K.R. MANGALAM UNIVERSITY
THE COMPLETE WORLD OF EDUCATION

SCHOOL OF MEDICAL AND ALLIED SCIENCES

(SMAS)

Programme Handbook

(MASTER OF PHARMACY)
(Programme Structure & Evaluation Scheme)

MASTER OF PHARMACY (PHARMACOLOGY)

Programme Code: 65

TWO YEAR POSTGRADUATE PROGRAMME

2024-2026

Approved in the 34th Meeting of Academic Council Held on 29 June 2024

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1. Preface

The KRMU envisions all its programs in the best interest of their students and in this endeavour it offers a new vision to all its courses. Through its programs it aims to provide a focused, student-centric syllabus with an agenda to structure the teaching-learning experiences experientially. The curriculum strengthens student's experiences and prepares the students for, academia and employability, sustainability and life-long learning. Each program reflects the promise to accomplish the learning outcomes by studying the courses. The graduate attributes encompass values related to well-being, emotional stability, critical thinking, social justice and also skills for entrepreneurship. The K.R. Mangalam University hopes the curriculum will help students in making an informed decision at the time of working in the field of pharmacy.

2. University Vision and Mission

2.1 Vision

K.R. Mangalam University aspires to become an internationally recognized institution of higher learning through excellence in inter-disciplinary education, research, and innovation, preparing socially responsible life-long learners contributing to nation building.

2.2 Mission

- Foster employability and entrepreneurship through futuristic curriculum and progressive

pedagogy with cutting-edge technology

- Instill notion of lifelong learning through stimulating research, Outcomes-based education, and innovative thinking
- Integrate global needs and expectations through collaborative programs with premier universities, research centers, industries, and professional bodies.
- Enhance leadership qualities among the youth having understanding of ethical values and environmental realities

3. About the School

School of Medical and Allied Sciences mainly focused on training to students for various subjects and practical aspects related to drug formulation and testing along with co-curricular development. School offers Diploma, undergraduate, post graduate courses in pharmacy and Bachelor degree in physiotherapy post. We provide an extra edge to our students by teaching and training by leading pharma industry experts to facilitate industry academia interaction, participation in conferences / workshops / skill development programs, carrier guidance, coaching for GPAT and other competitive

examinations. We encourage students to participate in various health camps organized by School of Medical and Allied Sciences to make general awareness amongst people regarding various diseases like diabetes, hypertension, communicable and non-communicable diseases. We provide placement assistance to students for getting jobs in various government and private laboratories. We have tie up with various pharmaceutical industries like Dabur Research Foundation, Sun Pharma, Arbro Pharma, Indian Pharmacopeial Commission, Catalyst Clinical Services, Suraksha Pharma, Medicamen Biotech , Mankind Pharma etc. which provide various carrier opportunities in pharmaceutical production, pharmaceutical quality control, quality assurance, pharmaceutical sales & distribution, drug information services, health insurance, medical coding, supply chain management, forensic sciences, Pharmacovigilance, product management team, clinical trials, clinical data management and in Indian Pharmacopeia Commission.

4. School Vision and Mission

4.1 School Vision

To become a premier educational institution dedicated to empowering students with the knowledge and skills needed to lead in pharmaceutical field and enhance healthcare access, thereby making a positive impact on society in India and globally.

4.2 School Mission

1. To empower students to become self-motivated, self-reliant, and socially aware healthcare professionals, effectively addressing the needs of academia, industry, and research.
2. To establish a dynamic centre of excellence for learning and research in pharmaceutical and allied health sciences, emphasizing interdisciplinary approaches and fostering collaboration between industry and academia.
3. To nurture translational research initiatives that benefit society and improve community health outcomes.
4. To integrate pharmaceutical and allied health sciences with interdisciplinary life sciences, promoting innovation and collaboration.
5. To offer lifelong learning opportunities in healthcare, equipping professionals with the skills to adapt and excel in a rapidly evolving field.

5. About the Programme

School of Medical and Allied Sciences strives to foster and maintain a creative environment with a deep commitment to inculcate excellence in academics and contribute towards students' development. The Master's programme is designed to provide a sound knowledge and training to students to prepare students for high-level research and leadership positions in pharmaceutical and biotechnology companies. The School of Medical and Allied Sciences offers Masters Programs in Pharmaceutics and Pharmacology that are designed to prepare exceptional students for productive and successful careers in pharmaceutical industry, academia, and research.

5.1 Definitions

Programme Educational Objectives (PEOs)

Program Educational Objectives (PEOs) are broad statements that outline the expected personal and professional growth and employment outcomes for graduates within a few years following graduation.

Programme Outcomes (POs)

Program Outcomes (POs) are specific skills, knowledge, and abilities that students are expected to acquire by the end of a program. They reflect the competencies necessary for graduates to succeed in their professional fields and contribute to society. POs are used to assess the effectiveness of the educational program and ensure alignment with industry standards.

Programme Specific Outcomes (PSOs)

Program Specific Outcomes (PSOs) define the expected knowledge and skills that graduates should possess in a particular discipline or specialization.

Credit

Credit refers to a unit of contact hours/tutorial hours per week or 02 hours of lab/practical work per week

5.2 Programme Educational Objectives (PEOs)

PEO-1: Become professional experts in careers associated to pharmaceutical Sciences, and allied fields, establishing knowhow and compliance.

PEO-2: Emerge as leaders, entrepreneurs, and managers, guiding pharma professionals within the healthcare field.

PEO-3: Maintain morals & ethics in their professional conduct, thereby taking responsible decisions which endorse the reliability of the professional healthcare person.

PEO-4: Support for sustainable practices and engage in environment-friendly methods of dealing with patients in healthcare.

PEO-5: Be as decent citizens with high value attributes towards society, demonstrating extraordinary professionalism, as a contribution towards well-being of the society.

5.3 Programme Specific Outcomes (PSOs)

PSO-1: Understanding theories related to pharmacology and acquiring the knowledge of drugs from natural and synthetic sources, synthesize drugs, explain drug mechanism of action, and understand structure activity relationships and ADMET profile.

PSO-2: Applying pharmacological knowledge to assess patient needs and formulate treatment Strategies for monitoring drug therapy and patient responses.

PSO-3: Analysing the data from experiments to identify patterns or anomalies in cellular behaviour for targeting various diseases.

PSO-4: Evaluating the implications of genetic mutations on cellular function and disease by understanding cellular and molecular mechanism.

PSO-5: Designing and executing complex assays for cell viability, apoptosis, and DNA fragmentation by integrating different techniques for evaluating safety and efficacy of drugs.

PSO-6: Observing various instrumental and analytical processes for screening of compounds/molecules for their pharmacological activity and evaluation of safety and efficacy for development of novel formulation.

PSO-7: Performing the experiments using instruments to identify and quantify the drug present in various biological samples.

5.4 Career Avenues

Academics/Research and development/ Pharmacovigilance/ Clinical Research/ Preclinical data analyst/ Medical writing/ Medical coder/ Toxicology/ Analytical R& D/ Formulation Development/ Drug Regulatory Affairs/ Product Marketing/ Sales and Marketing/ Drug inspectors/ Drug Safety Associate/ Overseas opportunity(GRE).

5.5 Duration

The program of study for M.Pharm shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

Name of the Program	Duration
Master of Pharmacy	2 Years / 4 Semesters

5.6 Eligibility Criteria for Award of Degree

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm.programme if he/she secures at least 50% marks in that particular course including internal assessment and end term examination.

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages). The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria and the class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of. 7.50 And above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

6 Student's Structured Learning Experience from Entry to Exit in the Programme

Education Philosophy and Purpose

- Learn to Earn Living
- Learn to Live

➢ University Education Objectives

- Focus Employability and Entrepreneurship through Holistic Education

➢ Importance of Structured Learning Experiences

Structured learning experiences in a Pharmacy programs are essential as they provide a systematic framework for acquiring comprehensive knowledge and practical skills essential for professional practice. By integrating theoretical coursework with hands-on labs, simulations, and clinical rotations, these experiences ensure students develop a thorough understanding of pharmacology, patient care, and professional ethics. This structured approach not only promotes consistency and standardization in education but also enhances critical thinking, problem-solving abilities, and preparedness for licensure exams. Ultimately, it equips future pharmacists with the competence and confidence needed to excel in a dynamic and demanding field.

- Educational Planning and Execution

  As per the norms laid by Pharmacy Council of India, New Delhi

- Academic Journey

- Curriculum Structure and Degree Requirements

  The minimum credit points required for the award of M. Pharm degree is 95. However based on the credit points earned by the students under the head of cocurricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester wise schedule of courses given in the syllabus.

- Course Registration and Scheduling

  As university academic calendar

  - Major and Minor Selection
  - Internships/Projects/Dissertations/Apprenticeships
  - Academic Support Services (Slow & Advanced Learners)

- Student Support Services
  - Mentor-Mentee
  - Counselling and Wellness Services
  - Career Services and Training

- Learning and Development Opportunities

- Laboratories and Practical Learning
- Experiential Learning
- Case-Based Learning/Problem-Based Learning/Project Based Learning
- Workshops, Seminars, Guest Lectures
- Inside & Outside Classroom Learning
- Holistic Education

➢ Assessment and Evaluation

- Grading Policies and Procedures for theory courses, practical courses, projects, Internships, Dissertation

% of marks	**Letter grade**	**Grade point**	**Performance**
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

- Feedback and Continuous Improvement Mechanisms

  Based on performance in the sessional examinations students were be categorised in slow and advanced learner. For slow learner remedial classes, assignments and presentation will be given and tried to convert them in advanced learners. For advanced learner more attention will be given and advised to write for various exams to be conducted in national level like GPAT and UGC net.

- Academic Integrity and Ethics

  In postgraduate pharmacy programs, academic integrity and ethics are paramount to ensure the credibility and professionalism of future practitioners. Upholding these principles

involves rigorous adherence to standards of honesty and transparency in research, coursework, and clinical practice. Students are expected to avoid plagiarism, falsification of data, and any form of academic dishonesty, while also embracing ethical considerations related to patient care, drug development, and professional conduct. An environment that fosters academic integrity not only enhances the quality of education but also prepares students to make ethical decisions in their professional careers, reinforcing the trust and reliability that are essential in the field of pharmacy.

- Examination and Evaluation Methods

  The schemes for internal assessment and end semester examinations are given in

  The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the subject experts at school level and the marks/grades shall be submitted to the university.

Schemes for internal assessments and end semester examinations

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL101T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL103T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL104P	Pharmacology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MPL106T	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Experimental Pharmacology practical- II	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Pharmacology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
MPL206T	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM101T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
MPL302S	Journal club	-	-	-	25	-	-	25
MPL303S	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
MPL304P	Research work*	-	-	-	-	350	1 Hr	350
							Total	**525**
SEMESTER IV								
MPL401S	Journal club	-	-	-	25	-	-	25
MPL402P	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
MPL403S	Research work and Colloquium	-	-	-	-	400	1 Hr	400
							Total	**500**

- **Programme Scheme**

Semester I				
S.No.	**Course Code**	**Course Title**	**Credits**	**Hours /week**
1	MPL101T	Modern Pharmaceutical Analytical Techniques	4	4
2	MPL102T	Advanced Pharmacology-I	4	4
3	MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4
4	MPL104T	Cellular and Molecular Pharmacology	4	4
5	MPL105P	Pharmacology Practical I	6	12
6	MPL106S	Seminar/Assignment	4	7
		TOTAL	**26**	**35**

Semester II				
S.No.	**Course Code**	**Course Title**	**Credits**	**Hours /week**
1	MPL201T	Advanced Pharmacology II	4	4
2	MPL 202T	Pharmacological and Toxicological Screening Methods-II	4	4
3	MPL203T	Principles of Drug Discovery	4	4
4	MPL204T	Experimental Pharmacology practical- II	4	4
5	MPL205P	Pharmacology Practical II	6	12
6	MPL206S	Seminar/Assignment	4	7
		TOTAL	**26**	**35**

Semester III				
S.No.	**Course Code**	**Course Title**	**Credits**	**Hours /week**
1	MRM301T	Research Methodology and Biostatistics	4	4
2	MPL302S	Journal Club	1	1
3	MPL303S	Discussion / Presentation (Proposal Presentation)	2	2
4	MPL304P	Research Work	14	28
		TOTAL	**21**	**35**

Semester IV				
S.No.	**Course Code**	**Course Title**	**Credits**	**Hours /week**
1	MPL401S	Journal Club	1	1
2	MPL402P	Research Work	16	31
3	MPL403S	Discussion / Final Presentation	3	3
		TOTAL	**20**	**35**

Total Credits: 93

Syllabus

SEMESTER I					
MPL 101T	**Modern Pharmaceutical Analytical Techniques**	**L**	**T**	**P**	**C**
Version 1		4	0	0	0
Category of Course	Theory				
Total Contact Hours	60				
Pre-Requisites/ Co-Requisites	Instrumental method of analysis				

Course Perspective

The course emphasizes the application of various analytical methods like spectroscopy, spectrometry, and chromatography in ensuring the safety, efficacy and quality of pharmaceuticals. This course is important for pursuing career in quality control, assurance, research and development departments of chemical and pharmaceutical industries.

Course Outcomes

Upon completion of the course student:

CO1: Understanding the basic concept and instrumentation of chromatography, spectroscopy and spectrometric techniques for qualitative and quantitative validation of pharmaceuticals.

CO2: Application of various analytical techniques for the standardization and identification of organic and inorganic compounds.

CO3: Analysing the data from experiment to identify impurities present in the samples.

CO4: Evaluating the standards for various products/formulation by understanding different analytical techniques.

CO5: Devising the analytical standards for identification and development of new chemical moieties.

Course Content

Unit 1 **11 hrs**

a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.

c) Spectrofluorimetric: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

Unit 2 **11 hrs**

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

Unit 3 **11 hrs**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

Unit 4 **11 hrs**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

Unit 5 **11 hrs**

Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.

Unit 6 **5 h**

Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

Learning Experience

The modern pharmaceutical analytical techniques course will integrate lectures, interactive discussions, and theoretical readings to offer a thorough understanding of advanced analytical techniques. Students will explore concepts through case studies, group discussions, and critical analysis of scientific literature. Assignments and peer reviews will encourage deeper engagement and collaborative learning. Additionally, E-notes videos links will provide on LMs. Assessments will include quizzes, written assignments, sessional and end term exams to measure students' grasp of theoretical knowledge.

Reference Books

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998

6. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume Marcel Dekker Series
7. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
8. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

Open Educational Resources (OER)

1. https://www.slideshare.net/Santachem/uv-visible-spectroscopy
2. https://personal.utdallas.edu/~scortes/ochem/OChem_Lab1/recit_notes/ir_presentation.pdf
3. https://www.chem.uci.edu/~dmitryf/manuals/Fundamentals/Fluorescence%20Spectroscopy.pdf
4. https://soe.unipune.ac.in/studymaterial/ashwiniWadegaonkarSelf/621%20Unit%206.pdf
5. https://www.researchgate.net/publication/338622124_Atomic_Absorption_Spectrophotometer_AAS/link/5e200e1d299bf1e1fab4e2cd/download
6. https://www.ru.nl › ms_lecture_notes_161003_mcf
7. http://nvi.ddc.moph.go.th/Download/eCTD/Module%201/8%20Mar/4_Immunoassay_surasukdi.pdf
8. https://webstor.srmist.edu.in/web_assets/srm_mainsite/files/files/X%20RAY%20CRYSTALLOGRAPHY.pdf
9. https://www.brown.edu/academics/chemistry/sites/academics-chemistry/files/NMR_Introductory_Lecture.pdf
10. https://gacbe.ac.in/pdf/ematerial/18MCH42E-U2.pdf
11. https://uomustansiriyah.edu.iq/media/lectures/4/4_2021_09_14!07_58_34_PM.pdf

Evaluation Scheme

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	--	10	

2	Sessional (Written Examination)	60 minutes	15	
4	End Term Examination (Written Examination)	180 minutes	75	
Total			**100**	

MPL 102 T	**Advanced Pharmacology- I**	**L**	**T**	**P**	**C**
Version 2.0		**4**	**0**	**0**	**4**
Category of Course	Theory				
Total Contact Hours	60 hrs				
Pre-Requisites/ Co-Requisites	Pharmacology-II/ Cellular and Molecular Pharmacology				

Course Perspective. Advanced pharmacology course is important for understanding the mechanism of drugs and their interaction in various biological systems. Preparing healthcare professionals to deliver safe, effective and personalized medication to the patient and promoting on-going research and ethical practice in the field of pharmacy.

1. Academic Goals: Foundational Knowledge: Advanced Pharmacology provides a deep understanding the major classes of drugs (e.g., antibiotics, antihypertensive, and analgesics) and their mechanisms of action.

Research Skills: Students engage in research methodologies specific Gain proficiency in laboratory techniques relevant to pharmacology, such as drug assays, bioassays, and pharmacokinetic studies

Interdisciplinary Learning: These fields often require integrating knowledge from chemistry, biology, pathophysiology and human anatomy and physiology.. This interdisciplinary approach enhances critical thinking and problem-solving skills.

2.Career Goals:

Pharmaceutical Industry: Knowledge of Advanced Pharmacology is valuable for careers in drug development and quality control. Understand how drugs are absorbed, distributed, metabolized, and excreted (ADME), and how they interact with biological systems to optimize drug efficacy and safety.

Regulatory Affairs: Focus on pharmacovigilance to track and analyse adverse drug reactions and ensure drug safety throughout the product lifecycle. Understand the scientific and clinical expertise to support drug development, marketing, and education. This includes creating educational materials and conducting scientific presentations.

3. Professional Development:

Clinical Applications: Advanced Pharmacology knowledge can be applied in clinical settings, particularly in integrative and complementary medicine. Understanding latest research and clinical guidelines to inform treatment decisions, ensuring that therapy is based on the best available evidence.

Education and Advocacy: Professionals can engage in education and advocacy roles, promoting the benefits and safe use of drugs. This can involve writing, teaching, or working with community health organizations.

Ethical and Sustainable Practices: understanding sustainable sourcing and ethical issues becomes important. Professionals can contribute to developing practices that balance efficacy with environmental and social responsibility.

Learning Goals:

Capstone Projects and Internships: Applying Pharmacology knowledge in practical settings through projects or internships can bridge the gap between academic learning and professional application.

Networking and Professional Organizations: Engaging with professional organizations, attending conferences, and participating in workshops can help students stay current with industry trends and expand their professional network.

Continued Education: These fields are dynamic, with ongoing research and discoveries. Pursuing further education and certifications can enhance career prospects and professional expertise.

Course Outcomes

On completion of this course, the student will be able to:

CO1: Understanding pharmacokinetic and pharmacodynamics action of drugs in various biological systems.

CO2. Applying pharmacological knowledge to assess patient needs and formulate treatment Strategies for monitoring drug therapy and patient responses.

CO3. Analysing case studies to identify appropriate pharmacotherapy to differentiate drug interaction, adverse drug effect and therapeutic effect of drug.

CO4. Developing personalized medication plans based on pharmacogenomics data for improvements in the existing pharmacotherapy protocols based on current treatment findings.

Course Content

Unit I: **12 Hours**

General Pharmacology

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

Unit II: **12 Hours**

Neurotransmission

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system

(Detailed study about neurotransmitters- Adrenaline and Acetyl

choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

d. Non adrenergic non cholinergic transmission (NANC). Cotransmission

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems Autonomic Pharmacology Parasympathomimetics and lytics, sympathomimetics and lytics,

agents affecting neuromuscular junction

Unit III: **12 Hours**

Central nervous system Pharmacology, General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety, Depression, psychosis, mania, epilepsy, neurodegenerative diseases.Narcotic and non-narcotic analgesics.

Unit IV: **12 Hours**

Cardiovascular Pharmacology,Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and antiplatelet drugs

Unit V: **12 Hours**

Autocoid Pharmacology, The physiological and pathological role of Histamine**,** Serotonin,Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.

Learning Experience

The "Advanced-Pharmacology-I" course typically builds on foundational knowledge from earlier coursework, diving deeper into the study of drugs and their mechanism of action.

In-Depth Study of mechanism of action of drugs: The course covers understanding to identify new drug targets and develop novel compounds. This involves screening for potential interactions and optimizing drug candidates based on their mechanism of action.

Interdisciplinary Approach: The course integrates knowledge from chemistry, biology, pharmacology, and medicine, fostering a comprehensive understanding how drugs interact with the immune system, influencing immune responses and autoimmune conditions

Industry Relevance: The course prepares students for careers in pharmaceuticals, synthetic drugs and natural products, and biotechnology by providing relevant knowledge and skills applicable in these fields.

Overall, "Pharmacology-II" offers a comprehensive and hands-on learning experience, bridging the gap between theoretical knowledge and practical application in the study of drugs and their mechanism of action.

Textbooks

1. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.

2. Pharmacology by H.P. Rang and M.M. Dale.

3. Robbins &Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)

4. KD.Tripathi. Essentials of Medical Pharmacology

Reference books/Materials:

1. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.

2. Basic and Clinical Pharmacology by B.G Katzung Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.

Open Educational Resources (OER)

1.https://accessmedicine.mhmedical.com/content.aspx?bookid=2249&sectionid=175215570
2.https://pubmed.ncbi.nlm.nih.gov/45339/#:~:text=The%20term%20neurohumoral%20transmission%20designates,amino%20acid%20or%20a%20peptide.
3.https://www.slideshare.net/sidrahena/neurohumoral-transmission-249086724

Evaluation Scheme

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-	10	
2	Sessional Examination (Written Examination)	60Minutes	15	
3	Attendance			
4	End Term Examination (Written Examination)	180 Minutes	75	
Total			**100**	

MPL103T	Pharmacological and Toxicological Screening Methods-I	L	T	P	C
Version 1		**4**	**0**	**0**	**4**
Category of Course	Theory				
Total Contact Hours	60				
Pre-Requisites/ Co-Requisites	Pharmacology-I				

Course Outcomes

This course provides deep insights in preclinical studies, clinical studies and bioethical standards. It gives knowledge and skills for evaluating safety and efficacy of drugs from various sources. The knowledge acquired is directly applicable in pharmaceutical research, enabling contribution towards development of novel treatment strategies for different diseases.

Course Outcomes

Upon completion of the course the learner will be capable of:

CO1: Understanding fundamental concepts of drug screening techniques using different animal models.

CO2: Applying the concept of drug screening methods for determination of drug concentration in various samples..

CO3. Analysing the data from experiments to identify different drug targets.

CO4. Evaluating the implications of results in development of new chemical moiety.

Course Content

Unit-I

Laboratory Animals

Common lab animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and

euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice.

Unit-II

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

Unit-III

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic,anti-diarrheal and laxatives.

Unit-IV

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antihyperlipidemic, and agents. Anti cancer agents

Unit V

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Immunosuppressants and immunomodulators General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay

methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans.

Reference book(s) [RB]:

1. Drug discovery and Evaluation by Vogel H.G

Evaluation Scheme

Evaluation Scheme:				
	Evaluation Component	**Duration**	**Weightage (%)**	**Date**
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-	10	
2	Sessional Examination (Written Examination)	60Minutes	15	
3	Attendance			
4	End Term Examination (Written Examination)	180 Minutes	75	
Total			**100**	

MPL104T	**Cellular and Molecular Biology**	**L**	**T**	**P**	**C**
Version 1		**4**	**0**	**0**	**4**
Category of Course	Core				
Total Contact Hours	60				
Pre-Requisites/ Co-Requisites	Advanced Pharmacology-I				

Course Perspective: Cellular and molecular biology imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help in understanding and utilizing the knowledge in the process of drug discovery.

Course Outcomes

Upon completion of the course the learner will be able to:

CO1: Understanding the processes of cell signalling and describe central dogma of molecular biology (DNA → RNA → Protein).

CO2. Applying the concept of laboratory techniques (e.g., PCR, gel electrophoresis) to analyse biological samples for the interpretation of experimental data.

CO3. Analysing the data from experiments to identify patterns or anomalies in cellular behaviour for targeting various diseases.

CO4. Evaluating the implications of genetic mutations on cellular function and disease by understanding cellular and molecular mechanism.

CO5: Designing of an experiment to investigate a specific cellular process or molecular interaction between cellular structure and function

Course Content

Unit No: I **12 Hours**

Cell biology: Structure and functions of cell and its organelles, Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of Apoptosis, Necrosis and autophagy.

Unit II: **12 Hours**

Cell signalling: Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

Unit III **12 Hours**

Principles and applications of genomic and proteomic tools: DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

Unit IV **12 Hours**

Pharmacogenomics: Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Unit V **12 Hours**

Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry

Learning Experience: In the cellular and molecular biology course, I gained a deep understanding of cellular structures and their functions, learned the mechanisms of genetic information flow, and developed practical skills in laboratory techniques like PCR and gel electrophoresis. The course emphasized critical thinking and problem-solving in understanding complex biological processes.

Reference Books/Materials

1. 1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

Open Educational Resources (OER)

1. https://www.britannica.com/science/cell-membrane
2. https://www.britannica.com/science/cell

Evaluation Scheme

	Evaluation Component	Duration	Weightage (%)
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-	02
2	Sessional Examination (Written Examination)	60 Minutes	15
3	Attendance		08
4	End Term Examination (Written	180 Minutes	75

	Examination)		
Total			**100**

MPL105P	**Pharmacology Practical I**	**L**	**T**	**P**	**C**
Version 1.0		**0**	**0**	**12**	**6**
Category of Course	Practical				
Total Contact Hours	180 Hrs				
Pre-Requisites/ Co-Requisites	Pharmacology/Pharmacological & Toxicological methods, Advanced Pharmacology-I				

Course Perspective: This course equips with hands-on experience in drug action, interaction, and therapeutic use. It enhances understanding of pharmacokinetics and pharmacodynamics through lab experiments and clinical case studies. Students learn to evaluate drug efficacy, safety, and patient responses, fostering critical thinking and decision-making skills. Ultimately, this course prepares future healthcare professionals to apply pharmacological principles in real-world settings**.**

Course Outcomes

Upon completion of the course the learner will be

CO 1: Understanding the principles behind nucleic acid isolation, chromatographic techniques, and the analysis of pharmaceuticals by applying these techniques in laboratory.

CO 2: Applying the knowledge to analyse concentration of drugs in various samples by using different analytical methods.

CO 3: Evaluating and interpreting experimental data related to screening of drugs for various biological activities.

CO 4: Designing and executing complex assays for cell viability, apoptosis, and DNA fragmentation by integrating different techniques for evaluating safety and efficacy of drugs.

Course Content

No. of Hours: 180 Hrs

1. Analysis of pharmacopeial compounds and their formulations by UV Vis

spectrophotometer

2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3. Experiments based on HPLC

4. Experiments based on Gas Chromatography

5. Estimation of riboflavin/quinine sulphate by fluorimetry

6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.

2. Techniques of blood sampling, anaesthesia and euthanasia of experimental animals.

3. Functional observation battery tests (modified Irwin test)

4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.

5. Evaluation of analgesic, anti-inflammatory, local anaesthetic, mydriatic and miotic activity.

6. Evaluation of diuretic activity.

7. Evaluation of antiulcer activity by pylorus ligation method.

8. Oral glucose tolerance test.

9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).

10. Isolation of RNA from yeast

11. Estimation of proteins by Braford/Lowry's in biological samples.

12. Estimation of RNA/DNA by UV Spectroscopy

13. Gene amplification by PCR.

14. Protein quantification Western Blotting.

15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).

16. Cell viability assays (MTT/Trypan blue/SRB).

17. DNA fragmentation assay by agarose gel electrophoresis.

18. DNA damage study by Comet assay.

19. Apoptosis determination by fluorescent imaging studies.

20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using software.

21. Enzyme inhibition and induction activity

22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)

23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

Learning Experience

This course is designed to be highly experiential and participatory, ensuring that students engage deeply with both theoretical and practical aspects of pharmacology. The course will be conducted through a combination of interactive lectures, hands-on laboratory sessions, case studies, group work, and individual assignments. Emphasis will be placed on active participation, with students encouraged to apply their knowledge in real-world scenarios.

Methods of Instruction:

- **Interactive sessions:** The course will begin with brief interactive sessions that introduce the theoretical foundation of each topic. These sessions will utilize multimedia presentations, including animations and video demonstrations, to enhance understanding of the topics.
- **Hands-On Laboratory Sessions:** Students will spend a significant portion of the course in the laboratory, where they will engage in practical experiments that align with the course outcomes. These sessions will allow students to apply theoretical knowledge in a controlled environment, developing their technical skills.

Use of Technology:

- **Laboratory Equipment:** Knowledge of utilisation and working of advanced analytical instruments such as UV-Vis spectrophotometers, HPLC, Gas Chromatography systems, and PCR machines will be provided to the students.
- **Simulation Software:** Pharmacological experimental studies, pharmacokinetic studies and data analysis will be conducted using specialized software that simulates drug behaviour in the body, helping students visualize complex concepts.
- **Online Resources:** Supplementary materials, including video tutorials, research articles, and online quizzes, will be made available on the course's online platform. This will support self-paced learning.

Types of Activities:

- **Group Work:** Students will collaborate on group projects and laboratory exercises, fostering teamwork and peer learning. Group discussions will be encouraged to solve complex problems, analyze case studies, and share different perspectives.
- **Assignments:** Regular assignments will be given to reinforce learning, including lab reports, data analysis exercises, and literature reviews. These assignments will help students consolidate their understanding and prepare for practical exams.
- **Classroom and Outside Classroom Experiences:** In addition to laboratory work, students will participate in seminars, workshops, and guest lectures that provide insights into the latest developments in pharmacology. Field visits to research labs or pharmaceutical companies may also be organized to give students exposure to professional practices.

Assessments:

- **Continuous Assessment:** Students will be assessed continuously through quizzes, lab reports, and participation in class discussions. This will ensure that they stay engaged and understand the material as the course progresses.
- **Practical Exams:** Students will undergo practical examinations where they will be required to demonstrate their ability to perform experiments, analyze data, and interpret results.

Practical Books

1. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
2. Modern Pharmacology with clinical Applications, by Charles R. Craig& Robert,
3. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
4. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

Open Educational Resources (OER)

Ex-Pharm Software

Evaluation Scheme

Course code	Course	Internal Assessment			End Semester Exams		Total Marks
		Continuous mode	Sessional Marks	Total	Marks	Duration	

			Marks	Duration				
MPL105P	Experimental Pharmacology-I	20	30	6 Hrs	50	100	6Hrs	150

MPL 106S	Seminar / Assignment	**L**	**T**	**P**	**C**
Version 1.0		0	0	7	4
Total Contact Hours	--				
Pre-requisites/Exposure	Pharmacology				
Co-requisites					

Course Perspective: The seminar fosters deep understanding and critical analysis of core concepts through interactive discussions and presentations. Students apply theoretical knowledge to real-world scenarios, enhancing their research and communication skills.

Course Outcomes

Upon completion of the course students will

1. Understanding of the seminar's core concepts and theories.
2. Appling the seminar content to real-world scenarios or case studies.
3. Critically analyse and evaluate various perspectives related to the seminar topics.
4. Effectively conduct and present research related to the seminar theme.
5. Demonstrate effective oral and written communication skills.

Evaluation Scheme

Course code	**Course**	**Internal Assessment**				**End Semester Exams**		**Total Marks**
		Continuous mode	**Sessional Marks**		**Total**	**Marks**	**Duration**	
			Marks	**Duration**				
MPL106S	Seminar / Assignment	-	-	-	-	100	-	100

MPL 201T	Advanced Pharmacology-II	L	T	P	C
Version	**1**	**4**	**0**	**0**	**4**
Category of Course	Theory				
Total Contact Hours	60 hr				
Pre-Requisites/ Co-Requisites	Cellular and Molecular Pharmacology				

Course Perspective: Advanced Pharmacology explores the intricate mechanisms of drug action and interactions at molecular, cellular, and systemic levels. The course emphasizes pharmacokinetics, pharmacodynamics, and the role of genetics in drug response. Students analyze complex case studies and emerging therapies to develop critical thinking and application skills. It integrates clinical and research perspectives to address contemporary issues in drug development and personalized medicine. Practical applications in drug therapy and patient management are key components.

Course Outcomes

Upon completion of the course the learner will be able to:

CO1: Understanding the principles of pharmacokinetics and pharmacodynamics of various drugs.

CO2: Applying pharmacological principles in diagnosis and treatment f various diseases.

CO3: Analysing effect on various drugs and their interactions for evaluating safety and efficacy.

CO4: Evaluating therapeutic effects of dugs by different experimental approaches and designing a comprehensive medication plan for a patient.

UNIT-I **12 Hours**

Endocrine Pharmacology, Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones, Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation

UNIT-II **12 Hours**

Chemotherapy, Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

UNIT-III **12 Hours**

Chemotherapy, Drugs used in Protozoal Infections, Drugs used in the treatment of Helminthiasis, Chemotherapy of cancer, Immunopharmacology, Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants

UNIT-IV **12 Hours**

GIT Pharmacology, Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation, and irritable bowel syndrome. Chronopharmacology, Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT-V **12 Hours**

Free radicals Pharmacology, Generation of free radicals, role of free radicals in etiopathology of various diseases ,such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant. Recent Advances in Treatment:

Learning Experience

In Advanced Pharmacology, students engage in a multifaceted learning experience that includes:

1. Interactive Lectures: Detailed discussions on drug mechanisms, pharmacokinetics, and pharmacodynamics, often enhanced with real-world examples and case studies.

2. Clinical Case Analysis: Application of pharmacological principles to complex patient scenarios, promoting critical thinking and problem-solving skills.

3. Research Integration: Exploration of recent studies and emerging therapies, fostering an understanding of current advancements and trends in pharmacology.

4. Hands-On Activities: Laboratory work or simulations to illustrate drug interactions, effects, and therapeutic strategies in a controlled environment.

5. Collaborative Learning: Group discussions and projects that encourage peer interaction and the exchange of insights on pharmacological concepts and clinical applications.

Textbooks

1. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.

2. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

Reference Books

1. The Pharmacological basis of therapeutics- Goodman and Gill man‘s

2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.

3. Basic and Clinical Pharmacology by B.G -Katzung

4. Pharmacology by H.P. Rang and M.M. Dale.

5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.

6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.

Open Educational Resources (OER)

1. https://www.slideshare.net/Sanzux/harmones-cology-ppt-finalppt1

2. https://www.slideshare.net/Drzulcaifahmad/anti-ulcer-drugs-classification

3. https://www.slideshare.net/samudragupta123/estrogen-62036581

4. https://medlineplus.gov/antibiotics.html

5. https://www.slideshare.net/ParasuramanParasuraman/11-anticancer-drugs-4-cytotoxic-drugs-and-antibiotics

Evaluation Scheme (Please refer to Notice Ref No: KRMU/CoE/Even/2023-24/018 dated 10 May 2025)

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore, Attendance)	-	10	
2	Mid Term Examination (Sessional I and II Written Examination)		15	
3	End Term Examination (Written Examination)	180 Minutes	75	
Total			**100**	

MPL 202T	Pharmacological and Toxicological Screening Methods-II	**L**	**T**	**P**	**C**
Version	**1**	**4**	**0**	**0**	**4**
Category of Course	Theory				
Total Contact Hours	60 hr				
Pre-Requisites/ Co-Requisites	Pharmacological And Toxicological Screening Methods-I				

Course Perspective The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process and screening methods. This subject is designed to impart a fundamental knowledge on various targets for drug discovery and various lead seeking methodology in toxicological and drug dose, toxic dose optimization.

Course Outcomes

CO1: Understanding fundamental concepts of drug screening techniques using different animal models.

CO2: Applying the concept of drug screening methods for determination of drug concentration in various samples..

CO3. Analysing the data from experiments to identify different drug targets.

CO4. Evaluating the implications of results in development of new chemical moiety.

Course Content

UNIT I **12 hrs**

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive), Regulatory guidelines for conducting toxicity studies OECD, ICH,

EPA and Schedule Y, OECD principles of Good laboratory practice (GLP), History, concept and its importance in drug development

UNIT II **12 hrs**

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulator toxicology studies

UNIT III **12 hrs**

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies

UNIT IV **12 hrs**

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.

Safety pharmacology studies- origin, concepts and importance of safety pharmacology.

Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

UNIT V **12 hrs**

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing

Learning Experience

Understanding Toxicology:

A. Toxic Effects and Mechanisms:

- Identification of Toxic Effects: Learn to identify and assess various toxic effects of substances on biological systems, including acute and chronic toxicity.
- Mechanisms of Toxicity: Study how toxic substances cause damage at the molecular, cellular, and systemic levels.

B. Safety Assessment:

- Dose-Response Relationships: Understand how different doses of a substance can affect toxicity and safety.
- Safety Margins: Learn to calculate and interpret safety margins to evaluate the risk associated with exposure to toxic substances.

C. Toxicological Testing:

- In Vivo Testing: Conduct experiments on live animals to observe and evaluate the toxic effects of substances, adhering to ethical guidelines.
- In Vitro Testing: Use cell cultures or tissue samples to assess toxic effects and mechanisms.

- Assessment Methods: Gain proficiency in various testing methods, such as LD50 (lethal dose for 50% of subjects) studies, organ toxicity tests, and mutagenicity assays.

Understanding Pharmacological Screening:

A. Drug Efficacy and Safety:

- Pharmacodynamic Testing: Assess the efficacy of drugs in producing a desired effect, such as pain relief or blood pressure reduction.
- Pharmacokinetic Studies: Study how drugs are absorbed, distributed, metabolized, and excreted in the body, and how these processes impact efficacy and safety.

B. Screening Methods:

- High-Throughput Screening (HTS): Learn about HTS techniques used to rapidly test large numbers of compounds for biological activity.
- Bioassays: Use biological assays to evaluate the effect of drugs on living systems, such as enzyme assays, receptor binding assays, and cell viability assays.

C. Data Analysis and Interpretation:

- Statistical Methods: Apply statistical techniques to analyze screening data and determine the significance of results.
- Dose-Response Curves: Construct and interpret dose-response curves to understand the relationship between drug dose and its effect.

Practical Skills Development:

A. Laboratory Techniques:

- Handling and Administration: Learn to handle and administer substances in experimental settings, including dosing protocols and safety procedures.
- Experimental Design: Design and conduct experiments, ensuring accuracy, reproducibility, and adherence to regulatory guidelines.

B. Safety and Ethical Considerations:

- Ethical Guidelines: Understand and follow ethical guidelines for conducting toxicological and pharmacological research, particularly concerning animal welfare and human safety.
- Personal Protective Equipment (PPE): Practice using PPE and following safety protocols to minimize risk during experiments.

Textbooks

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphandbook. pdf).

2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatory information/guidances/ucm073246.pdf)
6. Guidelines and Screening Methods of Pharmacology by Arin Bhattacharya, Parag Jain), Surendra H Bodakhe
7. Drug Screening Methods, S K Gupta., Jaypee Brothers Medical Publishers

Suggested Readings

1. OECD test guidelines.
2. Principles of toxicology by Karen E. Stine, Thomas M. Brown.

Open Educational Resources (OER)

1. https://www.atsdr.cdc.gov/training/toxmanual/modules/1/lecturenotes.html
2. https://rgcb.res.in/documents/Schedule-Y.pdf
3. https://www.oecd.org/env/ehs/oecd-guidelines-testing-chemicals-related-documents.htm
4. https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
5. https://www.oecd.org/env/ehs/44137608.pdf
6. https://www.oecd.org/chemicalsafety/testing/seriesontestingandassessmentte
7. https://www.peta.org/issues/animals-used-for-experimentation/alternatives-animal-testing/
8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7103756/

Evaluation Scheme (Please refer to Notice Ref No: KRMU/CoE/Even/2023-24/018 dated 10 May 2025)

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date
1	**Continuous Assessment (Quiz/Assignment/	-	10	

	Presentation/ Extempore, Attendance)			
2	Mid Term Examination (Sessional I and II Written Examination)		15	
3	End Term Examination (Written Examination)	180 Minutes	75	
Total			**100**	

MPL 203T	**Principles of Drug Discovery– Theory**	**L**	**T**	**P**	**C**
Version:	**1.0**	**4**	**0**	**0**	**4**
Category of Course	Theory				
Total Contact Hours	60				
Pre-Requisites/ Co-Requisites	Modern Analytical Techniques/ Clinical research and Pharmacovigilance				

Course Perspective: The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process. This subject is designed to impart a fundamental knowledge on various targets for drug discovery and various lead seeking method and lead optimization. This also emphasize the importance of

Course Outcomes:

Upon completion of the course the learner will be able to:

CO1: Remembering the key stages of the modern drug discovery process, including target identification, lead optimization, and the role of genomic and proteomic technologies.

CO 2: Understanding the principles of protein structure, including domains, motifs, and folds, and the significance of computational methods like homology modeling and NMR in predicting protein structures.

CO 3: Applying (CO3): Apply techniques of combinatorial chemistry, high-throughput screening, and *in silico* methods for lead identification and assay development in drug discovery.

CO 4: Analyzing the differences between traditional and rational drug design methods, including the use of molecular docking and QSAR approaches, to evaluate their effectiveness in virtual screening and drug development.

CO 5: Evaluating the principles and practical considerations of prodrug design, including the use of statistical methods like regression analysis and 3D-QSAR techniques, to enhance drug solubility, absorption, and targeted delivery.

Course Content

UNIT I **12 hours**

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

UNIT II **12 hours**

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

UNIT III **12 hours**

Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening

UNIT IV **12 hours**

Molecular docking**:** Rigid docking, flexible docking, manual docking Docking based screening. *De novo* drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

UNIT V **12 hours**

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA, Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site, specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

Learning Experience: This course will be conducted through a blend of lectures, presentation, and demonstration sessions during practical course, and interactive group work to provide a comprehensive learning experience. The learning outcomes of this syllabus encompass a comprehensive understanding of the modern drug discovery process, equipping students with the knowledge and skills required to contribute effectively to this field. Students will develop a solid foundation in the key stages of drug discovery, including target identification, validation, lead identification, and optimization. They will gain insights into the economic aspects of drug discovery, understanding the financial implications and strategic decisions involved. To support learning, regular feedback through will be provided through assessments, quizzes, and one-on-one consultations. The course in charge will be available for additional guidance, encouraging students to seek help when needed. Collaborative learning will be emphasized, with opportunities for students to work together, exchange ideas, and conduct peer reviews, ensuring a participatory and engaging educational experience.

Text Books

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.
3. Dev Bukhsh Singh. Computer-Aided Drug Design. Springer Publication.

4. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry"

Reference Books/Materials

1. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
2. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
3. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
4. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Abby L .Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.

Open Educational Resources (OER)

1. NPTELcourse: Computer Aided Drug Design, IIT Madras, Prof. Mukesh Doble

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)		10	
2	Sessional I/II Examination (Written Examination)	60Minutes	15	
3	End Term Examination (Written Examination)	180 Minutes	75	
Total			**100**	

MPL 204T	**CLINICAL RESEARCH AND PHARMACOVIGILANCE**	**L**	**T**	**P**	**C**
Version	**1**	4	0	0	**4**
Category of Course	Theory				

Total Contact Hours	60 hrs
Pre-Requisites/ Co-Requisites	Pharmacological And Toxicological Screening Methods-I

Course Perspective

Clinical research and pharmacovigilance are integral components of the pharmaceutical industry, focused on ensuring drug safety and efficacy. Clinical research involves systematic investigation to develop new therapies, assess their effectiveness, and evaluate their safety through clinical trials. Pharmacovigilance, on the other hand, is concerned with the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems post-market. Together, they ensure that new medications not only meet regulatory standards but also continue to provide benefits without undue risk to patients. This interdisciplinary approach integrates scientific research with patient safety, underpinning the on-going development and monitoring of pharmaceutical products.

Upon completion of the course the learner will be able to:

CO1: Understanding the principles of pharmacokinetics and pharmacodynamics of various drugs.

CO2: Applying pharmacological principles in diagnosis and treatment of various diseases.

CO3: Analysing effect on various drugs and their interactions for evaluating safety and efficacy.

CO4: Evaluating therapeutic effects of drugs by different experimental approaches and designing a comprehensive medication plan for a patient.

Course Content

UNIT I **12 hours**

Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines, Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR, Informed Consent Process: Informed Consent Process Ethical principles governing informed consent process

UNIT II **12 hours**

Clinical Trials: Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional • Clinical Trial Study Team Roles and

responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

UNIT III **12 hours**

Clinical Trial Documentation Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT, Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

UNIT IV **12 hours**

Basic aspects, terminologies and establishment of Pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance Centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

UNIT V **12 hours**

Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

UNIT VI **12 hours**

Pharmacoepidemiology, Pharmacoeconomics, Safety PharmacologyLearning Experience (describe how the course will be conducted and made experiential and participatory. Include the methods of instruction, use of technology, and the types of activities like case studies, hands-on learning, group work, assignments, and classroom and outside classroom experiences, and assessments that students will engage in to achieve the learning outcomes. Besides mentioning the support and feedback that shall be given, for eg course in charge will be available for additional support and feedback, students are encouraged to seek help as

needed. Students will have opportunities to collaborate and support each other through group activities and peer reviews).

Textbooks

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

2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996. 230

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

4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.

7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

Suggested Readings

1. Fundamentals of Clinical Trials, by Lawrence M. Friedman, Curt D. Furberg, David DeMets.
2. Designing Clinical Research, by Dr. Stephen B Hulley, MD, MPH, Steven R Cummings, MD, Warren S Browner, MD.
3. Publishing and Presenting Clinical Research, Third Edition, by Warren S. Browner MD.
4. Practical Guide to Clinical Data Management, Third Edition, by Susanne Prokscha.

Open Educational Resources (OER)

1. https://www.ich.org/page/ich-guidelines

2 https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx

3.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7939117/#:~:text=Pharmacoeconomics%20is%20a%20branch%20of,through%20data%20driven%20decision%20making.

4. https://ccsea.gov.in/Content/54_1_ACTS,RULESANDGUIDELINES.aspx

4. https://www.ich.org/page/quality-guidelines

5.https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

6. https://who-umc.org/

Evaluation Scheme

Evaluation Scheme:				
	Evaluation Component	**Duration**	**Weightage (%)**	**Date**
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-	10	
2	Sessional (Written Examination)	90Minutes	15	
3	Attendance			
4	End Term Examination (Written Examination)	180 Minutes	75	
Total			**100**	

MPL 205 P	Pharmacology Practical- II	**L**	**T**	**P**	**C**
Version	**1**	**-**	**-**	**12**	**6**
Category of Course	Practical				
Total Contact Hours	180				
Pre-Requisites/ Co-Requisites	Pharmacology Practical-I				

Course Perspective: This course equips with hands-on experience in drug action, interaction, and therapeutic use. It enhances understanding of pharmacokinetics and pharmacodynamics through lab experiments and clinical case studies. Students learn to evaluate drug efficacy, safety, and patient responses, fostering critical thinking and decision-making skills. Ultimately, this course prepares future healthcare professionals to apply pharmacological principles in real-world settings**.**

Course Outcomes:

Upon completion of the course the learner will be able to:

1. Understanding **d**rug mechanisms: Exploring how different drugs interact with biological systems.
2. Analysing drug effects**:** Observing and measuring the physiological and biochemical effects of drugs.
3. Applying laboratory techniques**:** Use of various techniques and equipment for conducting experiments.
4. Developing critical thinking: Interpretation of experimental data and understanding its implications for drug development and usage.

Course Content

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical tria.(3 Nos.)
17. Design of ADR monitoring protocol.

18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

Learning Experience

1. Mechanistic Insight Directly observe how drugs interact with biological systems, providing a clearer understanding of drug mechanisms at a molecular, cellular, and physiological level.
2. Dose-Response Relationships Investigate how varying doses of drugs affect their efficacy and safety, reinforcing theoretical knowledge about pharmacodynamics.
3. Pharmacokinetics and Pharmacodynamics: Apply concepts of drug absorption, distribution, metabolism, and excretion in practical scenarios, linking theory to practice.
4. Drug Development: Understand the process of drug testing and evaluation, from preclinical studies to clinical trials.

Reference books

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

Suggested Readings

3. Fundamentals of experimental Pharmacology-by M.N.Ghosh
4. Hand book of Experimental Pharmacology-S.K.Kulakarni
5. Text book of in-vitro practical Pharmacology by Ian Kitchen
6. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen

7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

Open Educational Resources (OER)

1. https://www.sciencedirect.com/book/9781483232669/screening-methods-in-pharmacology
2. https://link.springer.com/chapter/10.1007/978-981-15-5534-3_7
3. https://www.aitbspublishersindia.com/medical/pharmacology/Pharmacological-Screening-Methods
4. https://www.slideshare.net/sanyalhari/pharmacological-screening-by-harikesh-maurya

https://www.slideshare.net/TanuJa4/screening-methods-in-pharmacology

Evaluation Scheme (Please refer to Notice Ref No: KRMU/CoE/Even/2023-24/018 dated 10 May 2025)

Components	Sessional I and II	Continuous Mode	End Term Exam	Total
Weightage (%)	**30**	**20**	**100**	**150**

MPL 206S	Seminar / Assignment	**L**	**T**	**P**	**C**
Version 1.0		0	0	7	4
Total Contact Hours	7hr/week				
Pre-requisites/Exposure	Pharmacology				
Co-requisites					

Course Perspective: The seminar fosters deep understanding and critical analysis of core concepts through interactive discussions and presentations. Students apply theoretical knowledge to real-world scenarios, enhancing their research and communication skills.

Course Outcomes

Upon completion of the course students will be

1. Understanding of the seminar's core concepts and theories.
2. Appling the seminar content to real-world scenarios or case studies.
3. Critically analyse and evaluate various perspectives related to the seminar topics.
4. Effectively conduct and present research related to the seminar theme.
5. Demonstrate effective oral and written communication skills.

Evaluation Scheme

Course code	**Course**	**Internal Assessment**				**End Semester Exams**		**Total Marks**
		Continuous mode	**Sessional Marks**		**Total**	**Marks**	**Duration**	
			Marks	**Duration**				
MPL106S	Seminar / Assignment	-	-	-	-	100	-	100

SEMESTER III					
MRM301T	**Research Methodology and Biostatistics**	**L**	**T**	**P**	**C**
Version 1		**4**	**0**	**0**	**4**
Category of Course	Theory				
Total Contact Hours	60				
Pre-Requisites/ Co-Requisites	Pharmacology and Toxicology-I				

Course Perspective: Research Methodology focuses on the principles and procedures for designing, conducting, and analyzing research, ensuring scientific rigor and validity. Biostatistics applies statistical methods to biological and health-related data, aiding in the interpretation of experimental results and drawing meaningful conclusions. Together, they provide a foundation for rigorous and reliable research in various fields, particularly in the field of pharmaceutical sciences.

Course Outcomes

Upon completion of the course the learner will be able to:

CO1: Understanding the significance of ethical considerations in research and articulate the steps involved in the research process.

CO2: Applying the ability to select appropriate research methods and tools to address specific research questions or hypotheses.

CO3: Analysing research studies to assess their design, methodology, and findings, identifying strengths and weaknesses in the approaches used.

CO4: Evaluating the research proposals and existing studies, providing constructive feedback on methodology, data analysis, and interpretation of results.

Course Content

UNIT – I **12 hrs.**

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques

UNIT – II **12 hrs.**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis ofvariance, correlation, chi square test), null hypothesis, P values,degree of freedom, interpretation of P values.

UNIT – III **12 hrs.**

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV **12 hrs.**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V **12 hrs.**

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Learning Experience: Learning Research Methodology equips you with skills to design robust studies and critically evaluate research findings. Mastering Biostatistics enhances your ability to analyze and interpret complex data, revealing insights and guiding decision-making. Together, these disciplines build a strong foundation for conducting and assessing research with scientific accuracy.

Reading of and amazing raw data using statistical software.

Reference Books/Materials

1. Remington"s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.

Online Reference

1: https://pharmacyinfoline.com/laboratory-animals-cpcsea-guidelines/

2: https://ijcrt.org/papers/IJCRT2106825.pdf

3. https://eduvoice.in/types-research-methodology/

Evaluation Scheme

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-	10	
2	Sessional Examination (Written Examination)	60Minutes	15	
3	Attendance			
4	End Term Examination (Written Examination)	180 Minutes	75	
Total			**100**	

MPL 302S	Journal club (Presentation)	L	T	P	C
Version 1.0		0	0	1	1
Total Contact Hours	**15hrs/ Week**				
Pre-requisites/Exposure	Pharmacology				
Co-requisites	Advanced Pharmacology				

Course Perspective: Journal club discussions offer a platform to critically evaluate and dissect research findings, fostering a deeper understanding of scientific methodologies and implications. Participants benefit from diverse perspectives, enhancing their ability to assess the validity and impact of studies. This collaborative approach encourages ongoing learning and refinement of research skills.

Course Outcomes

Upon completion of the course the learner will be able to:

CO1: Understanding the ability to critically evaluate research methodologies, data interpretation, and study validity, leading to more informed and nuanced scientific discussions.

CO2: Improved Communication Skills: Strengthen the ability to articulate complex scientific concepts clearly and effectively, both in written and verbal formats, through presentations and group discussions.

CO3: Increased Research Literacy: Gain a comprehensive understanding of current trends and advancements in the field, fostering the ability to apply new knowledge to your own research or professional practice.

Evaluation Scheme

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-		
2	Sessional Examination (Written Examination)		25	
3	Attendance			

4	End Term Examination (Written Examination)			

MPL 303S	**Discussion/ Presentation**	**L**	**T**	**P**	**C**
Version 1.0		0	0	2	2
Total Contact Hours	--				
Pre-requisites/Exposure	Pharmacology				
Co-requisites	Advanced Pharmacology				

Course Perspective: Discussions and presentations foster a collaborative environment for scrutinizing research, allowing participants to articulate insights and raise critical questions. They provide an opportunity to clarify complex concepts and debate findings, enhancing collective understanding. This interactive process not only sharpens analytical skills but also hones the ability to communicate scientific ideas effectively.

Course Outcomes

Upon completion of the course the learner will be able to:

CO1: Enhanced Analytical Skills: Develop the ability to critically analyse and interpret research findings, identifying strengths, limitations, and implications through active discussion and presentation.

CO2: Effective Communication: Improve the ability to convey complex scientific ideas clearly and persuasively, both in oral presentations and written formats, while engaging in constructive dialogue with peers.

Evaluation Scheme

Evaluation Scheme:				
	Evaluation Component	**Duration**	**Weightage (%)**	**Date**
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-		
2	Sessional Examination (Written Examination)		50	

3	Attendance			
4	End Term Examination (Written Examination)			

MPL 304P	**Research Work**	**L**	**T**	**P**	**C**
Version 1.0		0	0	28	14
Total Contact Hours	--				
Pre-requisites/Exposure	Pharmacology				
Co-requisites	Advanced Pharmacology				

Course Perspective: Research work involves systematically investigating a specific question or problem to generate new knowledge or insights. It requires rigorous methodology, critical analysis, and synthesis of findings to contribute meaningfully to the field.

Course Outcomes

Upon completion of the course the learner will be able to:

CO1: Developing expertise in designing, conducting, and analyzing research using appropriate methodologies, ensuring rigor and reliability in generating valid results.

CO2: Enhancing the ability to critically evaluate research findings and apply them effectively to address practical problems or advance theoretical understanding within the field.

Evaluation Scheme

Evaluation Scheme:				
	Evaluation Component	**Duration**	**Weightage (%)**	**Date**
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-		
2	Sessional Examination (Written Examination)			
3	Attendance			
4	End Term Examination (Written Examination)		350	

SEM-IV

MPL 401S	Journal club (Presentation)	L	T	P	C
Version 1.0		0	0	1	1
Total Contact Hours	--				
Pre-requisites/Exposure	-				
Co-requisites	-				

Course Perspective: Journal club discussions offer a platform to critically evaluate and dissect research findings, fostering a deeper understanding of scientific methodologies and implications. Participants benefit from diverse perspectives, enhancing their ability to assess the validity and impact of studies. This collaborative approach encourages ongoing learning and refinement of research skills.

Course Outcomes

Upon completion of the course the learner will be able to:

CO1: Enhanced Critical Thinking: Develop the ability to critically evaluate research methodologies, data interpretation, and study validity, leading to more informed and nuanced scientific discussions.

CO2: Improved Communication Skills: Strengthen the ability to articulate complex scientific concepts clearly and effectively, both in written and verbal formats, through presentations and group discussions.

CO3: Increased Research Literacy: Gain a comprehensive understanding of current trends and advancements in the field, fostering the ability to apply new knowledge to your own research or professional practice.

Evaluation Scheme

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-		
2	Sessional Examination (Written Examination)		25	
3	Attendance			
4	End Term Examination (Written			

	Examination)			

MPL 402P	**Research Work (Practical)**	**L**	**T**	**P**	**C**
Version 1.0		0	0	31	16
Total Contact Hours	--				
Pre-requisites/Exposure	Pharmacology				
Co-requisites					

Course Perspective: Research work involves systematically investigating a specific question or problem to generate new knowledge or insights. It requires rigorous methodology, critical analysis, and synthesis of findings to contribute meaningfully to the field.

Course Outcomes

Upon completion of the course the learner will be able to:

CO1: Develop expertise in designing, conducting, and analyzing research using appropriate methodologies, ensuring rigor and reliability in generating valid results.

CO2: Enhance the ability to critically evaluate research findings and apply them effectively to address practical problems or advance theoretical understanding within the field.

Evaluation Scheme

Evaluation Scheme:				
	Evaluation Component	**Duration**	**Weightage (%)**	**Date**
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-		
2	Sessional Examination (Written Examination)			
3	Attendance			
4	End Term Examination (Written Examination)		400	

MPL 403S	Discussion/ Presentation	L	T	P	C
Version 1.0		0	0	3	3
Total Contact Hours	--				
Pre-requisites/Exposure	Pharmacology				
Co-requisites					

Course Perspective: Discussions and presentations foster a collaborative environment for scrutinizing research, allowing participants to articulate insights and raise critical questions. They provide an opportunity to clarify complex concepts and debate findings, enhancing collective understanding. This interactive process not only sharpens analytical skills but also hones the ability to communicate scientific ideas effectively.

Course Outcomes

Upon completion of the course the learner will be able to:

CO1: Develop the ability to critically analyse and interpret research findings, identifying strengths, limitations, and implications through active discussion and presentation.

CO2: Improve the ability to convey complex scientific ideas clearly and persuasively, both in oral presentations and written formats, while engaging in constructive dialogue with peers.

Evaluation Scheme

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date
1	**Continuous Assessment (Quiz/Assignment/ Presentation/ Extempore)	-		
2	Sessional Examination (Written Examination)		75	
3	Attendance			
4	End Term Examination (Written Examination)			