions methods of eliminations, understanding of their significance and application.

Two compartment open model. IV bolus, IV infusion and oral administration, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.

Introduction to non-compartmental pharmacokinetics, Statistical Moment Theory, MRT for various compartment models, Physiological Pharmacokinetic model.

Role of pharmacokinetics in improving therapeutic outcomes and reducing adverse effects. **(SDG 3: Good Health and Well-being)**

3.Multiple – Dosage Regimens (7 Hr.)

a. Repetitive Intravenous injections – One Compartment Open Model

b. Repetitive Extravascular dosing – One Compartment Open model

4. Nonlinear Pharmacokinetics. (7 Hr.)

a. Introduction

b. Factors causing Non-linearity.

c. Michaelis-Menton method of estimating PK parameters.

5. Bioavailability and Bioequivalence (10 Hr.)

a. Introduction.

Definition and objectives of bioavailability, absolute and relative bioavailability.

b. Methods of Assessment of Bioavailability

Pharmacokinetic Methods: Measurement of parameters such as C_{max}, T_{max}, and AUC. Urinary excretion data.
Pharmacodynamic Methods: Use of biomarkers and therapeutic response.
BCS-based Biowaiver.

c. Bioequivalence Studies:

Design of Bioequivalence Studies, regulatory Guidelines: Interpretation of confidence intervals for pharmacokinetic parameters. Importance in generic drug approval and substitution.

6. Pharmacokinetic variability. 7 Hr.

a. Variability due to body weight, age, sex, and genetic factor.
b. Variability due to disease state

7. Dosage adjustment in Renal and hepatic Disease 7 Hr.

- Renal impairment
- Pharmacokinetic considerations
- General approach for dosage adjustment in Renal disease.
- Measurement of Glomerular Filtration rate and creatinine clearance.
- Dosage adjustment for uremic patients. Extracorporeal removal of drugs.
- Effect of Hepatic disease on pharmacokinetics.

8. Population Pharmacokinetics. **4 Hr.**

- Introduction to Bayesian Theory.
- Adaptive method or Dosing with feedback. Analysis of Population Pharmacokinetic Data.

9. Design of dosage regimens 11 Hr.

- Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals. Loading dose, maintenance dose calculations -**2 Hr.**
- Metric measures – conversion factors**-1 Hr.**
- Milligram to Milliequivalent calculations -**1 Hr.**
- Drug dosing in the elderly, pediatrics and obese patients**. -7 Hr.**

ASSIGNMENTS:

1. Pharmacokinetic drug-drug interactions for the following category of drugs.
   Cardiovascular drugs
   Antidiabetic drugs
2. Write an assignment on in-vitro in-vivo correlation and collect representative data from literature to explain different levels of correlation (level A, B and C).
3. To calculate pharmacokinetic parameters using the software PK Solver for data sets collected from scientific literature for the following models
   a. One compartment model (iv bolus and extravascular)
   b. Two compartment model (iv bolus and extravascular)
   c. Noncompartment model (iv bolus and extravascular)

Note: Justify the use of different compartment models for the data.

4. To study the pharmacokinetic profile of complex injectables like liposomes and how does the PK profile change as compared to free drug injection.
5. Study the PK methods used for biologicals like monoclonal antibodies.
6. Prepare a list of drugs with different BCS classification and their corresponding bioavailability and PK parameters.
7. Drugs showing PK variability based on body weight and disease state.
8. Pharmacokinetics of concentration dependent antibiotics and time dependent antibiotic.

BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical: 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.

2. Comparison of dissolution studies of two different marketed products of same drug.

3. Influence of polymorphism on solubility and dissolution.

4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.

5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.

6. Calculation of Ka, Ke, $t_{1/2}$, Cmax, AUC, AUMC, MRT etc. from blood profile data.

7. Calculation of bioavailability from urinary excretion data for two drugs.

8. Calculation of AUC and bioequivalence from the given data for two drugs.

9. In vitro absorption studies.

10. Bioequivalency studies on the different drugs marketed e.g. Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.

11. Absorption studies in animal inverted intestine using various drugs.

12. Effect on contact time on the plasma protein binding of drugs.

13. Studying metabolic pathways for different drugs based on elimination kinetics data.

14. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.

Recommended Books: (Latest Editions)
TEXT BOOKS:

1. Gibaldi M. Biopharmaceutics and Clinical Pharmacokinetics, 4thedition PharmaMed Press, Hyderabad, 2005

3.Shargel L and Yu AB, Applied biopharmaceutics and pharmacokinetics, 7th edition McGraw Hill, 2016.

4. Brahmankar DM, JaiswalSB.Bio pharmaceutics and Pharmacokinetics-A Treatise, 3rd edn, VallabhPrakashan,Pitampura, Delhi, 2019.

REVIEW ARTICLE:

Sadybekov, A.V., Katritch, V. Computational approaches streamlining drug discovery. Nature 616, 673–685 (2023).

REFERENCE BOOKS:

1. Remington JP, Gennaro AR. Remington's Pharmaceutical Sciences, 18th edition, Mack Publishing Company, Pennsylvnia, 1990.

2. Gibaldi M and Perrier D. Pharmacokinetics, 2nd edition, Marcel Dekker Inc., New York, 1982

RECOMMENDED JOURNALS:

1. European Journal of Pharmaceutics and Biopharmaceutics, Elsevier
2. Journal of Pharmacokinetics and Pharmacodynamics, Springer
3. Drug Metabolism and Pharmacokinetics, Elsevier.

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
CLINICAL TOXICOLOGY (T)	**2**	**0**	**0**	**50**	**2**	**Pharm. D IV** **Pharm. D P. B I**	**PD.406T** **PDPB.106T**

SCOPE: Clinical toxicology deals with the complete understanding about the harmful effects of chemical or physical substances on the human beings and describes the principles of management of acute and chronic poisoning with different toxic substances. The subject also focused on the diagnosis, management, and prevention of poisoning and toxicity resulting from exposure to various substances, including drugs, chemicals, plants, venoms, and other potentially harmful agents.

The scope of clinical toxicology is broad and encompasses various aspects of toxicological assessment and intervention. To participate in the poison information awareness program in India and designing educational materials to raise awareness about toxic exposures and prevention strategies. Overall, the course provides a comprehensive framework that applies to diverse geographical settings, offering students the knowledge and practical skills to contribute to both local and global efforts in clinical toxicology, prevention, and public health initiatives.

COURSE OUTCOMES:

Upon successful completion of the course the student shall be able to:

KNOWLEDGE

K1. Identify signs and symptoms of specific poisonings.

K2. Discuss common decontamination techniques used in toxicology.

K3. Illustrate the principles of toxicokinetics and toxicodynamics.

K4. Apply the mechanisms of action of various toxic substances. Summarize the effects of toxins on different organ systems.

K5. Design educational materials to raise awareness about toxic exposures and prevention strategies.

K6. Evaluate the toxic component of a common household cleaning product.

SKILLS

S1. Develop comprehensive toxicology treatment plans for specific poisoning cases.

S2. Develop new strategies or protocols for managing toxicological emergencies.

S3. Correlate complex clinical cases involving multiple toxic agents to identify the causative agents.

S4. Analyze AI-generated clinical data to support diagnosis and treatment in toxicology.

S5. Ensure laboratory techniques to identify toxic substances in biological samples.

S6. Evaluate a research study on the effectiveness of a new antidote for a specific toxin, considering the study design and sample size.

ATTITUDE

A1. Distinguish patient education handout on poison prevention, highlighting common household hazards, and steps to take in case of accidental ingestion or exposure.

A2. Show recognition other healthcare professionals in educating society.

A3. Explore Poison information awareness program in India.

A4. Attain newer advancements in the healthcare system.

A5. Demonstrate the effectiveness of different treatment approaches for toxic exposures.

A6. Illustrate toxicology test results and correlate them with clinical findings.

LECTURE WISE CONTENTS:

UNIT-I Introduction to Clinical Toxicology **2 hours**

- Clinical toxicology and its application 1 Hr.
- Toxicological Risk Assessment 1 Hr.

UNIT-II Introduction to general principles involved in the management of poisoning: **4 hours**

- Stabilization 1 Hr.
- Evaluation Decontamination 1 Hr.
- Poison Elimination, Antidote and the clinical applications 1 Hr.

- Nursing and Psychiatric care 1 Hr.
- Poison information Centre

UNIT-III Gut Decontamination techniques **2 hours**

- Emesis, Gastric Lavage, Catharsis 1 Hr.
- Activated Charcoal and Whole Bowel Irrigation 1 Hr.

UNIT IV-Elimination Enhancement **2 Hours**

- Forced Diuresis and Extracorporeal Techniques (Haemodialysis, Haemoperfusion, Peritoneal Dialysis, Haemofiltration, Plasmapheresis, Plasma Perfusion and Cardiopulmonary Bypass). 2 hr.

UNIT V-Antidotes and the Clinical Applications **1 hour**

- Antidotes and classify antidotes.
- Clinical application of antidotes. 1 hr.

UNIT VI- Toxicokinetics **2 hour**

- Toxicokinetics. 1 hr.
- (Classification of Maternal/Fetal Risk in Toxicology. 1 hr.

Mechanism of Toxicity, Fatal dose or toxicity level, Clinical manifestations of acute and chronic poisoning, management of acute or chronic poisoning of the following:

UNIT VII **11 hours**

- Pesticide poisoning: organophosphorus compounds, carbamates (organochlorines, pyrethroids). 2 hr.
- Opiates overdose. 1 hr.
- Antidepressants. 1 hr.
- Barbiturates and benzodiazepines. 1 hr.
- Alcohol: ethanol, methanol. 1 hr.
- Paracetamol and salicylates. 1 hr.
- Non-steroidal anti-inflammatory drugs. 1 hr.
- Hydrocarbons: Petroleum products and PEG. 1 hr.
- Caustics: inorganic acids and alkali. 1 hr.
- Radiation poisoning 1 hr.

UNIT VIII-Heavy metals **5 hours**

- Arsenic 1 hr.
- Lead 1 hr.
- Mercury 1 hr.
- Iron 1 hr.
- Copper 1 hr.

UNIT IX-Venomous snake bites **4 hours**

- Families of venomous snakes 1 hr.
- Clinical effects of venoms 1 hr.
- General management as first aid 1 hr.
- Early manifestations, Complications and snake bite injuries. 1 hr.

UNIT X- Plant poisoning **2 hours**

- Mushrooms 1 hr.
- Mycotoxins. 1 hr.

UNIT XI- Food Poisoning **4 hours**

- Bacterial 1 hr.
- Viral 1 hr.
- Protozoal 1 hr.
- Parasitic poisoning 1 hr.

UNIT XII **1 hour**

- Envenomations – Arthropod bites and stings. 1 hr.

UNIT XIII-Substance abuse **6 hours**

- **Signs and symptoms of substance abuse and treatment of dependence**

  a) CNS stimulants: amphetamine 1 hr.
  b) Opioids and CNS depressants 1 hr.
  c) Hallucinogens: LSD 1 hr.
  d) Cannabis Group 1 hr.
  e) Tobacco 1 hr.
  f) Cough medicine, dextromethorphan and Inhalants 1 hr.

UNIT XIV- AI in Clinical Toxicology **4 hours**

- 1. Introduction to AI and Machine Learning in Toxicology 1 hour

  a) Basics of AI, ML, deep learning, and their relevance to toxicology
  b) Differences between AI-assisted diagnosis vs. traditional methods
- AI in Predictive Toxicology and Risk Assessment 1 hour

  a) QSAR models, deep neural networks for predicting toxicity
  b) AI in environmental and occupational toxicology
- AI in Poison Control and Clinical Decision Support Systems (CDSS) 1 hour

a) AI-enabled triage, treatment protocols, real-time alert systems
b) Integration with poison information centers

- 4. Ethical, Regulatory and Practical Challenges of AI in Toxicology 1 hour

a) Data bias, algorithm transparency, patient privacy
b) Regulatory guidance on AI in toxicological evaluation

ASSIGNMENTS

1. Describe the role of regulatory agencies in ensuring occupational and environmental health and safety. What are some examples of regulations and guidelines aimed at controlling exposures to toxic substances in workplaces and communities?

2. Discuss the significance of drug concentration interpretation in post-mortem toxicology. How does the concentration of a drug in post-mortem samples relate to its potential contribution to the cause of death?

3. Discuss the future directions and emerging trends in toxicology testing and biomonitoring, such as the use of advanced analytical techniques

4. Explain the role of pediatric poison control centers in managing pediatric toxicological emergencies.

5. Define the role of public awareness campaigns in poison prevention. How do education initiatives contribute to reducing the incidence of poisonings and promoting safe practices in homes, schools, and communities?

6. Describe the role and functions of poison centers as outlined in WHO guidelines. What services should poison centers provide to the community, healthcare providers, and public health agencies?

7. Discuss the concept of gene-environment interactions in toxicogenomics. How do genetic factors influence individual susceptibility to toxicants, and how can toxicogenomics approaches help elucidate the interplay between genetic variation, environmental exposures, and disease risk?

8. Examine future directions and emerging trends in telemedicine technology and applications for toxicology.

9. Explain the role of expert testimony in legal proceedings. What is the significance of expert witnesses in providing specialized knowledge and opinions to assist the court in understanding complex forensic evidence?

10. Explain the purpose of toxicity testing in drug development according to ICH-GCP safety guidelines.

TEXTBOOKS:

1. V V Pillay. Handbook of Forensic Medicine and Toxicology. Thirteenth edition 2003 Paras Publication, Hyderabad
2. Matthew J Ellenhorn. Ellenhorns Medical Toxicology – Diagnosis and Treatment of Poisoning. Second edition. Williams and Willkins publication, London
3. Lewis R. Goldfrank. Goldfrank's Toxicologic Emergencies. Eleventh edition. McGraw-Hill Education.

REFERENCE BOOKS:

1. Casarett and Doull's Toxicology by Curtis D. Klaassen; Louis J. Casarett; John Doull. 9th Edition.
2. Encyclopedia of Environmental Health by Jerome O. Nriagu (Editor-In-Chief). 2nd Edition.
3. Clarke's Analytical Forensic Toxicology. Negrusz, Adam; Cooper, Gail. 2nd edition.

JOURNALS:

1. International Journal of Toxicology, SAGE Publications.
2. Toxicological sciences, Oxford University Press
3. Forensic Toxicology, Springer.

**Latest edition of the text books & reference books can be referred.*

Course Title	L T P Hrs.	Credits	Year	Course Code
LIFE SKILLS	**3 0 0 75**	**3**	**Pharm. D IV** **Pharm. D P. B I**	**PD.407T** **PDPB.108T**

Scope

The objective of Life Skills course is to equip students with essentially required skills to conduct better and perform professionally during their personal and career life. Life Skills course is sub-grouped into three verticals namely Soft Skills, Aptitude Skills, and Verbal Skills. The topics covered under Soft Skills enable students to know more about self-awareness, assertiveness, communication, goal setting, time management, presentation, problem solving, team building, interview preparation etc. The topics covered under Aptitude Skills enable students to know more about numbers, equation, profit & loss, ratio & proportion, averages & mixtures, simple & compound interest, data interpretation etc. While the topics covered under Verbal Skills enable students to know more about vocabulary, grammar, reasoning, reading comprehension, e-mail writing etc.

Course Outcomes

Upon completion of this course, the students would be able

- To develop positive mindset, communicate professionally, manage time effectively and set personal goals and achieve them. To make formal and informal presentations with self-confidence.
- To demonstrate good interpersonal skills, solve problems and effectively participate in group discussions. To write technical resume and perform effectively in interviews.
- To analyse, understand and employ the most suitable methods to solve questions on arithmetic and algebra. To identify, investigate and arrive at appropriate strategies to solve questions on arithmetic, algebra and geometry with optimal time management.
- To analyse, understand and apply suitable techniques to solve questions on data analysis. To investigate, understand and use appropriate techniques to solve questions on logical reasoning and data analysis with optimal time management.
- To infer the meaning of words and use them in the right context. To have a better understanding of the nuances of English grammar and become capable of applying them effectively. To use diction that is more refined and appropriate and be competent in the knowledge of grammar to correct/improve sentences.
- To identify the relationship between words using reasoning skills. To understand and analyse arguments and use inductive/deductive reasoning to arrive at conclusions and communicate them convincingly. To examine, interpret, investigate passages, and generate ideas, structure them logically and express them in a style that is comprehensible to the audience/recipient.

Course Content

SOFT SKILLS	**25**
Introduction to Soft Skills.	1
Communication and Listening Skills	2
Communication process, verbal and non-verbal communications, elements of effective communication, listening skills, empathetic listening, role of perception in communication. Practice for empathetic conversations in clinics.	
Assertiveness Skills	1
The concept, assertiveness and self-esteem, advantages of being assertive, assertiveness and organizational effectiveness.	
Self-Perception and Self Confidence	1
Locus of control (internal v/s external), person perception, social perception, attribution theories-self presentation and impression management, the concept of self and self-confidence, how to develop self-confidence.	
Goal Setting	1
The concept, personal values and personal goals, goal setting theory, six areas of goal setting, process of goal setting: SMART goals, how to set personal goals (practice sessions). Setting SMART goal in align with five-year vision.	
Time Management	1
The value of time, setting goals/ planning and prioritizing, tools for time management, rules for time management, strategies for effective time management. Preparation of personal time management schedule.	
Presentation Skills	1
The process of presentation, adult learning principles, preparation and planning, practice, delivery, effective use of voice and body language, effective use of audio-visual aids, dos and don'ts of effective presentation. Difference between presentations on clinical case studies and informative presentations.	
Presentation Practice and Feedback	3
Every student will make an individual (or in a group) formal presentation on a chosen topic. The students will be given feedback for improvement	
Interpersonal Skill	1
The concept of interpersonal skills, understanding one's own interpersonal needs (activity), role of interpersonal skills in personal and professional success. Practice of phrases and gestures exhibiting interpersonal skills, in clinical scenarios as well as interviews.	
Group Problem Solving	1
The process, the challenges, the skills and knowledge required for the same. Activity/ demonstration	
Conflict Management	1

The concept, its impact and importance in personal and professional lives, (activity to identify personal style of conflict management, developing insights that helps in future conflict management situations.)

Team Building and Working Effectively in Teams 1

The concept of groups (teams), different stages of group formation, process of team building, group dynamics, characteristics of effective team, role of leadership in team effectiveness. (exercise to demonstrate the process of emergence of leadership in a group, debrief and reflection). Being flexible and adaptable in medical teams with professionals from diverse disciplines.

Group Discussions 1

The purposes of group discussions, types of group discussion and roles played in a group discussion, personality traits evaluated in a group discussion. Initiation techniques and maintaining the flow of the discussion, how to perform well in a group discussion.

Group Discussion Practice 3

CV Preparation 2

Preparation of industry relevant CV and reviewing the same.

Interview Skills 1

The purpose of a job interview, types of job interviews, how to prepare for an interview, dos and don'ts during interview. Focus on skills mentioned in job descriptions from Clinical area

Mock Interview Sessions 3

Few practice sessions in the class and individual sessions for all students outside the class time

APTITUDE SKILLS **25**

INTRODUCTION

Unit 1

Introduction to Numbers 2

Number line, classification of numbers, prime and composite numbers, co-prime numbers, number of zeros in an expression, LCM, HCF, remainder theorem, rules of divisibility, base system..

Basics of Equations 1

Introduction to simple and quadratic equations, roots of an equation, word problems, problems on ages, consistency of equations

Percentages, Profit & Loss 2

Introduction to percentages, percentage change, value appreciation and depreciation, comparison observations, fundamentals concepts of business/commercial terminologies like cost price, selling price, profit, loss, marked price and discount.

Ratio Proportion and Variation / Partnership 2

Fundamentals of ratios, duplicate ratio, triplicate ratio, sub duplicate ratio and sub triplicate ratio, direct and inverse proportion, joint variation, partnership and profit sharing.

Averages and Mixtures 1

Mean, median and mode, measure of central tendency, concept of assumed average and weighted average, AM, GM and HM – relationship between AM, GM and HM, cheaper quantity and dearer quantity, rule of allegation, profit v/s quality of items getting mixed.

Simple Interest and Compound Interest 1

Time value of money, capital/principle, period of investment, rate of return, period of compounding, SAGR and CAGR.

Data Interpretation 2

Representation of data using tables, bar charts, pie charts, case study, line graph, scatter diagram – analysing the data for decision making.

Venn Diagrams 1

Set theory – concept of sets, types of set, forms of set representation, power set, sub set and super set, 2 and 3 variable Venn-diagrams, familiarity with words like AND, OR, at least, at most, exactly 'n' elements.

Cubes 1

Importance of aligning cuts to minimize/maximize the number of pieces of small cubes, painting a cube and cutting the cube, disintegration and integration of cubes, diagonal cutting, volume/LSA/TSA of cubes.

Unit 2

Time and Distance 2

Speed, distance, displacement, relative speed, average speed, races, boats and streams-upstream and down-stream movement, problems on trains, concept of relative speed, motion in circular track – clockwise and anti-clockwise rotations.

Time and Work 2

Unitary method, concept of man-days, efficiency in task completion, sharing of wages proportionately, questions on pipes and cisterns.

Geometry, Mensuration 2

Line/ray/angles, length of segments, area and properties of geometrical figures, properties of angles, diagonals, LSA, TSA and volume of solids.

Seating Arrangements/ Puzzles 1

Linear arrangements, circular arrangements, selection, comparison and distribution of objects under given constraints, analysing given constraints and present definitive or probable solutions for a given problem.

Permutations and Combinations 2

Fundamental principle of counting-selection and arrangement of objects, factorial notations, permutations with/without repetition, rank of a word, sum of all permutations, team formation with certain constraints.

Probability 1

Chances, odds in favour and odds against favour, events-independent and mutually exclusive types, conditional probability.

Nonverbal Reasoning 1

Picture based series, mirror image, water image, paper folding, paper cutting, grouping of figures, figure matrix.

Quant Based Reasoning 1

Case study, application oriented problems.

VERBAL SKILLS **25**

Introduction

Unit I

Vocabulary Building 8

Introduction to the methods and practices of learning vocabulary, learning through practice sets to face questions on antonyms, synonyms, spelling error, analogy, wrong form of words, frequently confused words, understanding the nuances of spelling changes and wrong use of words.

Grammar 8

Analysing subject verb agreement, pronoun agreement, tense consistency, and misplaced or dangling modifiers, parallel construction, active and passive voices, faulty comparison. students take a few online practice tests to understand the test taking strategy and work on their specific areas of improvement, paragraph writing.

Unit II

Reasoning 2

Introduction to higher order thinking skills and deductive reasoning through critical thinking and syllogisms exercises. Students are trained to think critically and analyse an argument critically. They practice these skills extensively.

Logical Ordering of Sentences 2

Improve logical thinking and ability to put ideas cohesively.

Reading Comprehension 3

Intermediate & advanced level reading passages are provided to the students for practice. students are taught techniques to read a dense passage in a fast & accurate manner.

Punctuation and E-mail Writing 2

Students hone their e-mail writing skills and are taught the essentials of punctuation and e-mail etiquette.

References

Communication and Listening Skills

- Andrew J DuRbin , "Applied Psychology: Individual and organizational effectiveness", Pearson- Merril Prentice Hall, 2004
- Michael G Aamodt, "An Applied Approach, 6th edition", Wadsworth Cengage Learning, 2010

Assertiveness Skills

- Robert Bolton, Dorothy Grover Bolton, "People Style at Work..and Beyond: Making Bad Relationships Good and Good", Ridge Associates Inc., 2009
- John Hayes "Interpersonal skills at work", Routledge, 2003
- Nord, W. R., Brief, A. P., Atieh, J. M., & Doherty, E. M., "Meanings of occupational work: A collection of essays (pp. 21- 64)", Lexington, MA: Lexington Books, 1990

Self-Perception and Self-Confidence

- Mark J Martinko, "Attribution theory: an organizational perspective", St. Lucie, 1995
- Miles Hewstone,"Attribution Theory: Social and Functional Extensions", Blackwell, 1983

Time Management

- Stephen Covey, "The habits of highly effective people", Free press Revised edition, 2004
- Kenneth H Blanchard ,"The 25 Best Time Management Tools & Techniques: How to Get More Done Without Driving Yourself Crazy" , Peak Performance Press, 1st edition 2005
- Kenneth H. Blanchard and Spencer Johnson, "The One Minute Manager" , William Morrow, 1984

Team Building

- Thomas L.Quick, "Successful team building", AMACOM Div American Mgmt Assn, 1992
- Brian Cole Miller, "Quick Team-Building Activities for Busy Managers: 50 Exercises That Get Results in Just 15 Minutes", AMACOM; 1 edition, 2003.
- Patrick Lencioni, "The Five Dysfunctions of a Team: A Leadership Fable", Jossey-Bass, 1st Edition, 2002

Aptitude Skills

- Arun Sharma, “How to Prepare for Quantitative Aptitude for the CAT Common Admission Test”, Tata Mc Graw Hills, 5th Edition , 2012
- Arun Sharma, “How to Prepare for Logical Reasoning for the CAT Common Admission Test”, Tata Mc Graw Hills, 2nd Edition, 2014
- Arun Sharma, “How to Prepare for Data Interpretation for the CAT Common Admission Test”, Tata Mc Graw Hills, 3nd Edition, 2015
- R.S. Aggarwal, “Quantitative Aptitude For Competitive Examinations”, S. Chand Publishing, 2015
- R.S. Aggarwal, “A Modern Approach To Verbal & Non-Verbal Reasoning”, S. Chand Publishing, Revised -2015
- Sarvesh Verma, “Quantitative Aptitude-Quantum CAT” , Arihant Publications, 2016
- www.mbatious.com
- www.campusgate.co.in
- www.careerbless.com

Verbal Skills

- Lewis Norman, “Word Power Made Easy”, Goyal Publishers, Reprint edition, 1 June 2011
- S. Upendran, “Know Your English”, Universities Press (India) Limited, 2015
- Green, Sharon, and Ira K. Wolf, “Barron's New GRE”, Barron's Educational Series, 2011
- Kaplan, “New GMAT Premier”, Kaplan Publishing, U.K., 2013
- www.merriam-webster.com
- www.bbc.co.uk/learningenglish
- www.cambridgeenglish.org
- Kaplan GMAT 2012 & 13
- www.campusgate.co.in
- www.indiabix.com
- www.bristol.ac.uk/arts/skills/grammar/grammar_tutorial/page_55.htm

Course Title	L	T	P	Total Hrs.	Year	Course Code
PHARMACOTHERAPEUTICS – I &2 (Theory)	**2**	**1**	**0**	**75**	**Pharm. D P. B I**	**PDPB.107T**
PHARMACOTHERAPEUTICS – I & 2 (Practical)	**0**	**0**	**3**	**75**	**Pharm. D P. B I**	**PDPB.113T**

SCOPE: This course is designed to impart knowledge and skills necessary for the rational use of medicines. It provides an opportunity to learn the pharmacotherapeutic management of various diseases including recent advances, approved treatment algorithms and guidelines.

It gives an insight into the basis behind the selection of drugs in disease management and the role of pharmacological and non-pharmacological interventions. This course also highlights understanding, detection, assessment and prevention of various drug-related problems and promote health and well-being, reducing disease burden and ensure access to essential medicines to all thereby achieving standard development goals (SDG)-3.

Recent advancements in Pharmacotherapy and patient-specific management strategies including artificial intelligence (AI) are included and emphasized. The course emphasizes student-directed acquisition of necessary knowledge in the management of various diseases.

The course emphasizes student-directed acquisition of knowledge on pathogenesis, pharmacotherapy, dose adjustment and patient counselling and various AI-related techniques used in the management of various diseases.

COURSE OUTCOMES:

Upon successful completion of the course students shall be able to;

KNOWLEDGE

K1: State the definitions of various disorders.
K2: Outline the etiopathogenesis and clinical manifestations of various diseases.
K3: Enumerate the reference ranges for various laboratory parameters.
K4: Illustrate standard treatment guidelines used for various diseases/disorders.
K5: Discuss the role of pharmacological and non-pharmacological interventions in various diseases/disorders.
K6: Describe the patient-specific parameters relevant in initiating and continuing drug therapy. (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

SKILL

S1: Justify the relevance of changes in drug therapy in the management of various disorders.

S2: Interpret the variations in laboratory values.

S3: Apply pharmacological knowledge in prevention and treatment of various disorders.

S4: Demonstrate the ability to recognize and report various drug related problems.

S5: Solve the various drug-related problems in the patient drug therapy.

S6**:** Display proficiency in communicating clearly with a patient regarding the correct utilization of prescribed drugs.

ATTITUDE

A1: Appreciate and respect the cultural backgrounds, beliefs and values of patients.

A2: Recognize the emotional and psychological aspects of illness and demonstrate sensitivity in interactions with patients, families and caregivers.

A3: Communicate effectively with various stakeholders and exhibit professionalism in all clinical activities.

A4: Appreciate effective reporting of drug related problems among healthcare professionals.

A5: Display sincerity, punctuality and integrity in academic and nonacademic activities.

A6: Uphold the ethical values in maintaining the confidentiality of patient information.

LECTURE-WISE CONTENTS:

The lecture will provide a comprehensive overview of disease diagnosis and management, covering key aspects such as **Introduction, Differential Diagnosis, Therapeutic Goals, and Pharmacological Management** in alignment with the latest clinical guidelines and evidence-based treatment algorithms. Additionally, it will explore **non-pharmacological approaches** that complement medical therapies, emphasizing lifestyle modifications and behavioral interventions. The session will also highlight **recent advancements**, including the integration of **AI in diagnostics and disease management**, showcasing its role in enhancing precision medicine, predictive analytics, and personalized treatment strategies.

1. **Cardiovascular system:** **Total hours=13**
    - Hypertension 3
    - Congestive cardiac failure 3
    - Myocardial infarction 3
    - Angina Pectoris 2
    - Arrhythmias 2

2. **Respiratory system:** **Total hours=7**
   - Introduction to Pulmonary function test (Preliminary reading)
   - Asthma 3
   - Chronic obstructive airways disease 3
   - Drug induced pulmonary diseases 1

3. **Endocrine system:** **Total hours=6**
   - Diabetes 3
   - Thyroid diseases 2
   - Oral contraceptives and Hormone replacement therapy (preliminary reading)
   - Osteoporosis 1

4. **Infectious disease:** **Total hours=13**
   - Guidelines for the rational use of antibiotics and surgical Prophylaxis 1
   - Tuberculosis 1
   - Meningitis 1
   - Respiratory tract infections 1
   - Gastroenteritis 1
   - Endocarditis 1
   - Septicemia 1
   - Urinary tract infections 1
   - Protozoal infection- Malaria 1
   - HIV & Opportunistic infections 1
   - Fungal infections 1
   - Viral infections 1
   - Gonarrhoea and Syphillis 1

5. **Musculoskeletal disorders** **Total hours=6**
   - Rheumatoid arthritis 2
   - Osteoarthritis 1
   - Gout 1
   - Spondylitis 1
   - Systemic lupus erythematosus 1

6. **Renal system** **Total hours=7**
   - Acute Renal Failure and Drug induced renal disorders 3
   - Chronic Renal Failure 3
   - Renal Dialysis 1

7. **Hematological system** **Total hours=6**
   - Anemia- Microcytic, Macrocytic, Auto-Immune Hemolytic Anemia 3
   - Coagulation Disorders -Deep Vein Thrombosis- Venous Thromboembolism & Pulmonary Embolism 2
   - Drug induced blood disorders 1

8. **Central Nervous System** **Total hours=8**

- Alzheimer's Disease 2
- Parkinson Disease 2
- Epilepsy 2
- Stroke 2

9. Psychiatric Disorders **Total hours=9**

- Schizophrenia 3
- Affective Disorders 2
- Anxiety Disorders 2
- Sleep Disorders 1
- Obsessive Compulsive Disorders 1

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PHARMACOTHERAPEUTICS–II PRACTICAL
(Guidelines for Practical)

Students are required to collect cases from various departments of AIMS hospital and a minimum of 7 cases (including sessional exam) should be presented in SOAP format and 20 should be recorded covering the most common diseases included in the theory syllabus. During the case collection, students shall be able to

- Understand the changes in physiological functioning in the given disease condition of the patient.
- Learn the normal values of laboratory parameters applicable to each case
- Able to interpret the variations in laboratory parameters and justify the reasons for variations.
- Explain the rationale for the progress of changes in drug therapy & and clinical outcome
- Learn the PK/PD parameters of each drug in the treatment regimen and correlate it with the clinical outcome of the patient.
- Compare the current treatment regimen of the patients with the approved treatment guidelines
- Learn the antibiotic policies followed in our hospital.

Assignments:

- Case study analysis: Drug therapy for complex condition
- Pharmacogenomics applications in optimizing drug therapy for individual patients.
- Healthcare Technology and Digital Health in Drug Therapy Management
- Current challenges in managing multi-drug bacterial infections in hospitalized patients.
- Recent trends in the management of Tuberculosis in patients with chronic liver disease.
- Current management and challenges of invasive fungal infections in ICU.
- National Health schemes in India: Impact on pharmaceutical care.

Text Books:

- Walker, Roger. Clinical Pharmacy and Therapeutics.5th ed. Edinburgh: Churchill Living Stone publication;2012
- Dipiro JT. Pharmacotherapy: A Pathophysiologic approach. 11thed.NewYork: McGraw Hill;2017.
- Herfindal Eric T. Clinical Pharmacy and Therapeutics.5th ed. Philadelphia: LPWW;1988
- Robbins and Cotran. Pathologic basis of disease. 8th ed. Philadelphia: Elsevier;2003

Reference Books:

- Kodak-Kimble, Mary Ann. Applied Therapeutics: The Clinical Use of Drugs. 11th ed. Philadelphia: LPWW;2009
- Porth's Essentials of Pathophysiology. 5thed, Philadelphia: LPWW;2011
- Brunton L, Lazo JS. Goodman & Gilman's The Pharmacological Basis of Therapeutics. 13th ed. New York: McGraw Hill;2006

Journals

- Indian Journal of Medical Research
- Journal of American Medical Association
- Journal of Pulmonology and Respiratory Research
- Journal of Cancer

FIFTH YEAR

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
CLINICAL RESEARCH (T)	**2**	**0**	**0**	**50**	**2**	**Pharm. D V** **Pharm. D P. B II**	**PD.501T** **PDPB.201T**

SCOPE:

This course is designed to make the students to understand the principles and gain adequate knowledge regarding the various approaches to drug discovery including clinical phase of development. Also enables the students to understand and implement all regulatory and ethical requirements that are required during the process of drug development. The students will build a deeper understanding of drug characterization, clinical trials, Good Clinical Practice (GCP) guidelines, and ethical considerations in clinical research. This involves grasping the concepts and interpreting them within a real-world context.

Applying their knowledge in clinical trial designs, regulatory processes like Investigational New Drug Applications (INDA), and submission of Abbreviated New Drug Applications (ANDA), which will prepare them for professional practice in the field of drug development. Through assignments on clinical study documents and data management systems, students will be tasked with creating detailed reports, ensuring they can generate new ideas or solutions that improve clinical research practices. Students will also gain practical insights into the roles and responsibilities of clinical trial personnel, preparing them for professional roles in clinical research, data management, and regulatory affairs, ensuring a well-rounded skill set in drug development.

COURSE LEARNING OUTCOMES

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

KNOWLEDGE

K1: Describe the concept and process of new drug development.

K2: Discuss the various types of clinical trials and their designs.

K3: Illustrate the roles and responsibilities of key players in clinical trials.

K4: Apply the importance and application of regulatory and ethical requirements in clinical trials.

K5: Employ the data management aspects of clinical trials.

K6: Evaluate the detailed aspects and complexities of safety monitoring and reporting in clinical trials.

SKILL

S1: Compare the knowledge to conceptualize, design, and conduct clinical trial activities.

S2: Develop the significance and implications of different clinical trial designs.

S3: Correlate the clinical trial data.

S4: Analyze AI-based approaches for improving patient recruitment and trial efficiency.

S5: Ensure a clinical trial protocol based on study objectives and regulatory requirements.

S5: Evaluate various tools and techniques for effective data interpretation in clinical trials.

ATTITUDE

A1: Distinguish commitment to ethical standards in clinical research.

A2: Collaborate effectively with diverse teams in the clinical research environment.

A3: Explore emerging trends and advancements in clinical research.

A4: Attain a critical and analytical mindset towards clinical research data and processes.

A5: Demonstrate the ethical principles in conducting Clinical research.

A6: Illustrate clear and effective communication in clinical research settings.

LECTURE WISE CONTENT.

UNIT 1. Drug discovery and development process: 15 hours.

- **Introduction of drug discovery and development 4 hours**

- Need for drug discovery 1 hr.
- Drug discovery (Target identification and validation, Lead finding, Lead optimization, Early safety tests) 1 hr.
- Pathways of drug development (Discovery, Preclinical and clinical development) 2 hr.

- **Various Approaches to drug discovery 2 hours**

A) Pharmacological:

- Pharmacological profiling (*In vitro* profiling, *in vivo* profiling: Testing in animal models of disease) 1 hr.
- Validity criteria in context to animal testing (Face validity, Construct validity, Predictive validity), Safety pharmacology 1 hr.

B) Toxicological: **2 hour**

- Preclinical toxicity testing: Acute toxicity (Acute tolerance testing) Sub chronic and chronic toxicity 1 hr.
- Tissue specific toxicity 1 hr.

C) Investigational new drug Application (INDA): **3 hours**

- Importance and types of INDA and Laws 1 hr.
- Regulations, Policies, (USFDA CFR) 1 hr.
- Procedures of submission of INDA and Different criteria for IND application 1 hr.

D) Drug characterization and Dosage form: 4 hours

- Drug characterization techniques in drug development process, 1 hr.
- Dosage form design in pre-clinical and clinical stages, 1hr.
- Biopharmaceutical classification of drugs and Critical Pharmacokinetic parameter in drug development. 2 hr.

UNIT 2. Clinical development of drug: 31 hours

A) Introduction to Clinical trials 6 hours

- History, Purpose and Importance of clinical trials 1hr

- **Ethical guidelines in Clinical Research:** Ethical Issues in Biomedical Research – Principles of ethics in biomedical research 2 hr.
- Historical Perspectives: Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, Nuremberg trials 1h
    - The declaration of Helsinki, Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines. 2 hr.

B) . Good Clinical Practice 2 hours

- ICH-GCP 1 hr.
- Central drug standard control organization (CDSCO) guidelines 1 hr.

C) Challenges in the implementation of guidelines 4 hours

- Professional training on GCP, infrastructure, regulatory environment, and IRC/IEC 2 hr.
- ICD administration, safety reporting, investigational product, record keeping/source documents, grants/payments, trial report/publications. 2 hr.

D) Institutional Review Board (IRB) / Independent Ethics Committee (IEC) 1 hr.

- Composition, responsibilities, procedures of IRB / IEC7. 1 hr.

E) . Various phases of clinical trial: 3 hours

- Interventional trials and Observational trials 2 hr.
- Health outcome measures (Clinical & Physiological, Humanistic, and economic) 1 hr.

F) Methods of post marketing surveillance 2 hours

- Sources of Post Marketing Surveillance 1 hr.
- Types of Post Marketing Surveillance 1hr.

G) Abbreviated New Drug Application submission. 1 hours

- Introduction and Requirement of ANDA 1 hr.

H) Overview of regulatory environment in 1 hours

- Regulatory environment in India, USA and Europe 1 hr.

I) Role and responsibilities of clinical trial personnel as per ICH GCP 3 hours

- Sponsor and Investigators 1 hr.
- Contract research coordinators and Clinical research associate 1 hr.
- Auditors and Regulatory authority 1 hr.

J) Designing of clinical study documents **2 hours**

- Protocol, and CRF 1 hr.
- ICF, PIC with assignment 1 hr.

K) Informed consent Process **1 hour**

- Process and Types of ICF 1 hr.

L) Data management and its components: **3 hours**

- System Requirement for Data Management: Electronic data capture systems 1 hr.
- Clinical Trial Data Management: Standard Operating Procedures 1 hr.
- Quality Control and Quality Assurance in CDM 1 hr.

M) . Safety monitoring in clinical trials. **2 hours**

- Data and Safety Monitoring Board (DSMB) 1 hr.
- Interim analysis and Final analysis 1 hr.

UNIT III: Application of Artificial Intelligence in Clinical Research **4 hours**

A) AI in Clinical Trial Design and Patient Recruitment 1 hr.

- Predictive analytics for protocol design
- Patient stratification and inclusion/exclusion optimization
- Real-world data (RWD) integration

B) AI for Trial Monitoring, Data Management, and Outcome Prediction 1 hr.

- Risk-based monitoring and anomaly detection
- Natural language processing (NLP) for adverse event reporting
- AI in electronic data capture and remote monitoring

C) Ethical and Regulatory Considerations for AI in Clinical Trials 2 hr.

- Transparency and explainability of AI algorithms
- Regulatory perspectives (FDA, EMA) on AI use in clinical research
- Data privacy, informed consent, and bias mitigation in AI tools

TEXTBOOKS (THEORY)

1. Guru Prasad M. Textbook on Clinical Research, a guide for aspiring professionals and professionals, 2nd Edition, Pharma Med Press; 2018.
2. K.P.R. Chowadry. A textbook of clinical research and Pharmacovigilance, First Edition, PharmaMed Press; 2022.

REFERENCE BOOKS (THEORY)

1. Goodman Gilman A,Rall T.W, Nies, A.I.S. and Taylor, P. Goodman and Gilman's The Pharmacological Basis of therapeutics. 13th Ed, Mc Graw Hill: New York; 2017
2. Lawrence M.Friedman C.,FurbergD., David L., David M. Christopher B. G. Fundamentals of Clinical Trials 5th Edition, Springer; 2015.

GUIDELINES/ONLINE RESOURCES

1. ClinicalTrials.gov: https://www.clinicaltrials.gov
2. European Union Clinical Trials Register (EU CTR): https://www.clinicaltrialsregister.eu
3. International Council for Harmonisation (ICH): https://www.ich.org/
4. Central Drugs Standard Control Organization: https://cdsco.gov.in/opencms/opencms/en/Home/

ASSIGNMENTS

1. Evaluate the transformative impact of Artificial Intelligence and Machine Learning on optimizing clinical trial design and real-time monitoring strategies.
2. Discuss precision medicine concepts with biomarker-driven clinical trials to propose personalized therapeutic approaches.
3. Asssess the integration of wearables and mobile health technologies in enhancing data collection, patient adherence, and trial outcomes.
4. Analyze the complexities of globalized clinical trial supply chains and design innovative technology-driven solutions to mitigate risks and inefficiencies.
5. Evaluate the FDA Investigational New Drug (IND) review process by critiquing the roles of the IND Review Team and the regulatory approval workflow.
6. Analyze the organizational structure and regulatory strategies of the FDA's Center for Drug Evaluation and Research (CDER) to assess its effectiveness in drug approval.
7. Analyze current FDA guidance documents for New Drug Application (NDA) submissions to recommend improvements for regulatory compliance and efficiency.
8. Examine and interpret the Code of Federal Regulations (CFR) as it pertains to clinical trials, identifying regulatory gaps and proposing amendments to enhance compliance.
9. Design advanced statistical methodologies, including adaptive and Bayesian models, for improving clinical trial flexibility and decision-making.
10. Apply recent advancements in gene therapy with clinical trial design challenges, and propose innovative frameworks to address ethical, logistical, and scientific barriers.

Course Title	L	T	P	Total Hrs.	Credits	Year	Course Code
PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS	**2**	**0.5**	**0**	**50**	**2**	**Pharm. D V** **Pharm. D P. B II**	**PD.502T** **PDPB.202T**

SCOPE:

The course on the epidemiological and economical aspects of drugs and disease offers a comprehensive exploration into the intricate interplay between public health, pharmacology, and economics. Through an in-depth study of epidemiological patterns, students gain insights into how diseases propagate within populations and the corresponding utilization of pharmaceuticals. This includes analyzing disease prevalence, incidence rates, and the impact of various factors on health outcomes. The course delves into the economic dimensions of drug development, production costs, and the evaluation of cost-effectiveness in treatment modalities. By connecting theoretical frameworks with real-world scenarios, such as case studies and public health policies, students develop critical thinking skills essential for rational decision-making in healthcare settings. This includes assessing the risks and benefits of different therapies, interpreting epidemiological data, and understanding the broader implications of drug use on public health.

Ultimately, the course equips students with the knowledge and analytical tools necessary to navigate the complexities of drug utilization within populations, fostering a deep understanding of how to optimize healthcare practices while considering the economic implications, thereby preparing them for diverse roles in healthcare management, policy-making, and clinical practice.

COURSE OUTCOMES

Upon completion of the subject student shall be able to:

KNOWLEDGE

K1: Recognize the ethical considerations involved in conducting pharmacoepidemiological studies, especially concerning patient privacy and data handling.

K2: Describe the role of pharmacoepidemiology in providing reliable data to support drug safety and efficacy assessments.

K3: Explain the importance of evidence-based practice in pharmacy and healthcare decision-making..

K4: Consolidate information from pharmacoepidemiological studies to draw evidence-based conclusions about drug effects and adverse events.

K5: Evaluate the strengths and limitations of different epidemiological study designs in assessing causal relationships between drug exposure and health outcomes.

K6: Assess pharmacoeconomic models and studies to make informed decisions on drug pricing, formulary management, and resource allocation in healthcare settings.

SKILLS

S1: Identify epidemiological study designs and economic evaluation methods in pharmaceutical research.

S2: Apply pharmacoepidemiological methods to evaluate drug safety and effectiveness.

S3 Conduct analysis of pharmacoepidemiological data to identify drug-related effects

S4: Analyse the validity and reliability of pharmacoepidemiological studies and healthcare interventions.

S5:. Evaluate economic data to guide drug pricing and reimbursement decisions.

S6: Interpret trends in medication effectiveness to improve prescribing practices

ATTITUDE

A1: Respect ethical considerations in patient privacy and data handling during studies.

A2: Uphold ethical principles in pharmacoeconomic evaluations for fair resource allocation.

A3: Recognize the importance of evidence-based practice in healthcare decision-making.

A4: Value pharmacoepidemiology's role in ensuring drug safety and efficacy.

A5: Develop a problem-solving approach to address drug-related issues.

A6: Emphasize patient-centered care while considering economic implications on well-being.

LECTURE WISE CONTENTS

UNIT I: PHARMACOEPIDEMIOLOGY: **3 hours**

- Definition and Scope
- Origin and evolution of Pharmacoepidemiology 1 hour
- Need for Pharmacoepidemiology 1 hour
- Aims and applications of Pharmacoepidemology 1 hour

Measurement of outcomes in Pharmacoepidemiology **7 hours**

- Define and classify outcomes(ECHO model)- 1 hour
- Outcome measures and its classification 1 hour
- Statistical measures: Prevalence, incidence and incidence rate. 2 hours

- Drug use measures: Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement 3 hours

Concept of risk in pharmacoepidemiology 2 hours

- Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio 1 hour
- Case studies and relevant examples of measuring risk in pharmacoepidemiology 1 hour

UNIT II PHARMACOEPIDEMIOLOGICAL METHODS 16 hours

Includes theoretical and practical aspects of pharmacoepidemiology explained with aid of case studies:

- Pharmacoepidemological methods: observational and interventional 1 hour
- **Observational :** descriptive and analytical(Case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case – cohort studies, systematic review and meta – analysis studies, Drug utilization review (Relevance of DUR), 6 hours
- **Interventional:** Quasi-randomized trial, Randomised Control Trials including types of randomisation and trial design. 1 hour
- Spontaneous reporting 1 hour
- Prescription event monitoring and Record linkage system. 1 hour

Sources of data for pharmacoepidemiological studies 3 hours

- Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology 3 hours

- Studies of vaccine safety
- Hospital pharmacoepidemiology
- Pharmacoepidemiology and risk management,
- Drug induced birth defects.

UNIT III Pharmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations 2hours

- Role in formulary management decisions
- Decision models in pharmacoeconomics: markov model & decision tree model and its analysis

Pharmacoeconomic evaluation 16 hours

- Outcome assessment and types of evaluation 4 hours
- Includes theoretical and practical aspects of pharmacoeconomics explained with aid of case studies : Cost – minimization, cost- benefit, cost – effectiveness, cost utility **12 hours**

Applications of Pharmacoeconomics 4 hours

- Software and case studies

ASSIGNMENTS

- Explain hospital-based pharmacoepidemiology, including drug use, ADR monitoring, and formulary decisions.
- Review recent pharmacoepidemiology advances and present key findings.
- Discuss and compare vaccine types based on mechanism, efficacy, and safety.
- Investigate challenges and ethics of pharmacoepidemiological studies in hospitals.
- Review current pharmacoeconomics trends, policies, and challenges.
- Report on budget impact modeling processes and its importance in pharmacoeconomics.
- Analyze how Health Technology Assessments link pharmacoeconomics to healthcare outcomes.

TEXT BOOKS:

- Strom BL, Kimmel SE, editors. Textbook of Pharmacoepidemiology: Strom/Textbook of Pharmacoepidemiology.6th ed.Chichester, England: John Wiley & Sons; 2006.
- Revikumar KG. Pharmacoepidemiology and Pharmacoeconomics: Concepts and Practice.2nd ed.Pharmamed Press; 2016.

REFERENCE BOOKS:

- Holdford DA. Renee J. G. Arnold (editor). Pharmacoeconomics: From theory to practice.2nd ed. Am J Pharm Educ; 2010.
- Parashar A, SwapnaPeri. Concept Of Pharmacoepidemiology And Pharmacoeconomics.1st ed. 2020.
- Nour S, Plourde G. Pharmacoepidemiology and pharmacovigilance. 1st ed. San Diego, CA: Academic Press; 2018.

JOURNALS

- FARMAKOEKONOMIKA. Modern Pharmacoeconomics and Pharmacoepidemiology [Internet]. Pharmacoeconomics.ru. [cited 2022 Apr 11]. Available from: https://www.pharmacoeconomics.ru/jour
- Pharmacoepidemiology and drug safety. Wiley; 2006.

Course Title	L	T	P	Total Hrs.	Year	Course Code
Precision Medicine (T)	**2**	**0**	**0**	**50**	**Pharm. D V** **Pharm. D P. B II**	**PD.503T** **PDPB.203T**

SCOPE:

The scope of the subject of Precision Medicine covers a broad range of concepts that explore the relationship between genetic variations and drug response, ultimately leading to personalized medicine. The course addresses the fundamental genetic mechanisms that influence drug metabolism, highlighting key Precision Medicine concepts such as enzyme polymorphisms, gene-drug interactions, and the genetic basis of pharmacokinetics and pharmacodynamics. Additionally, it emphasizes the practical application of genetic testing in clinical practice, focusing on the use of Precision Medicine in optimizing drug safety, efficacy, and individualized treatment, particularly in oncology, psychiatry, and for adverse drug reactions. Ethical, legal, and social implications are integral to the field, addressing privacy concerns, genetic discrimination, and regulatory frameworks for Precision Medicine. Emerging technologies such as Next-Generation Sequencing (NGS), CRISPR, and artificial intelligence are discussed in relation to their potential in advancing pharmacogenomics and personalized medicine. The course ultimately aims to equip students with the knowledge, skills, and ethical awareness required to implement Precision Medicine practices effectively in clinical settings.

KNOWLEDGE

K1: Identify the impact of genetic variation on drug metabolism.

K2: Discuss the ethical implications of pharmacogenomic testing.

K3: Illustrate clinical guidelines for pharmacogenomic testing in specific drug therapies.

K4: Apply genetic factors involved in adverse drug reactions.

K5: Employ the role of pharmacogenomics in personalized oncology treatments.

K6: Evaluate the potential of next-generation sequencing and CRISPR technology in advancing pharmacogenomics.

SKILLS

S1: Apply pharmacogenomic principles to optimize drug dosing.

S2: Perform genetic testing using PCR, SNP arrays, or NGS to identify polymorphisms relevant to drug responses.

S3: Interpret genetic test results in clinical contexts to guide treatment decisions.

S4: Analyse emerging technologies like machine learning or AI into pharmacogenomic practice.

S5: Design case-based analyses to assess pharmacogenomic interactions with drugs.

S6: Evaluate the cost-effectiveness of pharmacogenomic testing in clinical settings.

ATTITUDE

A1: Recognize the importance of ethical considerations in pharmacogenomic testing.

A2: Demonstrate an openness to the integration of pharmacogenomic data into clinical practice.

A3: Exhibit sensitivity toward patients' cultural and socioeconomic contexts in the application of pharmacogenomics.

A5: Commit to continuous learning about the advancements in pharmacogenomic technologies.

A5: Value personalized medicine approaches to improve drug safety and efficacy.

A6: Exhibit ethical responsibility in considering the social impact of pharmacogenomics.

Unit I: Introduction to Pharmacogenomics (5 hours)

- **Definition and Scope of Pharmacogenomics** **1 hr.**
  - Understanding pharmacogenomics: Concept and significance
  - Historical perspective and major milestones
  - Relevance in personalized medicine
- **Basic Genetics and Genomics** **2 hr.**
  - Overview of human genetics: Genes, alleles, and polymorphisms
  - DNA structure and function
  - Gene expression and regulation
- **Key Terminologies in Pharmacogenomics** **2 hr.**
  - Pharmacogenetics vs Pharmacogenomics
  - Genomic variants: SNPs, INDELs, CNVs, and HLA types

Unit II: Pharmacogenomic Mechanisms (8 hours)

- **Pharmacokinetics and Pharmacodynamics: The Genetic Basis 4 hr.**
  - Enzyme polymorphisms: Cytochrome P450 (CYP2C19, CYP2C9, CYP3A4/5, CYP2D6,CYP1A2,CYP2E1), UGTs, NAT2, TPMT
  - Transporter polymorphisms: ABCB1, SLCO1B1
  - Receptors: ADRB2, VKORC1, ACE
- **Gene-Drug Interactions 2 hr.**
  - The impact of genetic variation on drug absorption, distribution, metabolism, and excretion (ADME)
  - Case studies: Warfarin, Clopidogrel, and Thiopurines
- **Genetic Testing Methods 2 hr.**
  - Genotyping technique: NGS (Demonstration)
  - Pharmacogenomic biomarkers

Unit III: Clinical Applications of Pharmacogenomics (8 hours)

- **Pharmacogenomic Testing in Clinical Practice 4 hr.**
  - Examples of pharmacogenetic testing: Warfarin, Carbamazepine, and statins
  - Clinical guidelines: CPIC, FDA recommendations
- **Pharmacogenomics and Drug Safety 2 hr.**
  - Adverse drug reactions and pharmacogenomics
  - Case study: Stevens-Johnson syndrome (Carbamazepine) and HLA-B*1502
- **Personalized Medicine in Oncology 2 hr.**
  - Targeted therapies: HER2, EGFR, ALK inhibitors
  - Pharmacogenomic approaches in cancer treatment

Unit IV: Ethical, Legal, and Social Implications of Pharmacogenomics (5 hours)

- **Ethical Issues 2 hr.**
  - Privacy and consent in genetic testing
  - Genetic discrimination and equity in healthcare
- **Legal Aspects 2 hr.**
  - Regulatory frameworks: FDA, EMA guidelines
  - Implications of pharmacogenomic data in clinical trials and drug approval
- **Social and Economic Impact 1 hr.**
  - Pharmacogenomics in developing countries
  - Cost-effectiveness of pharmacogenomic testing

Unit V: Emerging Trends and Technologies in Pharmacogenomics (8 hours)

- **Next-Generation Sequencing and Pharmacogenomics 3 hr.**
  - The role of whole-genome sequencing (WGS) in personalized medicine

    - CRISPR and gene editing technologies
- **Pharmacogenomics and Artificial Intelligence** **3 hr.**
    - Machine learning in drug discovery and genetic data analysis
    - Integration of pharmacogenomic data into electronic health records (EHRs)
- **Future Directions** **2 hr.**
    - Pharmacogenomics in rare diseases
    - The role of pharmacogenomics in vaccine development

Unit VI: Case Studies and Real-World Applications (8 hours)

- **Case Study 1: Warfarin and Genetic Testing** **3 hr.**
    - Understanding VKORC1 and CYP2C9 gene polymorphisms
    - Case-based analysis of therapeutic drug monitoring and dosing
- **Case Study 2: Pharmacogenomics in Psychiatry** **3 hr.**
    - Antidepressants and genetic testing: CYP450 polymorphisms
    - The impact of genetic testing on treatment outcomes
- **Case Study 3: Adverse Drug Reactions (ADRs) and Pharmacogenomics 2 hr.**
    - Identifying patients at risk for ADRs
    - Pharmacogenomic guidance in clinical decision-making

Unit VII: Therapeutic Drug monitoring (8hours)

- Introduction - 1hr
- **Individualization of drug dosage regimen** (Variability – Genetic, Age and Weight, disease, Inter- acting drugs). - 1hr
- Indications for TDM. 1hr
- Protocol for TDM. 1hr
- Pharmacokinetic/Pharmacodynamic Correlation in drug therapy 1hr
- TDM of drugs used in the following disease conditions**:** cardiovascular disease, seizure disorders, Psychiatric conditions and organ transplantations 1 hr
- Design TDM protocol for Digoxin, Phenytoin, Carbamazepine , Gentamycin, Colistin, vancomycin, voriconazole,Lithium, Everolimus, Tacrolimus, 2 hrs

ASSIGNMENT:

1. Write an essay on the historical evolution of pharmacogenomics, focusing on key milestones and their relevance to the development of personalized medicine.

2. Compare and contrast pharmacogenetics and pharmacogenomics. Provide examples of how each approach is used in clinical practice.

3. Analyze the role of genetic polymorphisms (SNPs, INDELs, CNVs, and HLA types) in determining drug responses. Use relevant examples from literature to support your analysis.

4. Prepare a detailed report on how cytochrome P450 polymorphisms affect drug metabolism and provide case studies illustrating these effects (e.g., Warfarin).

5. Conduct a critical review of genetic testing methods used in pharmacogenomics (PCR, SNP arrays, NGS). Discuss their advantages and limitations.

6. Create a table or infographic that summarizes the key pharmacogenomic biomarkers for common drugs (e.g., Warfarin, Clopidogrel, and Thiopurines).

7. Discuss the application of pharmacogenomic testing in the clinical management of Warfarin therapy, emphasizing VKORC1 and CYP2C9 polymorphisms.

8. Analyze a case study of an adverse drug reaction (ADR) caused by a pharmacogenomic interaction (e.g., Stevens-Johnson syndrome from Carbamazepine). Suggest clinical strategies for managing such cases.

9. Write a paper discussing the ethical implications of pharmacogenomic testing, focusing on privacy concerns, consent, and genetic discrimination.

10. Evaluate the social and economic impacts of implementing pharmacogenomic testing in developing countries. Discuss the cost-effectiveness and accessibility of pharmacogenomics technologies.

11. Identify and discuss the challenges faced in implementing TDM, including issues related to sample collection, timing, and interpretation.
12. Examine how pharmacokinetic (PK) and pharmacodynamic (PD) data are integrated to individualize drug therapy.with case studies where PK/PD correlation has led to improved therapeutic outcomes.

REFERENCES:

- Bertino JS, McLeod HL. *Pharmacogenomics: Applications to Patient Care*. 2nd ed. New York: McGraw-Hill Education; 2020.
- Primorac D, Höppner W, Bach-Rojecky L, editors. Pharmacogenomics in clinical practice. Berlin/Heidelberg, Germany: Springer; 2024 Jan 4.
- Leon Shargel , Andrew B.C.Yu. Applied Biopharmaceutics and Pharmacokinetics, Seventh Edition: McGraw-Hill Education
- Malcolm Rowland, Thomas N. Tozer. Rowland and Tozer's Clinical Kinetics – concepts and applications , Fifth edition , Wolters Kluwer Health/Lippincott William & Wilkins,

JOURNALS:

1. *The Pharmacogenomics Journal*: https://www.nature.com/tpj/
2. Pharmacogenomics : https://www.tandfonline.com/journals/ipgs20

Course Title	L	T	HP	Total Hrs.	Year	Course Code
CLERKSHIP (T)	**0**	**0**	**20**	**600**	**Pharm. D V** **Pharm. D P. B II**	**PD.504T** **PDPB.204T**

SCOPE:

The clerkship is designed to provide comprehensive clinical training and hands-on experience in a hospital setting. This program focuses on integrating theoretical knowledge with practical skills in the clinical department, enabling students to develop a deeper understanding of patient care, medication management, and the role of a clinical pharmacist. The primary aim is to enhance students' clinical competencies, critical thinking, and decision-making abilities, preparing them to contribute effectively to multidisciplinary healthcare teams.

During the clinical department posting, students will be immersed in various aspects of patient care under the guidance of experienced clinical pharmacists and healthcare professionals. They will participate in patient rounds, review medication charts, and collaborate with doctors and nurses to optimize pharmacotherapy. The curriculum includes activities such as monitoring drug therapy, identifying and resolving drug-related problems, providing drug information, and counselling patients on medication use. Additionally, students will be involved in clinical research, case presentations, and discussions, fostering an environment of continuous learning and professional development. This hands-on experience is crucial for understanding the dynamics of clinical settings and the pivotal role of pharmacists in enhancing patient outcomes.

COURSE OUTCOMES:

Upon successful completion of this course, students shall be able to;

KNOWLEDGE:

K1: Outline the Importance of the Clinical Pharmacist's role in clinical departments.

K2: Describe the mechanisms of action, therapeutic uses, adverse effects, and drug interactions of medications commonly used in the clinical setting.

K3: Discuss the process of patient assessment, including history taking, physical examination findings, and laboratory results interpretation.

K4: Compare current clinical guidelines and evidence-based practices for the management of chronic diseases.

K5: Generate the principles of medication safety, including error prevention strategies and reporting systems.

K6: Apply the pharmacokinetics and pharmacodynamics principles relevant to drug therapy in special populations, such as the elderly and those with renal impairment.

SKILLS:

S1: Practice documentation of clinical activities during clinical posting.

S2: Demonstrate effective patient counselling techniques, ensuring patients understand their medication regimens and the importance of adherence.

S3: Conduct medication reviews, identifying potential drug-related problems and recommending appropriate interventions.

S4: Apply accurate and detailed documentation of clinical interventions, patient interactions, and medication histories.

S5: Develop individualized patient care plans.

S6: Evaluate the evidence-based resources to support clinical decisions and improve patient outcomes.

ATTITUDE:

A1: Develop a commitment to providing patient-centered care and prioritizing patient safety

A2: Communicate effectively with healthcare professionals

A3: Exhibit a proactive attitude towards continuous learning

A4: Cultivate healthcare team management quality

A5: Display empathy and compassion in patient interactions, understanding the psychological and emotional aspects of patients.

A6: Accept responsibility and accountability for clinical decisions.

Pharm. D Clerkship posting: Students will be posted to different clinical departments of the hospital. The posting will be for the month of May from 8.30 -12.30pm , and the student should remain there and carry out the recommended activities.

The furnished clinical department list may likely to vary based on demand

Clerkship activities: Students posted in the department are expected to perform the following activities and document them properly

1. Students posted in the department possess thorough knowledge of common diseases and drugs prescribed in that department.Analyse the treatment practice in the department with published treatment guidelines
2. Learn the medications, their doses and their diluents for reconstitution / infusion with which mixing to be done.
3. Participate in ward rounds, conduct pre rounds, offering input on medication-related issues and patient care plans.
4. Suggest healthcare professionals on medication selection, dosing, and administration.
5. Actively engage in medication reconciliation and drug utilization reviews.
6. Assess appropriateness of medication use, identifying potential drug interactions and contraindications.
7. Provide pharmacokinetic assessments and dosing recommendations.
8. Optimize antibiotic use, reduce resistance, and improve patient outcomes.
9. Assist in coordinating medication plans for discharged patients and provide discharge counseling.
10. Offer up-to-date drug information and resources to healthcare professionals.
11. Identify and report medication errors and develop strategies to prevent medication errors.
12. Students posted in oncology department gain knowledge on compounding dosing and sterility of the chemotherapeutic agents.

NABH activities

1. Pharmaceutical Intervention
2. Adverse drug reactions analysis and reporting
3. Medication error
4. Medication Reconciliation
5. Patient counselling
6. Drug Information Query
7. Prescription Audit
8. LASA and High risk drugs counter check

Evaluation:

Formative assessment will be carried out by the faculty preceptor from the department of pharmacy practice. The student shall maintain documentation of work which is to be verified by the faculty preceptor. Scrutiny of work, assessment and evaluation of training shall be undertaken by an objective approach in clinical activities during and at the end of the training.

The preceptor must evaluate the respective students not only by evaluating their daily activities but also judge their knowledge by conducting presentations about cases and clerkship learning experience periodically. Each student has to present two case presentations, one-to the respective preceptor and another to the clerkship in charge.

Assessment and evaluation of Clerkship:

I. Formative assessment : 50 marks

A. Preceptor : 25 marks

i. Pharmacist intervention: 5 marks

ii. ADR reporting : 5 marks

iii. Other activities: Patient counselling, Prescription audit, Medical reconciliation:2.5 marks

iv. Learning in posted department: 7.5 marks – Commonly encountered diseases

v. Case presentation: 5 marks

Medications prescribed- dose, dose calculation, reconstitution fluid, volume and duration of administration, disease grading score and their calculation. Interacting drugs and suggestions, Name of treatment guideline. Disease and Drug induced complications

B . Sessional Exam Evaluation: 25 marks

i. Case presentation :10 marks

ii. Department learning : 10 marks

iii. Viva : 5 marks

Formative assessment carries 50 marks having two components: Preceptor component and sessional exam component each 25 marks.

Course Title	L	T	HP	Total Hrs.	Year	Course Code
PROJECT	**0**	**0**	**4**	**120**	**Pharm. D V** **Pharm. D P. B II**	**PD.505PR** **PDPB.205PR**

Fifth-year Pharm D students shall undertake a group project aimed at developing their key research, data collection-analysis, and reporting skills. The students can opt to work in the domains of community, hospital, and clinical pharmacy under the guidance of a designated faculty as a guide and with approval from the HOD or the Head of the Institution.

Objectives:

1. Develop student's research skills covering literature review, data collection, analysis, interpretation, and successful publication of research work.
2. Develop critical assessment and problem-solving skills to address pertinent issues in the domain of pharmacy practice.
3. Foster collaboration and teamwork among students through group work and shared responsibilities.
4. Promote effective communication skills through project presentations and reports, ensuring alignment with ethical standards and professional guidelines.

Rules and Regulations:

1. Students shall work on a group project comprising of a minimum three and a maximum of four members assigned to a Faculty guide in the 4^{th} year.
2. Students shall opt to work in community, hospital, and clinical pharmacy domains.
3. Projects involving patient data collection, interaction, or intervention require Institutional Ethics Committee (IEC) approval before the commencement of the study.
4. Each group shall present the project protocol to the research committee, covering the study aim, objectives, research question, hypothesis, relevance, and anticipated timelines.
5. The research committee shall forward the project protocol and recommendations to the IEC; students shall present the project proposal to the IEC for approval.
6. Mid-thesis evaluation shall be conducted internally by the Dept. of Pharmacy Practice in the presence of the principal to assess project progress.
7. Upon completion of the project, student shall submit the raw data and the soft copy of the thesis to the faculty guide for evaluation and corrections.
8. Final evaluation is done by the committee including internal & external examiners, HOD, & Principal.
9. After evaluation, the hard copy thesis and manuscript shall be submitted as per the guidelines

Evaluation Criteria:

Mid Thesis Evaluation: This shall be conducted internally by the Dept. of Pharmacy Practice in presence of Principal, to assess the progress of the project. The students shall be assessed based on the criteria below

Research Methodology and Literature Review	10
Progress and promptness of the research work	20
Question-answer skills and team involvement	20
Total	**50 Marks**

Final Evaluation: Upon completion of the project work, the students shall submit a thesis report for final evaluation by the committee composed of internal and external examiners, the HOD, and the Principal. The candidate (s) will be evaluated individually based on the criteria listed below.

Presentation of the work	50
Quality and Clinical relevance of the project	50
Question-answer & Justification skills	50
Total	**150 Marks**