CENTRAL UNIVERSITY OF PUNJAB BATHINDA



Master of Pharmacy (Pharmacology) MH-MPL-F

Batch-2023

Department of Pharmacology

Graduate attributes

M. Pharmacology graduate on completion of their study will demonstrate professional attitudes and behavior. They will acquire competencies in the acquisition of knowledge, teaching and training. They acquire a solid foundation of pharmacology principles and research experience in a lab setting. A graduate in M. Pharmacology can describe and apply pharmacological principles to explain the mechanisms of the effects of drugs used in diagnosis, prevention and treatment of diseases of all systems of human body and describe mechanisms of drug-drug interactions and their clinical importance. They can apply and integrate knowledge of pathophysiology of diseases and its modulation by drugs. They will acquire knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines. They can describe how to evaluate, analyse and monitor preclinical and clinical data in drug discovery. They can demonstrate knowledge of basics of research methodology, develop a research protocol, conduct the study, record experimental observations, analyse data using currently available statistical software, interpret results and disseminate these results and have the potential ability to pursue further specializations and eventually be competent to guide students. Students who graduated from the course can pursue higher studies and found employment in research positions either in academia or research industry. Other destinations include positions as consultants, medical writers, patent lawyers, regulatory affair officers and medical sales representatives.

Course structure for M. Pharm. (Pharmacology)

Course Name of the course Code		Credit points	Hrs/ wk	Marks
SEMESTER I			ı	
Modern Pharmaceutical Analytical techniques	4	4	4	100
Advanced Pharmacology- I	4	4	4	100
Pharmacological and Toxicological Screening Methods-1	4	4	4	100
Cellular and Molecular Pharmacology	4	4	4	100
Pharmacological Practical I (Analytical Instruments Handling, Handling of Laboratory Animals & Bio-Chemical analysis)	12	6	12	150
Seminar/Assignment	7	4	7	100
Total	<mark>35</mark>	<mark>26</mark>	35	<mark>650</mark>
SEMESTER II				
Advanced Pharmacology- II	4	4	4	100
Pharmacological and Toxicological Screening Methods- II	4	4	4	100
Principles of Drug Discovery	4	4	4	100
Clinical Research and Pharmacovigilance	4	4	4	100
Pharmacological Practical II (General Pharmacology, Toxicology & <i>In silico</i> studies)	12	6	12	150
Seminar/Assignment		4	7	100
Inter-Disciplinary Course		2	2	100
			37	<mark>750</mark>
	or other s	tudents)		
Prevention	2	2		100
	2	<u>2</u>	2	100
				T 400
			· ·	100
				25
			-	50
			- 5	350 525
	33	21	3	323
	1	1	1	25
Discussion and Final Presentation	3	3	-	75
Discussion and I man I foscillation			 	
Research Work	31	16	-	400
	Modern Pharmaceutical Analytical techniques Advanced Pharmacology- I Pharmacological and Toxicological Screening Methods-1 Cellular and Molecular Pharmacology Pharmacological Practical I (Analytical Instruments Handling, Handling of Laboratory Animals & Bio-Chemical analysis) Seminar/Assignment Total SEMESTER II Advanced Pharmacology- II Pharmacological and Toxicological Screening Methods- II Principles of Drug Discovery Clinical Research and Pharmacovigilance Pharmacological Practical II (General Pharmacology, Toxicology & In silico studies) Seminar/Assignment Inter-Disciplinary Course Total Total Seminary Course Total Drug Abuse: Problem, Management and	Modern Pharmaceutical Analytical techniques Advanced Pharmacology- I Pharmacological and Toxicological Screening Methods-1 Cellular and Molecular Pharmacology Pharmacological Practical I (Analytical Instruments Handling, Handling of Laboratory Animals & Bio-Chemical analysis) Seminar/Assignment Total SEMESTER II Advanced Pharmacology- II Pharmacological and Toxicological Screening Methods- II Principles of Drug Discovery 4 Clinical Research and Pharmacovigilance Pharmacological Practical II (General Pharmacology, Toxicology & In silico studies) Seminar/Assignment 7 Inter-Disciplinary Course Total S (Offer by Dept. of Pharmacology for other s Drug Abuse: Problem, Management and Prevention Rational use of Medicines SEMESTER III Research Methodology & Biostatistics 4 Journal club Discussion/Presentation(Proposal Presentation) 2 Research Work 28 Total SEMESTER IV	Modern Pharmaceutical Analytical techniques Advanced Pharmacology- I Pharmacological and Toxicological Screening Methods-1 Cellular and Molecular Pharmacology Pharmacological Practical I (Analytical Instruments Handling, Handling of Laboratory Animals & Bio-Chemical analysis) Seminar/Assignment Total Advanced Pharmacology- II Advanced Pharmacology- II Pharmacological and Toxicological Screening Methods- II Principles of Drug Discovery Clinical Research and Pharmacovigilance Pharmacological Practical II (General Pharmacology, Toxicology & In silico studies) Seminar/Assignment Total Total Seminar/Assignment Total Total Seminar/Assignment Total Research Methodology & Biostatistics A 4 Journal club Discussion/Presentation(Proposal Presentation) Research Work Total Total Seminary Course 2 2 2 2 2 3 37 28 38 4 4 4 4 4 4 4 4 4 4 4 4 4	Modern Pharmaceutical Analytical techniques 4 4 4 Advanced Pharmacology- I 4 4 4 Pharmacological and Toxicological 4 4 4 Screening Methods-1 Cellular and Molecular Pharmacology 4 4 4 Pharmacological Practical I (Analytical Instruments Handling, Handling of Laboratory Animals & Bio-Chemical analysis) 12 6 12 SEMESTER II Advanced Pharmacology- II 4 4 4 Pharmacological and Toxicological Screening Methods- II 4 4 4 Principles of Drug Discovery 4 4 4 Clinical Research and Pharmacovigilance 4 4 4 Pharmacology, Toxicology & In silico studies) 2 2 2 Seminar/Assignment 7 4 7 Inter-Disciplinary Course 2 2 2 Total 37 28 37 Iss (Offer by Dept. of Pharmacology for other students) 4 4 Proyal Abuse: Problem, Management and Prevention

Evaluation Criteria for Theory Courses

- A. Continuous Assessment: [25 Marks]
 - i. Surprise Test (minimum three) Based on Objective Type Tests (10 Marks)
 - ii. Term paper/Surprise interview/Clinical Case studies/Think pair share (10 Marks)
 - iii. Assignment(s) (Classroom or Home assignments)/open book Test (5 Marks)
- B. Mid Semester Test: Subjective Type Test [25Marks]
- C. End-Term Exam (Final): Subjective (70%) + Objective 30% [50 Marks]
- □ The objective type will include one-word answers, fill-in the blank, sentence completion, true/false, MCQs', matching.
- □ The subjective type will include very short answer (1-2 lines), short answer (one paragraph), essay type with restricted response, and essay type with extended response.

Evaluation Criteria for Practical Courses

I	tem	Synopsis	Experiment	Practical Notebook and day to day evaluation	Viva voce
Ma	arks	20	50	50	30

Evaluation Criteria for Research Work (3rd&4th Semester)

Thesis Proposal (Third Semester)				(I	Thesis Fourth mester)
	Marks	Evaluation		Marks	Evaluation
Supervisor	200	Thesis proposal and presentation	Supervisor	200	Continuous assessment (regularity in work, midterm evaluation), Thesis report, presentation, final viva-voce
HoD and senior-most faculty of the department	150	Thesis proposal and presentation	External expert, HoD and senior- most faculty of the department	200	Thesis report (100), presentation (50), final viva- voce (50)

PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and qualification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about,

Chemical and Excipients

The analysis of various drugs in single and combination dosage forms.

Theoretical and practical skills of the instruments

THEORY 60 Hrs

 a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. 	10 Hrs
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 ¹³ C NMR. Applications of NMR spectroscopy.	10 Hrs
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.	10 Hrs
4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra-High-Performance Liquid chromatography h. Affinity chromatography i. Gel chromatography	10 Hrs
5. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting	10 Hrs

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.

6. a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.

10 Hrs

b. 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.

c. Pharmaceutical Quality by design, qualitative and quantitative analysis of drugs and pharmaceuticals including impurity profiling in Active Pharmaceutical Ingredients (APIs) as per regulatory requirements, ICH guidelines for analysis of drugs and pharmaceuticals.

- 1. Principles of Instrumental Analysis Doglas A Skoog, F. James Holler, Timothy A. Nieman, 7th edition, Cengage, 2018.
- 2. Spectrometric Identification of Organic compounds Robert M Silverstein, 8thedition, John Wiley & Sons, 2014.
- 3. Instrumental methods of analysis Willards, 7 th edition, CBS publisher, 2018
- 4. Practical Pharmaceutical Chemistry Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 2007.
- 5. Organic Spectroscopy William Kemp, 3rd edition, ELBS, 2019.
- 6. Quantitative Analysis of Drugs in Pharmaceutical formulation P D Sethi, 3rd edition, CBS Publishers, New Delhi, 2008.
- 7. Pharmaceutical Analysis Modern Methods Part B J W Munson, Vol 11, Marcel, Dekker Series 1984 (Reprint 2012)
- 8. Spectroscopy of Organic Compounds, 8th Edition, P. S. Kalsi, New Age International Private Limited, 2020.
- 9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 2007.
- 10. Introduction to spectroscopy. 5th Edition, Pavia DL, Lampman GM, Kriz GS, Vyvyan JA.; Cengage Learning India Private Limited, 2015
- 11. Pharmaceutical quality by design: a practical approach. Schlindwein WS, Gibson M, editors. John Wiley &Sons; 2018.
- 12. HPLC in the Pharmaceutical Industry, (Volume 47) (Drugs and the Pharmaceutical Sciences Series) Edited by Godwin W. Fong, Stanley K. Lam, CRC press, 2010
- 13. Handbook of Pharmaceutical Analysis (Volume 117) (Drugs and the Pharmaceutical Sciences Series) Edited by Lena Ohannesian, Anthony J. Streeter, Marcel Dekker Inc. 2008

ADVANCED PHARMACOLOGY – 1 (MPL 102T)

Scope

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.

Objectives

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

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

THEORY 60 Hrs

General Pharmacology	12 Hrs
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.	
2. Neurotransmission	12 Hrs
a. General aspects and steps involved in neurotransmission.	
b. Neurohumoral transmission in autonomic nervous system (Detailed	
study about neurotransmitters – Adrenaline and Acetylcholine).	
c. Neurohumoral transmission in central nervous system (Detailed study	
about neurotransmitters - histamine, serotonin, dopamine, GABA,	
glutamate and glycine).	
d. Non adrenergic non cholinergic transmission (NAN). 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	
Parasympatho-mimetics and -lytics, sympatho-mimetics and -lytics,	
agents affecting neuromuscular junction	
3. Central nervous system Pharmacology	12 Hrs
General and local anesthetics	
Sedatives and hypnotics, drugs used to treat anxiety.	
Depression, psychosis, mania, epilepsy, neurodegenerative diseases.	
Narcotic and non-narcotic analgesics.	
4. Cardiovascular Pharmacology	12 Hrs
Diuretics, anti-hypertensives, anti-ischemics, anti-arrhythmics, drugs	
for heart failure and hyperlipidemia.	
Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet	
drugs	
5. Autacoid Pharmacology: The physiological and pathological role of	12 Hrs
Histamine, Serotonin, Kinins Prostaglandins Opioid autacoids.	
Pharmacology of antihistamines, SHT antagonists.	

- 1. Basic and Clinical Pharmacology by B. G Katzung, 14th edition, McGraw-Hill, 2018.
- 2. Handbook of Drug Metabolism, Third Edition (Drugs and the Pharmaceutical Sciences)3rd Edition, Paul G Pearson, Larry C. Wienkers, CRC Press, 2021
- 3. The Pharmacological Basis of Therapeutics, Goodman and Gillman's 13th edition by Laurence Brunton, Bjorn Knollman and Randa Hilal-Dandan, McGraw-Hill Education, 2017.
- 4. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy,4th edition by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers, 2016.
- 5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott, New York: ADIS Health Science Press, 1983.
- 6. Applied bioharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu. 7th edition, McGraw-Hill Education, 2016
- 7. Graham Smith. Oxford textbook of Clinical Pharmacology, 3rd edition, Oxford University Press, 2008.
- 8. Avery Drug Treatment by Trevor M. Speight and Nicholas H.G. Holford, 4th edition, Wiley India Pvt Ltd, 2012.
- 9. Dipiro Pharmacology: A pathophysiological approach. 10th edition, McGraw-Hill Education, 2017.
- 10. Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice 3rd Revised edition Russell J. Greene & Norman D. Harris Pharmaceutical Press, 2008
- 11. Robbins & Cortan Pathologic Basis of Disease, 10 th Ed. (Robbins Pathology), Elsevier, 2020
- 12. A Complete Textbook of Medical Pharmacology 2nd edition by Dr. S. K. Srivastava published by APC Avichal Publishing Company, 2017.
- 13. K.D. Tripathi, Essentials of Medical Pharmacology, 8th edition, Jaypee Brothers Medical Pub, 2018.
- 14. Modern Pharmacology with Clinical Applications, 6th edition, Craig Charles R. & Stitzel Robet E., Wolters Kluwer India Pvt. Ltd 2012.
- 15. Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications Hardcover, 5 th edition, Wolters Kluwer, Lippincott Williams & Wilkins Publishers, 2019.
- 16. Applied Biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists, 7th edition, 2016.
- 17. Gene Therapy: Treating Disease by Repairing Genes (The New biology Series)—Joseph Panno, Viva books private limited, 2017
- 18. Oxford Handbook of Clinical Pharmacy 3rd Edition Philip Wiffen, Marc Mitchell, Melanie Snelling, Nicola Stoner, Oxford university press, 2017
- 19. New Drug Approval Process: 190 (Drugs and the Pharmaceutical Sciences) Richard A. Guarino (Ed.), 5th Edition, CRC Press, 2009
- 20. Animal and Translational Models for CNS Drug Discovery (3 volumes Set)- Edited by Robert A. Mcarthur, Franco Borsini, Academic press, 2008
- 21. Drug-drug interactions, (Volume 179)(Drugs and the Pharmaceutical Sciences Series) Edited by A. David Rodrigues, 2nd Edition, Informa Healthcare, 2008
- 22. The chemical basis of Drug Action (Volume 2) (Foundations of Molecular Pharmacology Series) J.B. Stenlake, The Anthlone Press, 2009
- 23. Drug Facts Comparisons 2015 Facts & comparisons, 2014

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-1 (MPL 103T)

Scope

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.

Objectives

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

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 preclinical data to humans

THEORY 60 Hrs 1. Laboratory Animals 12 Hrs 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 2. Preclinical screening of new substances for the pharmacological activity using in 12 Hrs 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, Alzheimer's and multiple sclerosis, Drugs acting on Autonomic Nervous System. 3. Preclinical screening of new substances for the pharmacological activity using in 12 Hrs vivo. In-vitro, and other possible animal alternative models. Respiratory Pharmacology: ani-asthmatics, drugs for COPD and anti-allergic. Reproductive Pharmacology: Aphrodisiacs and anti-fertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti-ulcer, antiemetic, anti-diarrheal and laxatives. Preclinical screening of new substances for the pharmacological activity using in 12 Hrs vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: anti-hypertensives, anti-arrythmics, anti-anginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti- diabetic, anti-dyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods. Preclinical screening of new substances for the pharmacological activity using in vivo, 12 Hrs in vitro, and other possible animal alternative models, Immunomodulators, Immunosuppressants and immunostimulants. General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogeneous 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

- 1. Biological standardization by J.H. Burn, D.J. Finney and I.G. Goodwin, 2011.
- 2. Fundamentals of experimental Pharmacology by M.N. Ghosh, 2019.
- 3. Practical Manual of Experimental and Clinical Pharmacology 2nd edition by Bikash Medhi and Ajay Prakash, 2017.
- 4. Drug discovery and Evaluation: Pharmacological Assay by Vogel H.G. 2015.
- 5. Screening methods in Pharmacology by Robert Tuner A, 2013.
- 6. Evaluation of Drug Activities: Pharmacometrics by Laurence and Bachrach, Academic Press 2013.
- 7. Methods in Pharmacology by Arnold Schwartz 2013
- 8. Drug screening methods by SK Gupta, 2016.
- 9. Handbook of Experimental pharmacology, S.K. Kulkarni, 2016.
- 10. Practical Pharmacology and Clinical Pharmacy, S.K. Kulkarni, 3rd Edition. 2008.
- 11. Animal Models in Cardiovascular Research, by David R. Gross, 3rdEdition, 2009.
- 12. Screening Methods in Pharmacology, Robert A. Turner. 2013.
- 13. Viva Voce in Experimental Pharmacology by Jaggi A.S., Bali, A., and Singh, N. 2015
- 14. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee. 2018 (reprint)
- 15. G Protein-Coupled Receptor Screening Assays by Duarte Miguel F. Prazeres (Editor), Sofia Aires M. Martins (Editor), 2015

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

Scope:

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.

Objectives:

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

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

THEORY 60 Hrs 12 Hrs 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. 2. Cell signaling 12 rs Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; Gprotein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5trisphosphate, (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. 3. Principles and applications of genomic and proteomic tools DNA electrophoresis, 12 Hrs 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. 4. Pharmacogenomics 12 Hrs 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	
5. a. Cell culture techniques	12 Hrs
Basic equipment used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays, Principles and applications of flow cytometry b. Biosimilars	

- 1. The Cell, A Molecular Approach. 8th edition, Geoffrey M Cooper. 2019.
- 2. Pharmacogenomics: The Search for individualized Therapies. Edited by J. Licinio and M L. Wong, 2009.
- 3. Cellular and Molecular Pharmacology by Jaggi AS, Virdi K J, Bali A, Singh N, 2020
- 4. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. Bradshaw and Edward A. Dennis, 2009
- 5. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al, 2012.
- 6. Basic Cell Culture protocols, 4th edition by Cheril D. Helgason and Cindy L.Miller, 2013.
- 7. Basic Cell Culture (Practical Approach) 2nd revised edition by M. Davis (Editor), 2001.
- 8. Animal Cell Culture by Mohamed Al-Rubeai, 2016.
- 9. Current protocols in molecular biology vol l to VI edited by Frederick M. Ausuvelet la. 1988.

PHARMACOLOGICAL PRACTICAL-I (MPL 105P)

A. ANALYTICAL INTRUMENTS HANDLING)

- 1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
- 2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
- 3. Experiments based on HPLC
- 4. Experiments based on Gas Chromatography
- 5. Estimation of riboflavin/quinine sulphate by fluorimetry
- 6. Estimation of sodium/potassium by flame photometry
- 7. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
- 8. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

B. HADNLING 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.

C. BIO-CHEMICAL ANALYSIS

- 1. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
- 2. Isolation of RNA from yeast
- 3. Estimation of proteins by Braford/Lowry's in biological samples.
- 4. Estimation of RNA/DNA by UV Spectroscopy
- 5. Gene amplification by PCR.
- 6. Protein quantification Western Blotting.
- 7. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
- 8. Cell viability assays (MTT/Trypan blue/SRB).
- 9. DNA fragmentation assay by agarose gel electrophoresis.
- 10. DNA damage study by Comet assay.
- 11. Apoptosis determination by fluorescent imaging studies.
- 12. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using software
- 13. Enzyme inhibition and induction activity

- 1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines
- 2. Fundamentals of experimental Pharmacology by M.N.Ghosh, 2011.
- 3. Handbook of Experimental Pharmacology by S.K. Kulkarni.2016.
- 4. Drug discovery and Evaluation by Vogel H.G.2011.
- 5. Spectrometric Identification of Organic compounds 8th edition Robert M Silverstein. 2017.
- 6. Principles of Instrumental Analysis 7th edition- Doglas et al., 2018.
- 7. Vogel's Text book of quantitative chemical analysis 6th edition by Mendham et al, 2009
- 8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille, Springer, 2013.
- 9. Animal Cell Culture: A Practical Approach 3rd revised edition by John R. Masters (Editor) 2005
- 10. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics by Carl A Burtis; David E Bruns; Barbara G Sawyer; Norbert W Tietz, 8th Edition, Elsevier, 2019
- 11. Practical Manual of Experimental and Clinical Pharmacology 2nd edition by Bikash Medhi (Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd, 2017.

Course Title: Seminar/Assignment

Paper Code: MPL106S

Learning outcome: Students who successfully complete this course will be able to

Perform literature review on a given topic

Prepare a report on a given topic

Prepare a power point presentation on a given topic

Evaluation criteria:

Literature survey/background information

Organization of content

Physical presentation

Questions and answers

Report evaluation

ADVANCED PHARMACOLOGY - II (MPL 201T)

Scope:

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

Objectives:

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

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

THEORY 60 Hrs

1.	Endocrine Pharmacology	12 Hrs
	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	
2.	Chemotherapy	12 Hrs
	Cellular and molecular mechanism of actions and resistance of antimicrobial agents	
	such as \(\beta \- lactams, \) aminoglycosides, quinolones, Macrolide antibiotics. Antifungal,	
	antiviral, and anti-TB drugs.	
3.	Chemotherapy	
	Drugs used in Protozoal Infections	12 Hrs
	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	10.77
4.	GIT Pharmacology	12 Hrs
	Antiulcer drugs, Prokinetics, anti-emetics, anti-diarrheal 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	
5	Free radicals Pharmacology	12 Hrs
5.	Generation of free radicals, role of free radicals in etiopathology of various	12 1115
	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	
	Cancer, Diancies inclinus	

- 1. The Pharmacological basis of therapeutics 13th edition Goodman and Gilman's, 2017.
- 2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy 4th edition by DavidE Golan et al. 2016.
- 3. Basic and Clinical Pharmacology 15th edition by B.G –Katzung, 2020.
- 4. Pharmacology 9th edition by H.P. Rang and M.M. Dale. Elsevier, 2018.

- 5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.1983.
- 6. Text book of Therapeutics, drug and disease management 8th edition by E T. Herfindal and Gourley. 2011.
- 7. Applied biopharmaceutics and Pharmacokinetics 7^{th} edition by Leon Shargel and Andrew B.C.Yu.2015.
- 8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists. 7th edition, 2016.
- 9. Robbins & Cortan Pathologic Basis of Disease, 10th Ed. (Robbins Pathology) 2020
- 10. A Complete Textbook of Medical Pharmacology 2nd edition by Dr. S.K Srivastava published by APC Avichal Publishing Company. 2017.
- 11. K.D.Tripathi. Essentials of Medical Pharmacology, 8th edition, 2018.
- 12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy 4th edition, by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams &Wilkins Publishers, 2018.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL 202T)

Scope:

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.

Objectives:

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

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.

THEORY 60Hrs

1.	Basic definition and types of toxicology (general, mechanistic, regulatory and	12 Hrs
	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	
2.	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.	12 Hrs
	Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity	
	studies. Test item characterization-importance and methods in regulatory	
	toxicology	
3.	Reproductive toxicology studies, Male reproductive toxicity studies, female	
	reproductive studies (segment I and segment III), teratogenicity studies (segment II)	12 Hrs
	Genotoxicity studies (Ames Test, in vitro and in vivo	
	Micronucleus and chromosomal aberrations studies)	
	In vivo carcinogenicity studies	
4.	IND enabling studies (IND studies)- Definition of IND, importance of IND,	
	industry perspective, list of studies needed for IND submission.	12 Hrs
	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	
5.	Engineered nanomaterials, drug delivery, nanotoxicology and regulatory	
	requirements, Toxicokinetics- Toxicokinetic evaluation in preclinical studies,	12 Hrs
	saturation kinetics Importance and applications of toxicokinetic studies.	12 mis
	Alternative methods to animal toxicity testing.	

- 1. Drugs from discovery to approval 3rd edition by Rick NG. Wiley Blackwell, 2015.
- 2. Studies on Experimental Toxicology and Pharmacology (Oxidative Stress in Applied Research and Clinical Practice) by Stephen M. Roberts, James P. Kehrer, et al., 2016 Hand book on GLP, Quality practices for regulated non-clinical research and development 2nd edition, (http://www.who.int/tdr/publications/documents/glp-handbook.pdf).WHO, 2008.
- 3. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
- 4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
- 5. OECD test guidelines
- 7. https://link.springer.com/protocol/10.1007/978-1-60327-405-0_25 (AMES Test-OECD 471)
- 8. Principles of toxicology 3rd edition by Karen E. Stine, Thomas M. Brown. 2015.
- 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/guidancecomplianceregulatoryinformation/guidances/ucm07 3246.pdf)
- 10. Nanoparticle Technology for Drug Delivery (Volume 159) (Drugs and the Pharmaceutical Sciences Series) –Edited by Ram B. Gupta, Uday B. Komepella, 2nd Edition, Taylor & Frabcis Group, 2006
- 11. Clinical Trials. A Practical Approach by Jorgen Seldrup, Stuart J. Pocock, 1985
- 12. Lippincott Illustrated Reviews: Pharmacology (Lippincotts Illustrated Reviews Pharmacology) by Karen Whalen , 2018

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Scope:

The Subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process.

Objectives:

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

Explain the various stages of drug discovery.

Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery.

Explain various targets of drug discovery.

Explain various lead seeking method and lead optimization.

Appreciate the importance of the role of computer aided drug design in drug discovery.

THEORY: 60 Hrs

OKY:		60 Hrs
1.	An Overview of modern drug discovery process: Target identification, target	12 Hrs
	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.	
2.	Lead identification- combination chemistry & High throughput screening, in silico	12 Hrs
	lead discovery techniques, Assay development of hit identification.	
	Protein structure	
	Level 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	
2	prediction Design Design Design	10 11
3.	Rational Drug Design	12 Hrs
	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.	
4.		12 Hrs
4.	screening. De novo drug design.	12 1113
	Quantitative analysis of structure Activity Relationship	
	History and Development of QSAR, SAR versus QSAR, Physicochemical parameters,	
	Hanschanalysis, fee Wilson analysis and relationship between them.	
5.	QSAR Statistical methods- regression analysis, partial least square analysis (PLS)	
	and other multivariate statistical methods.	12 Hrs
	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	

- 1. Disease Gene Identification. Methods and Protocols.2nd edition by Johanna K. Di., 2018
- 2. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options by Mouldy Sioud, 2007.
- 3. InSilico Technologies in Drug Target Identification and Validation by Darryl León. Scott Markel, 2006
- 4. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. by Hugo Kubiny, 1993.
- 5. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry, Klaus Gubernator, Hans-Joachim Böhm by Publisher Wiley-VCH. 1998.
- 6. Rational Drug Design. Novel Methodology and Practical Applications. by Abby L . Parrill. M .Rami Reddy, 1999.
- 7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey, 2007.
- 8. Advances in QSAR Modeling: Applications in Pharmaceutical, Chemical, Food, Agricultural and Environmental Sciences (Challenges and Advances in Computational Chemistry and Physics) by Kunal Roy, 2017.
- 9. Computational Approaches for the Prediction of pKa Values (QSAR in Environmental and Health Sciences) by George C. Shields and Paul G. Seybold, 2017

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Scope:

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.

Objectives:

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

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

THEORY 60 Hrs

 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. 	
 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 Hrs
3. Clinical Trial Documentation- Guidelines to the preparation of docum Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical S Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	Study
4. Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monito Pharmacovigilance in India and international aspects, WHO international monitoring programme, WHO and Regulatory terminologies of ADR, evaluation medication safety, establishing pharmacovigilance centres in Hospitals, Industry National programmes related to pharmacovigilance. Roles and responsibilities Pharmacovigilance	drug on of and

5. Methods, ADR reporting and tools used in Pharmacovigilance	12 Hrs
International classification of diseases, International Nonproprietary names f	or
drugs, Passive and Active surveillance, Comparative observational studies, Targete	ed
clinical investigations and Vaccine safety surveillance. Spontaneous reporting	ng
system and Reporting to regulatory authorities, Guidelines for ADRs reportin	g.
Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating	ng
medication safety data.	
6. Pharmacoepidemiology, Pharmacoeconomics, safety pharmacology (ICH	12 Hrs
Guideline)	

- 1. Ethical Guidelines for Biomedical Research on Human Subjects 2017. Indian Council of Medical Research, New Delhi
- 2. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- 3. 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.
- 4. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, March 2013, Wiley Publications.
- 5. Handbook of clinical Research. 2nd edition Julia Lloyd and Ann Raven Ed. Churchill Livingstone. 1994.
- 6. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes. 2001.
- 7. Clinical Trials. A Practical Approach by Jorgen Seldrup, Stuart J. Pocock, 1985
- 8. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, 2nd edition, John Wiley and Sons.2010.
- 9. Principles of Research Methodology: A Guide for Clinical Investigators by Phyllis G. Supino and Jeffrey S. Borer, 2012
- 10. Principles of Pharmacogenetics and Pharmacogenomics by Russ B. Altman, David Flockhart, et al., 2012

PHARMACOLOGICAL PRACTICAL II (MPL 205P)

A. GENERAL PHARMACOLOGY

- 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.

B. TOXICOLOGY

- 1. Acute oral toxicity studies as per OECD guidelines.
- 2. Acute dermal toxicity studies as per OECD guidelines.
- 3. Repeated dose toxicity studies- Serum biochemical, hematological, urine analysis, functional observation tests and histological studies.
- 4. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
- 5. Protocol design for clinical trial. (3 Nos.)
- 6. Design of ADR monitoring protocol and reporting.

C. IN SILICO STUDIES

- 1. In silico physico chemical prediction
- 2. ADME prediction tools and software
- 3. In-silico docking studies. (2 Nos.)
- 4. In-silico pharmacophore-based screening.
- 5. In-silico QSAR studies.

- 1. Fundamentals of experimental Pharmacology-by M.N.Ghosh 2016.
- 2. Hand book of Experimental Pharmacology-S.K. Kulakarni. 2016.
- 3. Applied biopharmaceutics and Pharmacokinetics 8th edition by Leon Shargel and Andrew B.C.Yu.2022.
- 4. Text book of in-vitro practical Pharmacology by Ian Kitchen. 1984.
- 5. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal Choudhary and William Thomsen. 2017
- 6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Indu₂s₂trial Scientists. 7th edition, 2016.
- 7. Computational Toxicology: Risk Assessment for chemicals (Wiley Series on technologies for the pharmaceutical industry) Edited by Sean Ekins, John Wiley & Sons, 2018

Course Title: Seminar/Assignment

Paper Code: MPL206S

Learning outcome: Students who successfully complete this course will be able to

Perform literature review on a given topic

Prepare a report on a given topic

Prepare a power point presentation on a given topic

Evaluation criteria:

Literature survey/background information Organization of content Physical presentation

Questions and answers

Report evaluation

Semester III MRM 301T - Research Methodology & Biostatistics

UNIT – 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.

UNIT - 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.

UNIT – III

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

UNIT - IV

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

UNIT - V

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

REFERNCES:

- 1. Research Methodology and Statistical Techniques by Gupta S, 2010.
- 2. Research Methodology: Methods and Techniques by Kothari, C. R. 2019
- 3. Research Design: Qualitative, Quantitative, and Mixed Methods Approaches by Creswell D and Creswell J W, 2019
- Research Methodology: A Theoretical Approach by D. Napolean and B. Balaji Sathya Narayanan, 2014
- 5. World Trade Organization [website: www.wto.org].
- 6. Research Methodology in Behavioural Sciencesby Mangal S.K, 2013
- 7. Biostatistics: The Bare Essentials by Norman, G. and Streiner, D, 2008
- 8. Biometry: The Principles and Practices of Statistics in Biological Research by Sokal, R.R. and Rohlf, F.J., 1994.
- 9. Pharmaceutical statistics: practical and clinical applications. By CRC Press Bolton, S, & Bon, C. 2009
- 10. Biomedical Research from Ideation to Publication by Jagadeesh G., Murthy S., Gupta YK, Prakash A, 2010

Course Title: Journal Club Paper

Code: MPL302T

Course Title: Discussion/ Presentation (Proposal Presentation)

Paper Code: MPL303T

Course Title: Research Work

Paper Code: MPL600

Learning outcome: Students who successfully complete this course will be able to

• Design a research problem and prepare synopsis

- Plan and execute experiments in the laboratory
- Interpret and analyze the results

Evaluation criteria:

- Literature survey/background information
- Organization of content
- Physical presentation
- Questions and answers
- Report evaluation

Semester IV

Course Title: Journal Club Paper

Code: MPL401T

Course Title: Discussion/ Presentation Paper

Code: MPL402T

Course Title: Research Work: MPL601

Learning outcome: Students who successfully complete this course will be able to

- Design a research problem and prepare synopsis
- Plan and execute experiments in the laboratory
- Interpret and analyze the results

Evaluation criteria:

- Literature survey/background information
- Organization of content
- Physical presentation
- Questions and answers
- Thesis evaluation
- Viva-voce

The following are some of the modes of classroom transaction

- Lecture
- Demonstration
- Lecture Cum demonstration
- Project
- Seminar
- Group discussion
- Focus group discussion

The following tools can be used in different transactional modes:

Software tools

- Tracker
- Chem Draw
- Schrodinger
- Maestro/Autodock, etc.
- Endnote/reference

Inter disciplinary course-I (IDC-506)

Drug Abuse: Problem, Management and Prevention

Scope: This course will help the students to acquire the basic knowledge of drug abuse to reduce the burden of mortality and morbidity through the detection, prevention and treatment.

L	T	P	Credits
2	0	0	2

Course Code: IDC-506

Total Hours: 30hrs

Course Learning Outcomes

CLO 1: Types of abuse drugs and their effects

CLO 2: Drug trafficking and strategies for prevention of drug abuse

CLO 3: Knowledge of the etiology of drug abuse, addiction, prevention, and treatment

Unit/hr	Course Content			
Unit-1/15hr	Introduction to Drug Abuse: Concept and Overview, Drug Dependence, Drug			
	Addiction, Physical and Psychological Dependence, Drug Tolerance and			
	withdrawal symptoms, Signs and symptoms of Drug Abuse, Causes and			
	Consequences of Drug Abuse.			
	Types of Abused Drugs and their Effects:			
	1) Stimulants: Amphetamines– Benzedrine, Dexedrine, Cocaine.			
	2) Depressants: Alcohol, Barbiturates, Barbiturates.			
	3) Narcotics: Heroin, Morphine.			
	4) Hallucinogens: Cannabis, Marijuana, LSD.			
	5) Steroids			
	Organized crime and Drug trafficking, Drug Cartel, Drug Mafia, Drug Crime			
	Indian statistics and world data			
Unit-2/15hr	Management and Prevention of Drug Abuse: Management of Drug	CLO 3		
	Abuse, Prevention of Drug Abuse, Role of Family, Society, School, Media			
	in preventing substance abuse, Narcotic Drugs and Psychotropic			
	Substances Act, 1985, De-addiction Centers			

Suggested Readings:

- 1. Drug Abuse Concepts, Prevention and Cessation by Sussman S and Ames S, 2008.
- 2. Drugs and Crime in Lifestyle Perspective: The Drug Crime Connection by Inciardi JA, 1981
- 3. Drug Epidemic Among Indian Youth by Kapoor T, 1985
- 4. Alcohalism by Kessel, Neil and Walton H, 1982
- 5. Drug abuse: Prevention and Management. Gurmehar Publication by Bedi O, Arora S, Krishan P, 2019
- 6. Addiction: A Reference Encyclopedia by Padwa H Cunningham J, 2010
- 7. Encyclopedia of Drugs, Alcohol & Addictive Behavior by Korsmeyer, P Kranzler HR, 2008
- 8. Drugs, Crime, and Justice: Contemporary Perspectives by Gaines L and Kremling J, 2013

Inter disciplinary course-II (IDC-521)

Rational use of Medicines

Scope: This course will help the students to acquire the knowledge of essential medicines concept and rational use of medicine to reduce the burden of mortality and morbidity

L	T	P	Credits
2	0	0	2

Course Code: IDC-521

Total Hours: 30hrs

Course Learning Outcomes

CLO 1: Rational and irrational medicines use

CLO 2: Factors underlying irrational use of medicine

CLO 3: Adverse effects of irrational medicines use

CLO 4: Infectious diseases and their prevention

Unit/hr	Course Content	Course Learning
		Outcomes
Unit-1/20hr	Introduction to Rational use of drugs: Introduction and	CLO 1
	Definition of rational use of drugs, Introduction to essential drugs, Over the counter drugs (OTC), Role of physician, Pharmacist and Patient in rational use of drugs, Misuse of	CLO 2
	OTC and prescription of drugs Antibiotic Resistance and Rational use of antibiotics: Bacteria, Antibiotic resistance, Factors of antibiotic resistance, Mechanism of antibiotic resistance, Prevention of antibiotic resistance, rational antibiotic use	CLO 3
Unit-2/10hr	Communicable diseases: Definition, Types, Sign and Symptoms, Causes and Prevention of Food or water-borne diseases, Respiratory-borne diseases, Vector-borne diseases, Zoonotic diseases. Role of Pharmacist and Patient in prevention of communicable diseases.	CLO 4

Suggested Readings:

- 1. Improving Use of Medicines and Medical Tests in Primary Care by Weekes LM, 2020.
- 2. Rationale of Drug of Choice: A Comparative Analysis by Nirmala P, Chidambaram N 2017.
- 3. The tutorial manual for rational drug-use training by Dong YY, 2012.
- 4. Antibiotic Drug Resistance by Capelon Martínez JL and Igrejas G, 2019
- 5. No-Nonsense Guide to Antibiotics: Dangers, Benefits & Proper Use by Dolan Moira, Croft A, Hartmann DL, 2017.
- The rational use of antibiotics in bacterial infection. Symposium infections: Current Paediatrics by McLellan NJ, Gray J, 2001
- 7. Rational use of antibiotics. Internist by Walger P, 2016.
- 8. Antibiotic Essentials by Cheston BC, Burke AC, 2019.