Two-Year Post graduate Programme

Master of Pharmacy

Pharmacology

Faculty of Pharmacy

Parul University,

Vadodara, Gujarat, India

Faculty of Pharmacy
Master of Pharmacy in Pharmacology

1. **Vision of the Department**
   To nurture pharmacy aspirants to serve the society with comprehensive subject knowledge, high professional values, excellent skills and outstanding research aptitude.

2. **Mission of the Department**

   M1 Foster humanitarian values, passion for learning and creativity.

   M2 Move towards high quality, futuristic educational and research ecosystem.

   M3 Develop socially responsible future pharmacists; committed to creating self-reliant India.

3. **Program Educational Objectives**

PEO 1	Make available a complete applied pharmaceutical education leading to M. Pharm. Degree in Pharmacology.
PEO 2	Instruct the detailed concept of advanced pharmacology, pre-clinical pharmacology, molecular pharmacology, and toxicology along with clinical applications of drugs.

4. **Program Learning Outcomes**

Program Learning outcomes are statements conveying the intent of a program of study.

PLO 1	**In-depth Knowledge of Pharmaceutical Science**	Acquire in-depth knowledge of all the theories and principle involved in pharmaceutical science.
PLO 2	**Professional and Interpersonal Skill Development**	Demonstrate necessary skills in pharmaceutical science like working independently, communication, coordination, time management and organizational skills. The students will demonstrate an adaptable, flexible and effective approach towards organizational development.
PLO 3	**Competency Development**	Develop an ability to communicate scientific knowledge in in non-expert/lay term by adopting various modes of scientific
PLO 4	**Technical Expertise**	Enable student handle pharmaceutical instruments in experiments. The student will also learn to draft the protocols and results based on the various research experiments.
PLO 5	**Knowledge Enhancement and Project management abilities**	Gain the knowledge by continue updating of technologies involving management of Pharmaceutical Quality System for continual improvement of Process Performance and Product Quality.
PLO 6	**Innovative Approach for research**	Develop critical thinking quality, which leads to development of the novel ideas in the field of pharmaceutical science

PLO 7	**Individual and Team work**	Function individually as a member or as a leader in diverse team with technical expertise.
PLO 8	**Instrument handling skills**	Understand theoretical and practical skills of the instruments. To apply suitable methods, resources and standard procedures to handle all types of equipment for demonstrating Pharmaceutical activities
PLO 9	**Regulatory Compliance**	Understand the fine regulatory requirements for Pharmacy profession starting from drug discovery to final product marketing.
PLO 10	**Knowledge about Current Affairs and lifelong learning**	Exhibit latest and updated knowledge in the field of pharmacy and develop the attitude and aptitude for lifelong learning.
PLO 11	**Environment and sustainability**	Understand the impacts of any research in societal and environmental contexts and develop any innovation with a second eye on environment and sustainability.

5. Program Specific Learning Outcomes

PSO 1	Understand the pharmacological and toxicological actions of synthetic and phyto-molecules in the diagnosis, prevention, and treatment of various diseases.
PSO 2	Impart basic knowledge and skills to practice quality use of medicines in clinical practice, analysis methods, prospect of research, risk and benefits, and identify medication related problems.

6. Credit Framework

Semester wise Credit distribution of the programme	
Semester-1	26
Semester-2	26
Semester-3	21
Semester-4	20
Total Credits:	**93**

Category wise Credit distribution of the programme	
Category	**Credit**
Major Core	28
Multidisciplinary	8
Skill Development Courses	20
Research Project/Dissertation	37
Total Credits:	**93**

7. Program Curriculum

Semester 1						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lec.**	**Lab**	**Tut.**
1	MPL 101T	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	4	4	-	-
2	MPL102T	ADVANCED PHARMACOLOGY-I	4	4	-	-
3	MPL103T	PHARMACOLOGICAL & TOXICOLOGICAL SCREENING METHODS - I	4	4	-	-
4	MPL104T	CELLULAR AND MOLECULAR PHARMACOLOGY	4	4	-	-
5	MPL 105P	PHARMACOLOGICAL PRACTICAL - I	6	-	12	-
6		Seminar/Assignment	4	7	-	-
		Total	26	**23**	**12**	**-**
Semester 2						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lec.**	**Lab**	**Tut.**
1	MPL201T	ADVANCED PHARMACOLOGY-II	4	4	-	-
2	MPL202T	PHARMACOLOGICAL & TOXICOLOGICAL SCREENING METHODS - II	4	4	-	-
3	MPL203T	PRINCIPLES OF DRUG DISCOVERY	4	4	-	-
4	MPL204T	CLINICAL RESEARCH AND PHARMACOVIGILANCE	4	4	-	-
5	MPL 205P	PHARMACOLOGICAL PRACTICAL - II	6	-	12	-
6		Seminar/Assignment	4	7	-	-
		Total	26	**23**	12	**-**
Semester 3						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lec.**	**Lab**	**Tut.**

1	MRM301T	Research Methodology and Biostatistics	4	4	-	-
2	MPL302P	Pre-Dissertation-I	1	-	1	-
3	MPL303P	Pre-Dissertation-II	2	-	2	-
4	MPL304P	Pre-Dissertation-III	14	-	28	-
		Total	21	**4**	**31**	**-**
Semester 4						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lec.**	**Lab**	**Tut.**
1	MPL402P	Dissertation-I	1	-	1	-
2	MPL403P	Dissertation-II	16	-	30	-
3	MPL404P	Dissertation-III	3	-	3	-
		Total	20		**34**	**-**

ANNEXURE III

Semester- I

a. **Course Name:** MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
b. **Course Code:** MPL 101T
c. **Prerequisite:** Foundational understanding of organic chemistry and instrumental analysis.
d. **Rationale:** The subject of modern pharmaceutical analytical techniques in M.Pharm explores advanced instrumental methods such as NMR, Mass spectrometry, IR, HPLC, and GC, enabling students to proficiently identify, characterize, and quantify drugs, comprehend the analysis of individual and combined drug formulations, and develop theoretical and practical competencies with these instruments.
e. **Course Learning Objective:**

CLOBJ 1	Chemicals and Excipients
CLOBJ 2	Analysis of various drugs in single and combination dosage forms
CLOBJ 3	Theoretical and practical skills of the instruments
CLOBJ 4	Knowledge of various chromatographic techniques
CLOBJ 5	Analyze analytical methods and Remembrance of basic principles of separation of biomolecules and application of electrophoresis.

f. **Course Learning Outcomes:**

CLO 1	Describe the various advanced analytical instrumental techniques for identification, characterization and quantification of drugs like UV , IR flame and fluorescence spectroscopy
CLO 2	Understand basic concepts of Quantum numbers with NMR and Proton NMR and knowledge of FT NMR and 13 C NMR in interpretations of NMR spectrum
CLO 3	Analyze different fragmentation pattern and determine molecular mass of compounds via mass spectrum of mass spectroscopy.
CLO 4	Apply knowledge of various chromatographic techniques for the separation of API in presence of excipients.

CLO 5	Remember basic principles of separation of biomolecules and application of electrophoresis. To analyze the crystal nature of compound by X ray crystallography and various thermal analytical methods.

g. Teaching & Examination Scheme:

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**0**	**0**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T-** Tutorial; **P-** Practical; **C-** Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	**Content**	**Weightage (%)**	**Teaching Hours**
1	UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 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, Data Interpretation. Spectro-fluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	**17**	**10**
2	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.	**17**	**10**

3	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.	**17**	**10**
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: j) Thin Layer chromatography k) High Performance Thin Layer Chromatography l) Ion exchange chromatography m) Column chromatography n) Gas chromatography o) High Performance Liquid chromatography p) Ultra High-Performance Liquid chromatography q) Affinity chromatography r) Gel Chromatography	**17**	**10**
5	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 methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	**17**	**10**
6	Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	**17**	**10**
	Total	**100**	**60**

i. Text Book and Reference Book:

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, 5 th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
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, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2 nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3 rd Edition, John Wiley & Sons, 1982.

a. **Course Name:** ADVANCED PHARMACOLOGY - I
b. **Course Code:** MPL102T
c. **Prerequisite: B**asic knowledge of pharmacology concepts, including drug action mechanisms, pharmacokinetics, and pharmacodynamics.
d. **Rationale:** The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved
e. **Course Learning Objective:**

CLOBJ 1	Relate and understand the pathophysiology and pharmacotherapy of certain diseases
CLOBJ 2	Explain the mechanism of drug actions at cellular and molecular level
CLOBJ 3	Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases
CLOBJ 4	Recognize the underlying mechanism of drug actions at cellular level
CLOBJ 5	Analyze adverse effects, contraindications and clinical uses of CVS and ANS

f. **Course Learning Outcomes:**

CLO 1	Understand the advanced concepts of pharmacology, Pharmacokinetics and pharmacodynamics
CLO 2	Illustrate Neurotransmission and systemic and autonomic Pharmacology
CLO 3	Explain the advances in Pharmacology of drugs acting on CNS
CLO 4	Explain the advances in Pharmacology of drugs acting on CVS
CLO 5	Outline the advances in Pharmacology of drugs acting on autacoids

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	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.	**20**	**12**
2	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). Co-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 Parasympathomimetic and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction	**20**	**12**
3	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.	**20**	**12**
4	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	**20**	**12**
5	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	**20**	**12**
	Total	**100**	**60**

i. Text Book and Reference Book:

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.
10. 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.

a. **Course Name:** Pharmacological And Toxicological Screening Methods - I
b. **Course Code:** MPL 103T
c. **Prerequisite:** Understanding of pharmacology, toxicology, biochemistry, and physiology.
d. **Rationale:** This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes
e. **Course Learning Objective:**

CLOBJ 1	Appraise the regulations and ethical requirement for the usage of experimental animals
CLOBJ 2	Describe the various animals used in the drug discovery process
CLOBJ 3	Explain good laboratory practices in maintenance and handling of experimental animals
CLOBJ 4	Describe the various newer screening methods involved in the drug discovery process
CLOBJ 5	Appreciate and correlate the preclinical data to humans

f. **Course Learning Outcomes:**

CLO 1	State the concepts of GLP, Bioassay and ethical use and maintenance of laboratory animals and transgenic animals as per the CCSEA guidelines
CLO 2	Outline preclinical screening of new substances for CNS and ANS pharmacology
CLO 3	Understand about preclinical screening of new substances for Respiratory, Reproductive, NSAIDs & GI diseases.
CLO 4	Describe preclinical screening of new substances for CVS, Cancer, Hepatoprotectives
CLO 5	Understand and evaluate about preclinical screening of new substances for immunopharmacology & understanding general principles of immunoassay, alternatives to animal experimentation & preclinical to human extrapolation of data.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	Laboratory Animals Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anesthesia 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	**20**	**12**
2	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, Alzheimer's and multiple sclerosis. Drugs acting on Autonomic Nervous System.	**20**	**12**
3	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, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: anti-ulcer, anti -emetic, anti- diarrheal and laxatives	**20**	**12**
4	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, anti-atherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods.	**20**	**12**
5	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Immunomodulators, 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	**20**	**12**
	Total	**100**	**60**

i. Text Book and Reference Book:

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)

a. **Course Name:** Cellular And Molecular Pharmacology
b. **Course Code:** MPL 104T
c. **Prerequisite:** Foundational knowledge in pharmacology, biochemistry, cell biology, molecular biology, physiology
d. **Rationale:** The subject 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 the student to apply the knowledge in drug discovery process.
e. **Course Learning Objective:**

CLOBJ 1	Explain the receptor signal transduction processes
CLOBJ 2	Understand the molecular pathways affected by drugs
CLOBJ 3	Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process
CLOBJ 4	Demonstrate molecular biology techniques as applicable for pharmacology
CLOBJ 5	Explain Cell culture techniques

f. **Course Learning Outcomes:**

CLO 1	Define concepts of cell biology.
CLO 2	Understand the concepts of cell signalling
CLO 3	Describe the principles and applications of genomic and proteomic tools.
CLO 4	Discuss the principles and applications of Pharmacogenomics and Immunotherapeutics.
CLO 5	Explain Cell culture techniques, Principles and applications of flow cytometry and Biosimilars.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	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	**20**	**12**
2	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 transcription (STAT) signaling pathway	**20**	**12**
3	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	**20**	**12**
4	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 immunotherapeutic Types of immunotherapeutic, humanization antibody therapy, Immunotherapeutic in clinical practice	**20**	**12**
5	a. 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	**20**	**12**

	assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars		
	Total	**100**	**60**

i. Text Book and Reference Book:

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 AL.

ANNEXURE IV

Semester - I

a. **Course Name:** Pharmacological Practical - I
b. **Course Code:** MPL 105P
c. **Prerequisite:** Knowledge of basic pharmacology principles laboratory safety procedures
d. **Rationale:** This subject deals with understanding the principle and methodology of spectroscopic and chromatographic techniques and screening of drugs on various system using animal models.

e. **Course Learning Objective:**

CLOBJ 1	Analyze organic compounds techniques
CLOBJ 2	Understand effect of various drugs on CNS
CLOBJ 3	Isolation of DNA, RNA and enzyme-based study.

f. **Course Learning Outcomes:**

CLO 1	Analyse organic compounds by understanding the principle and methodology of spectroscopic and chromatographic techniques.
CLO 2	Evaluate the preclinical and molecular biology techniques for evaluation of drugs for various pharmacological actions.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
-	**-**	**12**	**6**	**-**	**-**	**50**	**-**	**100**	**150**

L- Lectures; **T-** Tutorial; **P-** Practical; **C-** Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. **Text Book and Reference Book:**

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.

i. Experiment List

Exp. No.	Name of the Experiment
1	To perform the analysis of Metformin in bulk and in tablet dosage form by UV VIS spectrophotometer.
2	Simultaneous estimation of Paracetamol and Ibuprofen using simultaneous equation method by UV spectrophotometry.
3	Estimation of Caffeine using HPLC.
4	Estimation of quinine sulphate by fluorimetry.
5	To study the effect of quenching of Potassium iodide on Fluorescence intensity of Quinine Sulphate.
6	Estimation of sodium/potassium in the given sample of ORS by flame photometry
7	To study various routes of drug administration.
8	To study various methods of blood sampling in laboratory animals.
9	To study various techniques anaesthesia and euthanasia in laboratory animals.
10	To perform Functional Observation Battery Tests (Modified Irwin Test).
11	To study the anti-convulsive activity of drug using chemical induce convulsions methods.
12	To study the CNS depressant activity of drug using actophotometer.
13	To evaluate the analgesic potency of drug by thermal method.
14	To evaluate diuretic activity of furosemide in rats.
15	To evaluate antiulcer activity of drug by pylorus ligation method.
16	To measure glucose clearance of an oral glucose load in mice by oral gavage glucose tolerance test
17	To perform isolation and identification of DNA from bacteria.
18	To perform isolation of RNA from yeast.
19	Estimation of proteins by Lowry's method in given biological sample.
20	Estimation of proteins by Bradford method given biological sample.
21	To perform PCR amplification of specific target sequence from genomic
22	DNA and to analyse the amplified product by agarose gel electrophoresis.

Exp. No.	Name of the Experiment
23	To perform enzyme based In-vitro Assays (Myeloperoxidase, Acetylcholine Esterase, α Amylase, α glucosidase).
24	To study DNA damage by comet assay (single cell gel electrophoresis)

ANNEXURE III

Semester II

a. **Course Name:** Advanced Pharmacology-II
b. **Course Code:** MPL201T
c. **Prerequisite:** Foundational knowledge in pharmacology, biochemistry, cell biology, molecular biology, physiology
d. **Rationale:** The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved
e. **Course Learning Objective:**

CLOBJ 1	Understand the molecular mechanisms of drug action on various physiological systems to predict and analyze pharmacological responses.
CLOBJ 2	Analyze advanced pharmacokinetic concepts to optimize drug dosage regimens and therapeutic outcomes.
CLOBJ 3	Evaluate the principles of drug development and design, integrating knowledge of pharmacodynamics and pharmacokinetics.
CLOBJ 4	Evaluate the principles of drug development and design, integrating knowledge of pharmacodynamics and pharmacokinetics.
CLOBJ 5	Demonstrate proficiency in designing and conducting pharmacological experiments, and effectively communicate findings through scientific writing and presentations.

f. **Course Learning Outcomes:**

CLO 1	Discuss the advances in Pharmacology of drugs acting on Endocrine System
CLO 2	Recognize the advances in Pharmacology of Chemotherapeutic agents.
CLO 3	Describe the advances in Pharmacology of Chemotherapeutic agents for protozoal infections, helminthiasis, Cancer, Immune system & respiratory system.
CLO 4	Understand the advances in Pharmacology of drugs acting on GI Diseases and to learn about Chronopharmacology
CLO 5	Illustrate free radical pharmacology and recent advances in treatment of selected diseases.

g. Teaching & Examination Scheme:

Teaching Scheme				Evaluation Scheme					
L	T	P	C	Internal Evaluation			ESE		Total
				MSE	CE	P	Theory	P	
4	-	-	4	15	10	-	75	-	100

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	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	20	12
2	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	20	12
3	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	20	12
4	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	20	12
5	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	20	12
	Total	100	60

i. Text Book and Reference Book:

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, 9th 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

a. **Course Name:** Pharmacological & Toxicological Screening Methods- II
b. **Course Code:** MPL202T
c. **Prerequisite:** Understanding of pharmacology, toxicology, biochemistry, and physiology.
d. **Rationale:** This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.
e. **Course Learning Objective:**

CLOBJ 1	Identify and describe various types of toxicity studies used in preclinical evaluation of drugs and new chemical entities.
CLOBJ 2	Assess the significance of ethical considerations and regulatory requirements in conducting toxicity studies for pharmaceutical development.
CLOBJ 3	Demonstrate proficiency in executing practical techniques essential for conducting preclinical toxicity studies.
CLOBJ 4	Analyze and interpret toxicity data obtained from preclinical studies to evaluate the safety profile of drugs and new chemical entities.
CLOBJ 5	Formulate comprehensive reports integrating theoretical knowledge and practical skills in preclinical toxicology for regulatory evaluation.

f. **Course Learning Outcomes:**

CLO 1	Explain the various types of toxicity & Appreciate the importance of ethical and regulatory requirements for toxicity studies.
CLO 2	Memorise about various toxicity studies according to OECD guidelines and test item characterization.
CLO 3	Understand the concept of Reproductive & Genotoxicity toxicology studies
CLO 4	Apply the concept of IND enabling studies & Safety pharmacology studies
CLO 5	Assess the concept of Toxicokinetic evaluation in preclinical studies & Alternative methods to animal toxicity

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	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	**20**	**12**
2	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	**20**	**12**
3	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	**20**	**12**
4	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	**20**	**12**
5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	**20**	**12**
	Total	**100**	**60**

i. Text Book and Reference Book:

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, 3rd 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

a. **Course Name:** Principles of Drug Discovery
b. **Course Code:** MPL203T
c. **Prerequisite:** Foundational knowledge in pharmacology, biochemistry, cell biology, molecular biology, physiology
d. **Rationale:** The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process
e. **Course Learning Objective:**

CLOBJ 1	Explain the various stages of drug discovery.
CLOBJ 2	Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
CLOBJ 3	Explain various targets for drug discovery.
CLOBJ 4	Explain various lead seeking method and lead optimization
CLOBJ 5	Appreciate the importance of the role of computer aided drug design in drug discovery

f. **Course Learning Outcomes:**

CLO 1	Understand the basics of drug discovery process including the role of genomics, proteomics & Bioinformatics
CLO 2	Outline the basics and applications of Lead Identification & protein structure
CLO 3	Explore Rational Drug Design and virtual screening techniques
CLO 4	Understand and apply concepts of Molecular docking & basics of QSAR
CLO 5	Understand and apply the QSAR Statistical methods, basics and rationale of pro-drug design

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T-** Tutorial; **P-** Practical; **C-** Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	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	**20**	**12**
2	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	**20**	**12**
3	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,	**20**	**12**
4	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	**20**	**12**
5	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	**20**	**12**
	Total	**100**	**60**

i. Text Book and Reference Book:

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markel In. 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.

a. **Course Name:** Clinical Research and Pharmacovigilance
b. **Course Code:** MPL204T
c. **Prerequisite:** Knowledge in pharmacology, clinical pharmacy, drug safety, regulatory affairs, data analysis, and research methodology.
d. **Rationale:** This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.
e. **Course Learning Objective:**

CLOBJ 1	Explain the regulatory requirements for conducting clinical
CLOBJ 2	Demonstrate the types of clinical trial designs
CLOBJ 3	Explain the responsibilities of key players involved in clinical trials
CLOBJ 4	Execute safety monitoring, reporting and close-out activities
CLOBJ 5	Explain the principles of Pharmacovigilance

f. **Course Learning Outcomes:**

CLO 1	Recognise the regulatory perspectives of clinical trials
CLO 2	understand the types and design of clinical trials & roles and responsibilities of Clinical trial personnel
CLO 3	Explain the concepts of ADR & maintenance of Clinical Trial Documentation
CLO 4	Memorise the basic aspects, terminologies and establishment of pharmacovigilance
CLO 5	Interpret various methods and tools of pharmacovigilance along with the concepts of Pharmacoepidemiology, pharmacoeconomics & safety pharmacology

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
				Internal Evaluation			**ESE**		**Total**
L	**T**	**P**	**C**	**MSE**	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	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: Structure and content of an Informed Consent Process Ethical principles governing informed consent process	**20**	**12**
2	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	**20**	**12**
3	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 reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR	**20**	**12**
4	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	**20**	**12**
5	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.	**20**	**12**
	Total	**100**	**60**

i. Text Book and Reference Book:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. NewDelhi: 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.
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

ANNEXURE IV
Semester II

a. **Course Name:** Pharmacological Practical -II
b. **Course Code:** MPL205P
c. **Prerequisite:** Knowledge of basic pharmacology principles laboratory safety
d. **Rationale:** The "Pharmacological Practical – II" lab is vital for learning practically relevant skills and reinforcing the theoretical knowledge by applying the concepts of pharmacology and toxicology.
e. **Course Learning Objective:**

CLOBJ 1	Analyze and interpret experimental data obtained from pharmacological experiments to draw meaningful conclusions
CLOBJ 2	Demonstrate proficiency in the use of laboratory equipment and instrumentation relevant to pharmacological experiments.
CLOBJ 3	Develop and execute research methodologies to investigate drug actions, dose-response relationships, and physiological effects

f. **Course Learning Outcomes:**

CLO 1	Assess the methodology and interpret experiments for understanding of pharmacodynamic characteristics of drugs.
CLO 2	Understand and practice planning and conduction of toxicity studies, clinical trials and in-silico studies

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
-	**-**	**12**	**6**	**-**	**-**	**50**	**-**	**100**	**150**

L- Lectures; **T-** Tutorial; **P-** Practical; **C-** Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. **Text Book and Reference Book:**

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.

i. Experiment List:

Exp. No.	Name of the Experiment
1	To record the DRC of Acetylcholine using chicken ileum.
2	To study the effects of antagonist on DRC of agonist.
3	To determine the strength of unknown sample of Ach by matching bioassay by using rat/chicken ileum.
4	To determine the strength of unknown sample of Ach by Interpolation bioassay by using rat/chicken ileum.
5	To determine the strength of unknown sample of Histamine by bracketing bioassay by using rat/chicken ileum.
6	To determine the strength of unknown sample of Ach by three-point bioassay by using rat/chicken ileum.
7	To determine the PA2 value of atropine by using rat/chicken ileum.
8	To study the effects of various drugs on isolated heart preparation.
9	To record blood pressure, heart rate and ECG of rat.
10	To perform drug absorption studies by averted rat ileum preparation.
11	To perform acute oral toxicity studies as per OECD guidelines.
12	To perform Acute dermal toxicity studies as per OECD guidelines.
13	To perform Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
14	To perform drug mutagenicity study using mice bone-marrow Chromosomal Aberration test
15	To design protocol for clinical trial.
16	To understand ADR reporting: Basics and general considerations.
17	To design of ADR monitoring protocol.

ANNEXURE III

Semester III

a. **Course Name: Research Methodology and Biostatistics**
b. **Course Code: MRM301T**
c. **Prerequisite:** Foundational knowledge in pharmacology, statistics, research design, data analysis, and critical appraisal of scientific literature.
d. **Rationale:** The course is designed to study research methodology in terms of basic concepts of statistical analysis, principles of medical research, ethics and patents, maintenance of laboratory animals and design research work.
e. **Course Learning Objective:**

CLOBJ 1	Analyze the value, scope, objectives and requirements of research
CLOBJ 2	Discuss the basic concepts of statistical analysis
CLOBJ 3	Apply the basic principles of medical research and ethics.
CLOBJ 4	Understand the guidelines for the maintenance of laboratory animals.
CLOBJ 5	Create efficiency in solving practical difficulties and Understand to design research work.

f. **Course Learning Outcomes:**

CLO 1	Learn general research methodology helps to select the appropriate study design and develop appropriate research hypothesis for a research project
CLO 2	Understand the basic concepts of biostatistics and Learn different parametric and non-parametric tests
CLO 3	Understand the functions of ethics committees in medical research
CLO 4	Learn CCSEA guidelines for laboratory animal facility
CLO 5	Study the genesis of bioethics with special reference to Helsinki declaration

g. Teaching & Examination Scheme:

Teaching Scheme				Evaluation Scheme					
L	T	P	C	Internal Evaluation			ESE		Total
				MSE	CE	P	Theory	P	
4	-	-	4	15	10	-	75	-	100

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	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.	20	12
2	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.	20	12
3	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.	20	12
4	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities	20	12

	to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.		
5	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**20**	**12**
	Total	**100**	**60**

i. Text Book and Reference Book:

1. Research Methodology : Methods & Techniques, C.R. Kothari, Viswa Prakashan,
2. Research Methods- A Process of Inquiry, Graziano, A.M., Raulin, M.L, Pearson Publications.
3. Pharmaceutical Statistics: Practical and Clinical Applications, Sanford Bolton and Charles Bon.
4. Thesis projects in Science & Engineering – Richard M. Davis.
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. How to Write a Thesis: Murray, R. Tata McGraw Hill
8. Writing For Academic Journals, Murray, R., McGraw Hill International.
9. A Handbook of Academic Writing, Murray, R. and Moore, S., Tata McGraw Hill International
10. Writing for Publication, Henson, K.T., Allyn & Bacon.
11. Effective Business Report Writing –Leland Brown
12. Manual for evaluation of industrial projects-United Nations
13. Practical Introduction to copyright.- Gavin Mcfarlane
14. Operational research by Dr. S.D. Sharma, Kedarath, Ramnath & Co.
15. Various Guidelines like: ICH – GCP- International Conference on Harmonisation of
16. Technical requirements for registration of pharmaceuticals for human use. ICH