Department of Pharmacy

Programme: Master of Pharmacy (Pharmacology)

Central University of Rajasthan
NH-8, Bandarsindri,
Kishangarh-305817, Dist. Ajmer

1. ABOUT THE PROGRAMME

Among the many branches in Pharmacy, Pharmacology can be regarded as the important basic streams of Pharmacy. However, unlike other basic sciences, In the realm of Pharmacy, Pharmacology stands out as a fundamental pillar. Unlike other basic sciences, it intertwines principles from various scientific domains, serving as an indispensable nexus. This program equips pharmacy students with a comprehensive grasp of disease pathophysiology and pharmacotherapy, encompassing adverse effects, contraindications, and clinical applications of medications. It delves into preclinical safety and toxicological assessments of drugs and novel chemical entities, fostering competence in regulatory toxicological evaluation. Structured to fortify foundational pharmacological knowledge and illuminate recent therapeutic advancements, the curriculum elucidates drug mechanisms and their effects. It also instills proficiency in maintaining laboratory animals and understanding in vitro and in vivo preclinical evaluation methodologies. By comprehending the chemical underpinnings of drug action alongside pharmacodynamics, pharmacy students gain the ability to judiciously address the "why" and "how" of drug interactions, thus fine-tuning drug attributes to modulate activity. This specialized knowledge elevates pharmacists to a distinctive role among healthcare professionals. Through exclusive coursework, these programs cultivate critical thinking and evidence-based problem-solving skills, empowering students to make informed decisions within the pharmacy domain.

2. PROGRAM OBJECTIVES (PO)

PO1	Appreciation of deeper insights for basics and advances including modern knowledge of pharmacology and in-particular to discuss the pathophysiology and pharmacotherapy of various diseases with reference of their adverse effects, contraindications and clinical uses.
PO2	Building foundation for higher studies as well as capable to get suitable employment in the area of Pharmacology.
PO3	Development of positive attitudes to realize the importance of hard work, commitment, ethics and excellence.
PO4	Development of better scientific attitude, analytical and rational thinking among students.
PO5	Developing confidence for independent pursuit of projects, start-ups and entrepreneurship in the students.

3. APPROVED INTAKE: 15 (Fifteen)

4. MINIMUM ELIGIBILITY FOR ENTRY

A pass in the following examinations –

a. B. Pharm degree examination of an Indian University established by Law in India from an institution approved by Pharmacy Council of India and has scored not less than 55% (50% for the candidate belonging to SC/ST/OBC/PWD/EWS category) of the maximum marks (aggregate of four years of B. Pharm).

b. Every student should have obtained Registration with the State Pharmacy Council or should obtain the same within one month from the date of his admission, failing which the admission of the candidate shall be cancelled. A candidate with valid GPAT Score will be given preference for admission; however such candidate has to register for CUCET 2020.

5. COURSE STRUCTURE

Core Courses (C)	**Course Code**
Advanced Pharmacology -I	MPL 102T
Pharmacological and Toxicological Screening Methods - I	MPL 103T
Cellular and Molecular Pharmacology	MPL 104T
Advanced Pharmacology -II	MPL 201 T
Pharmacological and Toxicological Screening Methods - II	MPL 202T
Principles of Drug Discovery	MPL 203T
Clinical Research And Pharmacovigilance	MPL 204T
Discussion / Presentation (Proposal Presentation)	MPL303PP
Research Work	MPL304RW& MPL402RW
Discussion/Final Presentation	MPL403FP
Discipline Elective Courses (D)	
Modern Pharmaceutical Analytical Techniques	MPL101T
Seminar/Assignment	MPL 106S & MPL 206S
Journal Club	MPL302JC&MPL401JC
Elective Courses (Ex-discipline; E)	

Research Methodology and Biostatistics	MRM 301T
Elective 2	
Elective 3	
Lab Courses (L)	
Pharmacology Practical I	MPL105P
Pharmacology Practical II	MPL205P

SEMESTER WISE DISTRIBUTION OF THE COURSES

Semester I

Code	Title of Course	Type of Course	Credit
MPL101T	Modern Pharmaceutical Analytical Techniques	D	4
MPL102T	Advanced Pharmacology -I	C	4
MPL103T	Pharmacological and Toxicological Screening Methods - I	C	4
MPL104T	Cellular and Molecular Pharmacology	C	4
MPL05P	Pharmacology Practical -I	L	6
MPL106S	Seminar/Assignment	D	2

Total Credit: 24

C-Core Courses; D-Discipline Elective Course; E-Elective Course

Semester II

Code	Title of Course	Type of Course	Credit
MPL201T	Advanced Pharmacology -II	C	4
MPL202T	Pharmacological and Toxicological Screening Methods - II	C	4
MPL203T	Principles of Drug Discovery	C	4
MPL204T	Clinical Research And Pharmacovigilance.	C	4
MPL205P	Pharmacology Practical -II	L	6
MPL206S	Seminar/Assignment	D	2

Total Credit: 24

C-Core Courses; D-Discipline Elective Course; E-Elective Course

Semester III

Code	Title of Course	Type of Course	Credit
MRM 301T	Research Methodology and Biostatistics	E	4
MPL302JC	Journal club	D	2
MPL303PP	Discussion / Presentation (Proposal Presentation)	C	4
MPL304RW	Research Work	C	14

C-Core Courses; D-Discipline Elective Course; E-Elective Course
Total Credit: 24

Semester IV

Code	Title of Course	Type of Course	Credit
MPL401JC	Journal Club	D	2
MPL402RW	Research Work	C	18
MPL403FP	Discussion/Final Presentation	C	4

C-Core Courses; D-Discipline Elective Course; E-Elective Course; S-Societal Course
Total Credit: 24

Central University of Rajasthan
Department of Pharmacy

Semester-wise structure for the
M. Pharm. in Pharmacology (MPL) Programme
Semester I

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/D/E/L		L	I.L	P	T	P	IA-I	IA-II	
1.	MPL 101T	Modern Pharmaceutical Analytical Techniques	D	4	3	1	-	3	-	20	20	60
2.	MPL 102T	Advanced Pharmacology -I	C	4	3	1	-	3	-	20	20	60
3.	MPL 103T	Pharmacological and Toxicological Screening Methods - I	C	4	3	1	-	3	-	20	20	60
4.	MPL 104T	Cellular and Molecular Pharmacology	C	4	3	1	-	3	-	20	20	60
5.	MPL 105P	Pharmacology Practical I	L	6	-	-	12	-	6	20	20	60
6.	MPL 106S	Seminar/Assignment	D	2	-	2	-	1	-	-	-	100

Total Credits: Semester I–24 Credits

CIE: Continuous Internal Evaluation; **ESE:** End Semester Examination; **IA:** Internal Assessment, **L:** Lectures, **I. L:** Integrated Learning involving Tutorials, Group Discussions, Assignments, Field Work; **L**:Practicals, Lab. work, Project, **C:** Core, **E:** Elective, **D:** Discipline Elective Course.

The guide will be chosen based on mutual consent of the student and faculty member. After selection of the research guide the student will formulate his/her Seminar topic (MPH106S).

Semester II

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/DE/E/L		L	I.L	P	T	P	IA-I	IA-II	
1	MPL201T	Advanced Pharmacology - II	C	4	3	1	-	3	-	20	20	60
2	MPL202T	Pharmacological and Toxicological Screening Methods - II	C	4	3	1	-	3	-	20	20	60
3	MPL203T	Principles of Drug Discovery	C	4	3	1	-	3	-	20	20	60
4	MPL204T	Clinical Research And Pharmacovigilance.	C	4	3	1	-	3	-	20	20	60
6	MPL205P	Pharmacology Practical -II	L	6	-	-	12	-	6	20	20	60
7	MPL206S	Seminar/Assignment	D	2	-	2	-	1	-	-	-	100

Total Credits: Semester II –24

CIE: Continuous Internal Evaluation; **ESE:** End Semester Examination; **IA:** Internal Assessment, **L:** Lectures, **I. L:** Integrated Learning involving Tutorials, Group Discussions, Assignments, Field Work; **L**: Practicals, Lab. work, Project, **C:** Core, **E:** Elective, **D:** Discipline Elective Course.

Semester III

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/D/E/L		L	I.L	P	T	P	IA-I	IA-II	
1	MRM 301	Research Methodology and Biostatistics	E	4	3	1	-	3	-	20	20	60
2	MPL302JC	Journal club	D	2	1	1	-	3	-	-	-	100
3	MPL303PP	Discussion / Presentation (Proposal Presentation)	C	4	-	4	-	1	-	-	-	100
4	MPL304RW	Research Work	C	14	-	-	-	1	-	-	-	100

Total Credits: Semester III –24

The research work will commence this Semester. The students will submit a progress report and present seminar(s) based on the progress of his/her research work that should be attended by all students in the department, the research guide, the HOD, and other faculty of the Department. The student will be evaluated by an external expert. The progress report should be handed in by the student the next day after the delivery of the seminar.

*During this semester, the student is free to opt one open elective course of his/her interest, offered by any department of the University, however, the subject will appear in the Marks Sheet (if examination is qualified), but credits will not be accumulated.

Semester IV

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/D/E/Lab		L	I.L	P	T	P	IA-I	IA-II	
1	MPL 401JC	Journal Club	D	2	-	2	-	1	-	-	-	100
2	MPL 402RW	Research Work	C	18	-	4	-	1	-	-	-	100*
3	MPL403FP	Discussion / Presentation (Final Presentation)	C	4	-	-	-	1	-	-	-	100

Total Credits: Semester IV –24

This Semester is devoted totally to research which will culminate in the submission of a thesis. The student will deliver a pre-submission seminar before submission of his/her thesis at a date and time fixed by the department, that should be attended by all students in the department, the research guide, the HOD and other faculty of the Department. The Seminar will be followed by a discussion.

* MPL 402RW will be evaluated by an external subject expert.

Strong emphasis should be placed on the novelty/IPR aspects of the plagiarism free research work, beside publications in peer reviewed journals of good impact factors. Students should be encouraged to attend conferences, seminars where they will present their research work.

Semester I

MPL101T Modern Pharmaceutical Analytical Techniques Credit: 4

Course Outcome

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosageforms
- Theoretical and practical skills of the instruments

Unit	Details	Contact Hours
I	a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visiblespectroscopy. 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 IRspectroscopy c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescencespectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	11
II	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 NMRspectroscopy.	11
III	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	11
IV	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of thefollowing: a) Paper chromatography b) Thin Layerchromatography c) Ion exchange chromatography d) Column chromatography e)Gas chromatography f)High Performance Liquid	11

	chromatography g) Affinity chromatography	
V	a. 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 electricfocusing b. 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 X- ray diffraction.	11
VI	Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescenceassays.	5

Suggested Readings

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, Timothy A. Nieman, 5th edition, Eastern press, Bangalore,1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBSpublishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi,1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS,1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi,1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel DekkerSeries

MPL 102T	Advanced Pharmacology -I	Credit: 4

Course Outcome

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

- ✓ Discuss the pathophysiology and pharmacotherapy of certain diseases.
- ✓ Explain the mechanism of drug actions at cellular and molecular level.
- ✓ Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

Unit	Details	Contact Hours
I	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.	12
II	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). Co	12

	transmission 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	
III	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.	12
IV	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs	12
V	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	12
Suggested Readings 1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘ s		

2. 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.

3. Basic and Clinical Pharmacology by B.G Katzung

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

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

6. Graham Smith. Oxford textbook of Clinical Pharmacology.

7. Avery Drug Treatment

8. Dipiro Pharmacology, Pathophysiological approach.

9. Green Pathophysiology for Pharmacists. 21310. Robbins & Cortan Pathologic Basis of Disease, 9 th Ed. (Robbins Pathology)

11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company

12. KD.Tripathi. Essentials of Medical Pharmacology.

13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.

14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.

15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.

16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MPL 103T	Pharmacological and Toxicological Screening Methods - I	Credit: 4

Course Outcome

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

- ✓ Appraise the regulations and ethical requirement for the usage of experimental animals.
- ✓ Describe the various animals used in the drug discovery process and good laboratory. practices in maintenance and handling of experimental animals.
- ✓ Describe the various newer screening methods involved in the drug discovery process.
- ✓ Appreciate and correlate the pre-clinical data to humans.

Unit	Details	Contact Hours
I	Laboratory Animals Common laboratory 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. Bioassay-Principle, scope and limitations and methods	10
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 co ordination, 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.	10
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	10

	laxatives.	
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, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.	10
V	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Iimmunomodulators, Immunosuppressants and immunostimulants 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	10

Suggested Readings

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin

2. Screening methods in Pharmacology by Robert Turner. A

3. Evaluation of drugs activities by Laurence and Bachrach

4. Methods in Pharmacology by Arnold Schwartz.

5. Fundamentals of experimental Pharmacology by M.N.Ghosh

6. Pharmacological experiment on intact preparations by Churchill Livingstone

7. Drug discovery and Evaluation by Vogel H.G.

8. Experimental Pharmacology by R.K.Goyal.

9. Preclinical evaluation of new drugs by S.K. Guta

10. Handbook of Experimental Pharmacology, SK.Kulkarni

11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3 rd Edition.

12. David R.Gross. Animal Models in Cardiovascular Research, 2 nd Edition,

Kluwer Academic Publishers, London, UK.

13. Screening Methods in Pharmacology, Robert A.Turner.

14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.

15. Practical Manual of Experimental and Clinical Pharmacology by Bikash

Medhi (Author), Ajay Prakash (Author)

MPL 104T	Cellular and Molecular Pharmacology	Credit: 4

Course Outcome

Upon completion of the course, it is expected that the students will be able to understand

- ✓ Explain the receptor signal transduction processes.
- ✓ Explain the molecular pathways affected by drugs.
- ✓ Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- ✓ Demonstrate molecular biology techniques as applicable for pharmacology.

Unit	Details	Contact Hours
I	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.	12
II	Cell signaling 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	12

	transcription (STAT) signaling pathway.	
III	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.	12
IV	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.	12
V	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.	12

	Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars	

Suggested Readings

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.

MPL 105P	PHARMACOLOGY PRACTICALS – I	Credit: 6

Details
1.Analysis of pharmacopoeial compounds and their formulations by UV Visible 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, anesthesia 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 anesthetic, 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 softwares

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).

Suggested Books:-

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,

2. Fundamentals of experimental Pharmacology by M.N.Ghosh

3. Handbook of Experimental Pharmacology by S.K. Kulkarni.

4. Drug discovery and Evaluation by Vogel H.G.

5. Spectrometric Identification of Organic compounds - Robert M Silverstein,

6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,

7. Vogel‘ s Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,

8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille

9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)

10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers’ medical publishers Pvt. Ltd.

Semester II

MPL 201	ADVANCED PHARMACOLOGY - II	Credit: 4

Course Outcome

Upon completion of the course student shall be able to understand:-

- ✓ Explain the mechanism of drug actions at cellular and molecular level.
- ✓ Discuss the Pathophysiology and pharmacotherapy of certain diseases.
- ✓ Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

Unit	Details	Contact Hours
I	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	12
II	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.	12
III	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.	12
IV	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	12

	cardiovascular disease, diabetes, asthma and peptic ulcer	
V	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: Alzheimer' s disease, Parkinson' s disease, Cancer, Diabetes mellitus	12

Suggested Readings

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.

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

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

10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.

11. KD.Tripathi. Essentials of Medical Pharmacology

12. 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

MPL 202 PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II **Credit: 4**

Course Outcome

Upon completion of this course it is expected that students will be able understand,

- ✓ Explain the various types of toxicity studies.
- ✓ Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- ✓ Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Unit	Details	Contact Hours
I	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	12
II	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 regulatory toxicology studies	12
III	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	12
IV	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry	12

	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	
V	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12

Suggested Readings

1.Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp- handbook.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, 3 rd Edition, Lower and Bryan

5. OECD test guidelines.

6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.

7. 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/guidancecomplianceregulatoryinform

ation/guidances/ucm073246.pdf)

MPL 203T	PRINCIPLES OF DRUG DISCOVERY	Credit: 4

Course Outcome

Upon completion of this course it is expected that students will be able to understand,

- ✓ Explain the various stages of drug discovery.
- ✓ Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
- ✓ Explain various targets for drug discovery.
- ✓ Explain various lead seeking method and lead optimization.
- ✓ Appreciate the importance of the role of computer aided drug design in drug discovery.

Unit	Details	Contact Hours
I	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 fi nger proteins. Role of transgenic animals in target validation.	12
II	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	12
III	Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational	12

	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,	
IV	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.	12
V	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	12

Suggested Readings

1.MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.

2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and

Francis Group, LLC.

3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.

4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series;

American Chemical Society: Washington, DC, 1999.

7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

MPH 204T	CLINICAL RESEARCH AND PHARMACOVIGILANCE	Credit: 4

Course Outcome

Upon completion of the course, the students shall be able to understand

- ✓ Explain the regulatory requirements for conducting clinical trial.
- ✓ Demonstrate the types of clinical trial designs.
- ✓ Explain the responsibilities of key players involved in clinical trials.
- ✓ Execute safety monitoring, reporting and close-out activities.
- ✓ Explain the principles of Pharmacovigilance.
- ✓ Detect new adverse drug reactions and their assessment.
- ✓ Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

Unit	Details	Contact Hours
I	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 ParticipantSchedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process	12
II	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	12
III	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial MonitoringSafety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and	12

	reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	
IV	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	12
V	Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Non- proprietary 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.	12
VI	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	12

Suggested Readings

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. 2293. 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.

MPL 205P	PHARMACOLOGY PRACTICALS – II	Credit: 6

Details
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 trial.(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

REFERENCES

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.

Semester III

MRM 301T Research Methodology & BiostatisticsCredit: 4

Course Outcome

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics andcosmeceuticals.
- Key building blocks for variousformulations.
- Current technologies in themarket
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, andefficacy.

Unit	Details	Contact Hours
I	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.	
II	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 of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	
III	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.	
IV	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.	
V	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	