COURSE BOOK M. PHARM PHARMACOLOGY I YEAR





CURRICULUM STRUCTURE & SYLLABUS

Effective from the Session: 2025-26

| Index Page | | | | | | | | |
|------------|---|----------|--|--|--|--|--|--|
| | Contents | Page No. | | | | | | |
| 1. | Teaching Scheme of M. Pharm Pharmacology 1 st & 2 nd Semester | 3 | | | | | | |
| 2. | Theory and Practical's Courses Detail Syllabus | 4 | | | | | | |
| 3. | Annexure-1 | 24 | | | | | | |

Teaching Scheme of (M. Pharm. Pharmacology I Year)

| | | | | M. Pharm-Pharmaco | log | y 1s | t Sem | | | | | | | | |
|-------|-------------|-----------|----------------|--|-----|------------------------------|-------|------------------------------|-----|----------------------|------------------------|-----------------------|--------------------------------|--|--------------|
| S No. | Course Type | BOS | Course Code | Course Name | | Academic Learning (AL) | | Academic Learning (AL) | | Examination (CIE) | Continuous Internal | Mid Sem Exam (MSE) | End Semester Examination (ESE) | | Total Credit |
| | | | | | L | T | P | MSE | CA | TOTAL | | CIE+ESE | Cr | | |
| 1 | M.Pharm | KSOP | MPL101T | Modern Pharmaceutical Analytical Techniques | 4 | 0 | 0 | 15 | 10 | 25 | 75 | 100 | 4 | | |
| 2 | M.Pharm. | KSOP | MPL102T | Advanced Pharmacology-I | 4 | 0 | 0 | 15 | 10 | 25 | 75 | 100 | 4 | | |
| 3 | M.Pharm | KSOP | MPL103T | Pharmacological and Toxicological Screening Methods-I | 4 | 0 | 0 | 15 | 10 | 25 | 75 | 100 | 4 | | |
| 4 | M.Pharm | KSOP | MPL104T | Cellular and Molecular Pharmacology | 4 | 0 | 0 | 15 | 10 | 25 | 75 | 100 | 4 | | |
| 5 | M.Pharm | KSOP | MPL1 305 | Soft Skills | 1 | 0 | 0 | 10 | - | 10 | 40 | 50 | NC | | |
| La | b/Internsh | ip/Projec | t work/Worksho | op | | | | | | | | | | | |
| 8 | M.Pharm | KSOP | MPL105P | Experimental Pharmacology-I | 0 | 0 | 12 | 30 | 20 | 50 | 100 | 150 | 6 | | |
| 9 | M.Pharm | KSOP | MPL106S | Seminar/Assignment | 0 | 0 | 7 | - | 100 | 100 | - | 100 | 4 | | |
| | Total | Hours = | 36 hrs. | | 17 | 0 | 19 | | | | | 700 | 26 | | |

M. Pharm-Pharmacology 2nd Sem Continuous Internal Examination (CIE) Mid Sem Exam (MSE) End Semester Examination (ESE) Course Code Total Credit Course Type Course Name S No. BOS TOTAL CIE+ESE Cr MSE CA \mathbf{L} Т P M.Pharm KSOP MPL201T Advanced Pharmacology II 4 0 15 10 25 75 100 4 KSOP Pharmacological and Toxicological 0 15 10 25 75 100 M.Pharm MPL202T 4 0 4 Screening Methods-II Principles of Drug Discovery 25 75 M.Pharm KSOP MPL203T 4 0 0 15 10 100 4 Clinical Research and 0 15 10 25 75 100 M.Pharm KSOP MPL204T 4 0 4 Pharmacovigilance Lab/Internship/Project work/Workshop M.Pharm KSOP MPL205P Experimental Pharmacology-II 0 0 12 30 20 50 100 150 6 0 0 100 100 M.Pharm KSOP MPL206S Seminar/Assignment 100 4 KSOP MPL1 207 Internship on Clinical Research by 0 0 25 25 1 M.Pharm 2 25 IIPH/Pharmacovigilance by CPA or Experimental Pharmacology and Toxicology/Medical Writing or Any Relevant Industry Internship/ 8-12 weeks MOOC Course (NPTEL) Total Hours: 37 hrs. 16 0 21 675 27

2. Teaching Scheme of (M. Pharm. Pharmacology I Year)

| Course Code: MPL101T | Course Name: Modern Pharmaceutical Analytical Techniques | L | T | P | C |
|-------------------------------------|--|---|---|---|---|
| Course Offered in: KIET School of P | 4 | 0 | 0 | 4 | |

Pre-requisite: NA

Course Objectives: Upon completion of this course the student should be able to know-

- Chemicals and excipients.
- The analysis of various drugs in single and combination dosage forms.
- Theoretical and practical skills of the instruments.

Course Outcome: After completion of the course, the student will be able to

- Apply the concepts and applications of UV, IR, Fluorimetry, Flame and AAS.
- Interpret the basics and applications of NMR.
- 3. Outline the theory, principle, instrumentation and illustrate the applications of Mass spectroscopy.
- 4. Acquire theory, principle, instrumentation and applications of chromatography and electrophoresis.
- Apply the theory, principle, instrumentation and applications of X-ray crystallography, Potentiometry, thermal techniques and Immunological assays.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High) **CO-PO Mapping** PO₃ **PO4 PO5 PO6** PO₁ PO₂ CO₁ 3 2 2 CO₂ 3 1 2 1 2 **CO3** 3 2 2 1 2 **CO4** 3 2 1 **CO5** 3 2 10 hours UV-Visible, IR, Flame emission spectroscopy Unit 1

UV-Visible spectroscopy: Introduction, theory, laws, instrumentation associated with UV-Visible spectroscopy. Choice of solvents and solvent effect. Applications of UV visible spectroscopy.

IR Spectroscopy: Theory, modes of molecular vibrations, sample handling. Instrumentation of dispersive and Fourier-Transform IR spectrometer. Factors affecting vibrational frequencies. Applications of IR spectroscopy.

Spectrofluorimetry: Theory of fluorescence, factors affecting fluorescence, quenchers. Instrumentation and applications of fluorescence spectrophotometer.

Flame Emission spectroscopy and Atomic Absorption Spectroscopy: Principle, instrumentation, interferences and applications.

Unit 2 NMR Spectroscopy

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.

Mass Spectroscopy

Mass Spectroscopy: Principle, theory, instrumentation of mass spectroscopy. Different types of ionization like electron impact, chemical, field, FAB and MALDI, APPI analyzers of quadrupole and time of flight. Mass Fragmentation and its rules, meta stable ions, isotopic peaks. Applications of mass spectroscopy.

Chromatography

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

- a. Thin layer chromatography
- b. High performance Thin Layer chromatography
- c. Ion exchange chromatography
- d. Column chromatography
- Gas chromatography
- High performance liquid chromatography
- Ultra High performance liquid chromatography



- h. Affinity chromatography
- Gel chromatography

Unit 5 Electrophoresis, X-ray Crystallography

10 hours

- a. Electrophoresis: Principle, instrumentation, working conditions, factors affecting separation and applications of the following:
- a) Paper electrophoresis
- b) Gel electrophoresis
- c) Capillary electrophoresis
- d) Zone electrophoresis
- e) Moving boundary electrophoresis
- f) Isoelectric focusing.
- B. X-ray Crystallography: Production of X-rays, different X-ray diffraction methods, Bragg's law, rotating crystal technique. X-ray powder technique, types of crystals and applications of X-ray diffraction.

Potentiometry, Thermal techniques 10 hours

- a. Potentiometry: Principle, working, Ion selective electrodes and application of potentiometry.
- 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.

Total Lecture Hours 60 hours

Textbook:

- Spectrometric Identification of Organic Compounds by Robert M Silverstein, Sixth Edition, John Wiley & Sons, 2004.
- Principles of Instrumental Analysis by Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
- 3. Instrumental Methods of Analysis by Willards, 7th edition, CBS publishers.
- Practical Pharmaceutical Chemistry by Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
- Organic Spectroscopy by William Kemp, 3rd Edition, ELBS, 1991.
- A Text Book of Pharmaceutical Chemistry by Chatten L.G., Vol. I & II, Marcel Dekker, New York.

- Quantitative Analysis of Drugs in Pharmaceutical Formulation by P.D. Sethi, 3rd Edition, CBS Publishers New Delhi,
- 2. Pharmaceutical Analysis Modern Methods- Part B by J. W. Munson, Volume 11, Marcel Dekker Series.
- 3. Introduction to Spectroscopy by Pavia D.L., Lampman G.M., and Kriz G.S., 3rd Edition, Harcourt College Publishers, Philadelphia.

| Mode of | Mode of Evaluation | | | | | | | | | |
|---------|--------------------|-----|-------|---|-----|----------|--|--|--|--|
| MSE | | | CA | | ESE | Total | | | | |
| MSE1 | MSE2 | CA1 | CA2 | | | | | | | |
| 60 | 60 | 2 | (ATT) | | | | | | | |
| | | | 8 | | | | | | | |
| Conver | Converted to 15 | | 10 | • | 75 | 100 | | | | |
| | | | | | | <u> </u> | | | | |



| Course Code: MPL102T | Course Name: Advanced Pharmacology-I | L | T | P | C |
|--|--------------------------------------|---|---|---|---|
| Course Offered in: KIET School of Pharmacy | | | | | 4 |

Course Objectives: Upon completion of the course, students shall be able to understand-

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

Course Outcome: After completion of the course, the student will be able to

- 1. Understand the basics of pharmacokinetics and pharmacodynamics.
- 2. Illustrate the pharmacology of drugs acting on peripheral nervous system.
- 3. Analyze the pharmacology of drugs acting on central nervous system Psychopharmacological disorders.
- 4. Explore the pharmacology of drugs used for management of cardiovascular disorders.
- 5. Evaluate the pharmacological and physiological roles of autacoids and drugs acting on their receptors.

| CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High) | | | | | | | | | | | |
|--|-----|-----|-----|-----|-----|-----|--|--|--|--|--|
| CO-PO Mapping | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | | | | | |
| CO1 | 1 | - | 3 | 2 | - | - | | | | | |
| CO2 | 1 | - | 3 | 3 | - | - | | | | | |
| CO3 | 1 | - | 3 | 3 | - | - | | | | | |
| CO4 | 1 | - | 3 | 3 | - | - | | | | | |
| CO5 | 1 | - | 3 | 3 | - | - | | | | | |
| Unit 1 General Pharmacology 1 | | | | | | | | | | | |

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

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

Unit 2 Neurotransmission & Systemic Pharmacology 12 hours

Neurotransmission

- a. General aspects and steps involved in neurotransmission.
- b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters-Adrenaline and Acetyl choline).
- c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).
- d. Non-adrenergic non-cholinergic transmission (NANC). Cotransmission.

Systemic Pharmacology: A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systemsAutonomic Pharmacology Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction.

Unit 3 12 hours

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

Unit 4 | 12 hours

Diuretics, antihypertensives, antiischemics, antiarrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet Drugs

Unit 5 12 hours

The physiological and pathological role of histamine, serotonin, kinins prostaglandins opioid autocoids. Pharmacology of antihistamines, 5HT antagonists

Total Lecture Hours 60 hours

Textbook:

- 1. Goodman and Gilman, The Pharmacological Basis of Therapeutics by Hardman J.G., Le L., Molinoss P.B., Ruddon R.W. and Gil A.G., Pergamon Press, Oxford.
- 2. Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy by Golan D.E., Armstrong E.J., Armstrong A.W., Wolters Kluwer, Alphen aan den Rijn.
- 3. Basic and Clinical Pharmacology by Katzung, B.G. Prentice Hall International, New Delhi.



- 4. Pharmacology by Rang M.P., Dale MM, Riter J.M, Churchill Livingstone, London
- Biopharmaceutics & Clinical Pharmacokinetics by Gibaldi, M., Pharma Book Syndicate, Hyderabad

- 1. Clinical Pharmacy and Therapeutics by Herfindal E.T. and Hirashman J.L., Lippincott Williams and Wilkins, Philadelphia.
- 2. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists by Kwon Y., Springer, New York.
- 3. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
- 4. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
- 5.Oxford Textbook of Clinical Pharmacology by Graham Smith Dipiro Pharmacology, Pathophysiological Approach

| Mode of Evaluation | | | | | | | | | | |
|--------------------|------|-----|-----------|-----|-------|--|--|--|--|--|
| M | SE | | CA | ESE | Total | | | | | |
| MSE1 | MSE2 | CA1 | CA2 (ATT) | | | | | | | |
| 60 | 60 | 2 | 8 | | | | | | | |
| Converted to 15 | | | 10 | 75 | 100 | | | | | |
| | | | | | | | | | | |



| Course Code: MPL103T | Course Name: Pharmacological and Toxicological Screening Methods-I | L | T | P | С |
|-------------------------------------|--|---|---|---|---|
| Course Offered in: KIET School of P | 4 | 0 | 0 | 4 | |

Course Objectives: Upon completion of the course, students shall be able to understand-

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

Course Outcome: After completion of the course, the student will be able to

- 1. Understand the regulations and ethical requirements for the usage of experimental animals and good laboratory practices in maintenance and handling of experimental animals
- Examine the screening methods for the drugs used in treatment of CNS disorders
- 3. Apply the Preclinical screening of new substances for the pharmacological activity for drugs acting on respiratory system, gastrointestinal system
- 4. Evaluate the Preclinical screening of new substances for the pharmacological activity on cardiovascular system, diabetes, cancer and liver
- 5. Analyze the screening methods for drugs affecting immune system and to correlate the preclinical data to humans.

| CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High) | | | | | | | | | | | |
|--|---------|-------------|-----|-----|-----|-----|----------|--|--|--|--|
| CO-PO Mapping | | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | | | | |
| CO1 | | 3 | 1 | 2 | - | 3 | 1 | | | | |
| CO2 | | 2 | - | 2 | 1 | 3 | 1 | | | | |
| CO3 | | 2 | - | 2 | 1 | 3 | 1 | | | | |
| CO4 | | 2 | - | 2 | 1 | 3 | 1 | | | | |
| CO5 | | 2 | - | 2 | 1 | 3 | 1 | | | | |
| Unit 1 | Laborat | ory Animals | • | | | | 12 hours | | | | |

Laboratory Animals:

Common laboratory animals: Description, handling and applications of different species and strains of animals.

Transgenic animals: Production, maintenance and applications. Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals. Good laboratory practices. Bioassay: Principle, scope and limitations and methods.

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

| | , | | | | 88 | | | |
|--------|-------------|-------------|--------|------|--------------|-------------|----------------|----------|
| Unit 3 | Preclinical | screening | of | new | substances | affecting | Respiratory | 12 hours |
| | Pharmacolo | gy, Reprodu | ıctive | Phar | macology aci | idosis & ga | strointestinal | |
| | drugs | | | | | | | |

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 anti-fertility agents. Analgesics, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: anti-ulcer, anti-emetic, anti-diarrheal and laxatives

| Unit 4 | Preclinical screening of new substances affecting Cardiovascular system, | 12 hours |
|--------|--|----------|
| | drugs for metabolic disorders and Cancer | |

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

| Unit 5 | Preclinical screening of immunomodulators, Immunoassay, Extrapolation 12 hours | |
|-----------------------------|---|---|
| Preclinical screening of ne | w substances for the pharmacological activity using in vivo, in vitro, and other possible anima | 1 |
| alternative models. Iimmur | nomodulators, 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.

Total Lecture Hours 60 hours

Textbook:

- 1. Screening Methods in Pharmacology by Turner R.A., Hebborn P., Academic Press, Cambridge.
- 2. Evaluation of drugs activities by Laurence D.R., Bacharach A.L., Academic Press, Cambridge.
- 3. Methods in Pharmacology by Arnold S., Springer, New York
- 4. Fundamentals of Experimental Pharmacology by Ghosh M.N. Scientific Book Agency, Calcutta
- 5. Practicals in Pharmacology by Goyal R.K., B.S. Shah Prakashan, Ahmadabad.
- 6. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

- 1. Pharmacological Experiment on Intact Preparations by Mcleod, L.J., Churchill Livingstone, London.
- 2. Drug discovery and Evaluation by Vogel H.G., Springer-Verlag, Heidelberg.
- 3. Preclinical Evaluation of New Drugs by Gupta S.K., Jaypee Brothers Medical Publishers Private Limited, New Delhi.
- 4. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
- 5. Handbook of Experimental Pharmacology, S.K.Kulkarni
- 6. Screening Methods in Pharmacology, Robert A. Turner

| Mode of Evaluation |
|--------------------|
|--------------------|

| MSE | CA | | E Total |
|-----------------|-----------|--|---------|
| MSE1 MSE2 CA1 | CA2 (ATT) | | |
| 60 60 2 | 8 | | |
| Converted to 15 | 10 | | 100 |



| Course Code: MPL104T Course Name: Cellular and Molecular Pharmacology | | | | P | C |
|---|--|--|---|---|---|
| Course Offered in: KIET School of Pharmacy | | | 0 | 0 | 4 |

Course Objectives: Upon completion of the course, students shall be able to understand-

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

Course Outcome: After completion of the course, the student will be able to

- 1. Review the fundamental knowledge of the structure, and functions of cellular components and their interaction of these components with drugs.
- Analyze the receptor signal transduction processes and molecular pathways affected by drugs.
- 3. Explore the concept and applications of molecular biology techniques and biomarkers in the drug discovery process.
- 4. Apply the concepts and applications of pharmacogenomics and immunotherapeutics in drug discovery and development.
- 5. Demonstrate the cell culture techniques as applicable to molecular pharmacology.

| CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High) | | | | | | | | | | |
|--|-----------------------|------|-----|-----|-----|----------|--|--|--|--|
| CO-PO Mapping | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | | | | |
| CO1 | - | - | 2 | - | - | - | | | | |
| CO2 | - | - | 2 | 1 | - | - | | | | |
| CO3 | 2 | 2 | 2 | 2 | 2 | 1 | | | | |
| CO4 | 2 | 2 | 2 | 2 | 2 | 1 | | | | |
| CO5 | 2 | 2 | 2 | 2 | 2 | 1 | | | | |
| Unit 1 | Cell Biology, Cell de | eath | | | | 12 hours | | | | |

Cell Biology: Structure and functions of cell and its organelles Genome organization.

Gene expression and its regulation, importance of siRNA and microRNA, gene mapping and gene sequencing.

Cell cycles and its regulation.

Cell death—events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

Unit 2 12 hours **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

Principles and applications of genomic and proteomic tools

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 **Pharmacogenomics** 12 hours

Pharmacogenomics: Gene mapping and cloning of disease gene.

Genetic variation and its role in health/pharmacology.

Polymorphisms affecting drug metabolism.

Genetic variation in drug transporters.

Genetic variation in G protein coupled receptors.

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics.

Immunotherapeutics.

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Unit 5 Cell Culture Techniques, Biosimilars 12 hours

Cell Culture Techniques:

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.

Biosimilars

Total Lecture Hours 60 hours

Textbook:

- 1. The Cell, A Molecular Approach. Geoffrey M Cooper, Sinauer Publisher, USA.
- Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong, Wiley-VCH, Weinheim.
- Handbook of Cell Signaling by Bradshaw R.A., Denis E.A., Academic Press, Cambridge (Second Edition) Edited by Ralph A. et.al.
- 4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al., Wiley, Colorado.

Reference Books:

- 1. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller, Springer, New York.
- Basic Cell Culture (Practical Approach) by J. M. Davis (Editor), Oxford University Press, Oxford
- Animal Cell Culture: A Practical Approach by John R. Masters (Editor), Oxford University Press, Oxford.
- Current protocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et al., Wiley, New Jersey.

Mode of Evaluation

| MSE1 MSE2 CA1 CA2 (ATT) 60 60 2 8 | M | SE | CA | | | ESE | Total |
|-----------------------------------|--------|-----------|-----|-----------|----|-----|-------|
| | MSE1 | MSE2 | CA1 | CA2 (ATT) | | | |
| Converted to 15 10 75 100 | 60 | 60 | 2 | 8 | | | |
| | Conver | ted to 15 | 10 | | 75 | 100 | |



| Course Code: MPL105P | Course Name: Experimental Pharmacology I (Practical) | L | T | P | C |
|--|--|---|---|----|---|
| Course Offered in: KIET School of Pharmacy | | | 0 | 12 | 6 |

Course Objectives: This course aims to:

- Apply fundamental knowledge of the route of administration, blood collection, anesthesia, and euthanasia in experimental animals.
- Apply experiments for the screening of standard/test drugs for CNS activity.
- Evaluate screening of gastroprotective agents, oral glucose tolerance test for antidiabetic drugs.
- Apply pharmacokinetic studies and data analysis of biological samples by using UV and HPLC methods.

Course Outcome: After completion of the course, the student will be able to

- Perform quantitative analysis of drugs and formulations using advanced analytical techniques such as UV-Vis spectrophotometry, fluorimetry, flame photometry, HPLC, and GC.
- Demonstrate proficiency in animal handling techniques, drug administration routes, and in-vivo pharmacological evaluations including CNS, analgesic, anti-inflammatory, and antiulcer activities.
- Isolate, quantify, and analyze biomolecules such as DNA, RNA, and proteins using techniques like PCR, Western blotting, UV spectroscopy, and enzyme assays.
- Assess cellular and molecular effects of drugs through in-vitro assays, including cell viability, DNA damage (Comet assay), DNA fragmentation, and apoptosis studies.
- Conduct pharmacokinetic studies and analyze drug concentrations in biological fluids using analytical extraction techniques and software-based data analysis.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

| CO-PO Mapping | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 |
|------------------|-----|-----|-----|-----|-----|-----|
| CO1 | 3 | 1 | 3 | 2 | 1 | 2 |
| CO2 | 1 | 1 | 1 | - | 2 | 1 |
| CO3 | 2 | 1 | 2 | 2 | 1 | 1 |
| CO4 | 2 | 1 | 2 | 1 | 2 | 1 |
| CO5 | 2 | 1 | 2 | 1 | 2 | 1 |

List of Experiments (Indicative & not limited to) (MPL105P)

- Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
- Simultaneous estimation of multi component containing formulations by UV spectrophotometry 2.
- 3. Experiments based on HPLC
- 4. Experiments based on Gas Chromatography
- Estimation of riboflavin/quinine sulphate by fluorimetry 5.
- Estimation of sodium/potassium by flame photometry

Handling of laboratory animals

- Various routes of drug administration.
- Techniques of blood sampling, anesthesia and euthanasia of experimental animals. 2..
- 3. Functional observation battery tests (modified Irwin test)
- Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
- Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
- Evaluation of diuretic activity.
- Evaluation of antiulcer activity by pylorus ligation method.
- Oral glucose tolerance test.
- Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
- 10. Isolation of RNA from yeast
- 11. Estimation of proteins by Braford/Lowry's in biological samples.
- 12. Estimation of RNA/DNA by UV Spectroscopy



- 13. Gene amplification by PCR.
- 14. Protein quantification Western Blotting.
- 15. Enzyme based in-vitro assays (MPO, ĂChEs, α amylase, α glucosidase).
- 16. Cell viability assays (MTT/Trypan blue/SRB).
- 17. DNA fragmentation assay by agarose gel electrophoresis.
- 18. DNA damage study by Comet assay.
- 19. Apoptosis determination by fluorescent imaging studies.
- 20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
- 21. Enzyme inhibition and induction activity
- 22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
- 23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC).

| | 12 hrs./week | | | | | | |
|----------------|--------------|-----|-----------|--------------------|-----|-------|--|
| Mode of Evalua | ation | | | | | | |
| MSE | | CA | | | ESE | Total | |
| MSE1 30 | MSE2 30 | CA1 | CA2 10 | CA3 (ATT) 10 | | | |
| Avg. of MSE1 | 20 | | | 100 | 150 | | |



| Course Code: MPL1 305 | Course Name: Soft Skills | L | T | P | C |
|-----------------------------|--------------------------|---|---|----|---|
| Course Offered in: KIET Sch | 1 | 0 | 0 | NC | |

Course Objectives: This course aims to:

- Enhance communication, interpersonal, and professional skills essential for effective collaboration in healthcare and research environments.
- It also focuses on developing leadership, time management, and problem-solving abilities to prepare students for diverse roles in the pharmaceutical industry and academia.

Course Outcome: After completion of the course, the student will be able to

- Express themselves well in professional contexts.
- Enhance their employability quotient.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

| CO-PO Mapping | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 |
|------------------|-----|-----|-----|-----|-----|-----|
| CO1 | | 2 | | | 3 | 3 |
| CO2 | | 2 | | | 3 | 3 |

| CO2 | CO2 2 | | 3 | | 3 |
|--------|--|--|--|---------------|--------------|
| S. No. | Topic Covered | Suggested Activity | Objective of Ac | etivity | No. of Hours |
| 1 | The ABCDP of Soft Skills | The ABCDP of Soft Skills Tagging themselves with an apt adjective | | areness | 1 |
| 2 | Creating a Professional Introduction using F-B analysis | Writing & narration of the professional introduction | Introduce themselves contexts | s in formal | 1 |
| 3 | 4Ts of GD | GD Sessions | Awareness & Group | Dynamics | 2 |
| 4 | Case-based GDs Team presentations on VUCA, BANI, RUPT, TUNA | | Coping with change by cognitive flexibility thinking & problem | (critical | 2 |
| 5 | Formal Writing | Paragraph writing on topics related to the healthcare/pharma sector | To enhance creativity and written expression abilities | | 1 |
| 6 | Image Building | Resume - Traditional & ATS, LinkedIn Profile, E-portfolio | Networking and person | nal branding | 1 |
| 7 | 4Ts of Interview | Mock Interview | Preparing for recruitme | nt interviews | 4 |
| 8 | Public Speaking | JAM/Extempore | To enhance - Commu Confidence | | 1 |
| 9 | Presentation Skills | Individual presentations on topics related to the healthcare/pharma sector | To enhance - Content, communication, & confidence | | 2 |
| | | Total number of hours | | | 15 |

Note: As per the number of weeks available during this semester - common to all three specializations - QA, Pharmacology, and Pharmaceutics

Course Outcomes: The students will be able to -

1) express themselves well in professional contexts 2) enhance their employability quotient

Assessment/Evaluation Methodology: MSE (10 marks) - based on formal introduction; ESE (40 marks) - 20 marks for the interview, 10 marks for the Resume and 10 marks for the presentation.



| Course Code: MPL201T | Course Name: Advanced Pharmacology-II | L | T | P | C |
|--|---------------------------------------|---|---|---|---|
| Course Offered in: KIET School of Pharmacy | | 4 | 0 | 0 | 4 |

Course Objectives: Upon completion of the course, students shall be able to understand-

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

Course Outcome: After completion of the course, the student will be able to

- Elaborate the molecular and cellular mechanisms of hormone action, pharmacological interventions in endocrine disorders, including diabetes and thyroid dysfunction.
- 2. Explore strategic approaches to overcome antimicrobial resistance by applying the cellular and molecular mechanisms of action of antimicrobial agents.
- 3. Analyze evidence-based therapeutic regimens for protozoal and helminthic infections, cancer chemotherapy, and immunomodulation by integrating knowledge of immunopharmacology and inflammatory mediators.
- Evaluate chronopharmacological principles with disease pathophysiology to optimize treatment strategies for conditions like cardiovascular diseases, diabetes, asthma, and peptic ulcers.
- Blueprint the novel antioxidant-based therapeutic approaches through free radical generation, oxidative stress-related pathologies, and recent advancements in treating neurodegenerative disorders and cancer.

| CO-PO Mapping (Scale 1: Low, 2: Medium, | 3: High) | | | | | CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High) | | | | | | | | | |
|---|----------|-----|-----|-----|-----|--|--|--|--|--|--|--|--|--|--|
| CO-PO Mapping | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | | | | | | | | | |
| CO1 | 1 | 1 | 1 | 2 | 2 | - | | | | | | | | | |
| CO2 | 1 | 1 | 1 | 2 | 2 | - | | | | | | | | | |
| CO3 | 1 | 1 | 1 | 2 | 2 | - | | | | | | | | | |
| CO4 | 1 | 1 | 1 | 2 | 2 | - | | | | | | | | | |
| CO5 | 1 | 1 | 1 | 2 | 2 | - | | | | | | | | | |

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

Unit 2 Chemotherapy 12 hours

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

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 immunostimulant

GIT Pharmacology Unit 4 12 hours

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

Unit 5 Free Radicals Pharmacology, Recent Advances in Treatment 12 hours

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

Alzheimer's disease, Parkinson's disease, Cancer, Diabetes Mellitus.

Total Lecture Hours 60 hours

Textbook:

- Goodman and Gilman, The Pharmacological Basis of Therapeutics by Hardman J.G., Le L., Molinoss P.B., Ruddon R.W. and Gil A.G., Pergamon Press, Oxford.
- Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy by Golan D.E., Armstrong E.J., Armstrong A.W., Wolters Kluwer, Alphen aan den Rijn.
- Basic and Clinical Pharmacology by Katzung, B.G. Prentice Hall International, New Delhi.



- Pharmacology by Rang M.P., Dale MM, Riter J.M, Churchill Livingstone, London
- Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
- Text book of Therapeutics, Drug and Disease Management by E T. Herfindal and Gourley, Williams and Wilkins, Philadelphia
- Essentials of Medical Pharmacology, K.D. Tripathi.

- Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu
- 2. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
- 3. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
- 4. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

| Mode of E | valuation | | | | | | |
|-----------|--------------------|-----|-----------|----|-----|-------|--|
| MSE | | CA | | | ESE | Total | |
| MSE1 | MSE2 | CA1 | CA2 (ATT) | | | | |
| 60 | 60 | 2 | 8 | | | | |
| Conve | Converted to 15 10 | | - | 75 | 100 | | |
| | | | | | | • | |



| Course Code: MPL202T | Course Name: Pharmacological and Toxicological Screening Methods-II | L | T | P | C |
|-------------------------------------|---|---|---|---|---|
| Course Offered in: KIET School of P | 4 | 0 | 0 | 4 | |

Course Objectives: Upon completion of the course, students shall be able to understand-

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

Course Outcome: After completion of the course, the student will be able to

- 1. Apply the basics and regulatory guidelines for conducting toxicity studies.
- 2. Illustrate OECD Guidelines for Acute, sub-acute and chronic- oral, dermal and inhalational studies.
- 3. Examine the concepts of reproductive toxicity and genotoxicity.
- 4. Explore the IND enabling studies and safety pharmacological studies.
- 5. Evaluate the toxicokinetic assessments in various studies and alternatives to animal testing.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

| CO-PO Mapping | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | |
|---------------|-----|-----|-----|-----|-----|-----|--|
| CO1 | 3 | - | 1 | - | 3 | - | |
| CO2 | 3 | - | 1 | - | 3 | - | |
| CO3 | 3 | - | 1 | - | 3 | - | |
| CO4 | 3 | - | 1 | 1 | 3 | - | |
| CO5 | 3 | - | 1 | 1 | 3 | - | |
| | | | | | | | |

Unit 1 Basic definition and types of toxicology 12 hours

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive), Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y, OECD principles of Good laboratory practice (GLP).

History, concept and its importance in drug development

Unit 2 Acute, sub-acute and chronic studies 12 hours

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.

Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.

Test item characterization- importance and methods in regulatory toxicology studies

Reproductive toxicology studies, Genotoxicity studies

12 hours

12 hours

12 hours

Reproductive toxicology studies, male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II)

Genotoxicity studies (Ames test, in vitro and in vivo micronucleus and chromosomal aberrations studies). In vivo carcinogenicity studies.

Unit 4 IND enabling studies (IND studies & Safety Pharmacology studies

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

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

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

Unit 5 **Toxicokinetics, Alternative methods Toxicokinetics**- Toxicokinetic evaluation in preclinical studies, saturation kinetics.

Importance and applications of toxicokinetic studies.

Alternative methods to animal toxicity testing.

Total Lecture Hours 60 hours

Textbook:

- 1. Handbook on GLP, Quality practices for regulated non-clinical research and development
- 2. (http://www.who.int/tdr/publications/documents/glphandbook.pdf).
- 3. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and
- 4. family welfare (department of health) New Delhi
- 5. Drugs from discovery to approval by Rick NG.

- 1. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
- OECD test guidelines.



- Principles of toxicology by Karen E. Stine, Thomas M. Brown.
- Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and
- 5. Marketing Authorization for Pharmaceuticals. (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm07324

Mode of Evaluation

| MSE1 MSE2 CA1 CA2 (ATT) 60 60 2 8 | M | SE | CA | | | ESE | Total |
|-----------------------------------|--------|-----------|----|-----------|--|-----|-------|
| | MSE1 | MSE2 | | CA2 (ATT) | | | |
| G + 1 + 4 # 100 | 60 | 60 | 2 | 8 | | | |
| Converted to 15 10 75 100 | Conver | ted to 15 | 10 | | | 75 | 100 |



| Course Code: MPL203T | L | T | P | C | |
|-------------------------------------|---------|---|---|---|---|
| Course Offered in: KIET School of P | harmacy | 4 | 0 | 0 | 4 |

Course Objectives: Upon completion of the course, students shall be able to understand.

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

Course Outcome: After completion of the course, the student will be able to

- 1. Apply combinatorial chemistry, high-throughput screening, and in silico techniques for lead identification and optimization in drug discovery.
- 2. Examine the role of genomics, proteomics, and bioinformatics in target identification and validation to understand their impact on drug discovery.
- 3. Assess the effectiveness of rational drug design approaches, including structure-based and pharmacophore-based methods, in developing potential drug candidates.
- 4. Compare various molecular docking techniques, such as rigid, flexible, and manual docking, to determine their relevance in virtual screening.
- 5. Evaluate QSAR models and prodrug strategies to improve drug solubility, bioavailability, and targeted delivery for enhanced therapeutic efficacy.

| CO-PO Mapping (Scale 1: I | CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High) | | | | | | | | | |
|---|--|-----|-----|-----|-----|-----|--|--|--|--|
| CO-PO Mapping | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | | | | |
| CO1 | 3 | - | 1 | - | 3 | - | | | | |
| CO2 | 3 | - | 1 | - | 3 | - | | | | |
| CO3 | 3 | - | 1 | - | 3 | - | | | | |
| CO4 | 3 | - | 1 | 1 | 3 | - | | | | |
| CO5 | 3 | - | 1 | 1 | 3 | - | | | | |
| Unit 1 An Overview of Modern Drug Discovery Process 1 | | | | | | | | | | |

Target identification, target validation, lead identification and lead optimization. Economics of drug discovery. Target discovery and validation-Role of genomics, proteomics and bioinformatics. Role of nucleic acid microarrays, protein microarrays, antisense technologies, siRNAs, antisense oligonucleotides, zinc finger proteins. Role of transgenic animals in target validation.

Unit 2 Lead Identification 12 hours

Combinatorial chemistry & high throughput screening, in silico lead discovery techniques. Assay development for hit identification.

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

Unit 3 Rational Drug Design 12 hours

Traditional vs rational drug design, methods followed in traditional drug design, high throughput screening. Concepts of rational drug design.

Rational drug design methods: Structure and pharmacophore-based approaches. Virtual Screening techniques: Drug likeness screening, concept of pharmacophore mapping and pharmacophore-based screening.

Unit 4 Molecular Docking 12 hours

Rigid docking, flexible docking, and manual docking: Docking based screening. De novo drug design. Quantitative analysis of structure activity relationship: History and development of QSAR, SAR versus QSAR, physicochemical parameters, Hansch analysis, Fee-Wilson analysis and relationship between them.

Unit 5 QSAR Statistical Methods 12 hours

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.

Total Lecture Hours 60 hours

Textbook:

- 1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
- 2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation.
- 3. 2006 by Taylor and Francis Group, LLC.
- 4. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
- 5. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.

- 1. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.
- 2. Abby L. Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
- 3. J. Rick Turner. New drug development design methodology and analysis. John Wiley & Sons, Inc., New Jersey.

| Mode of | Evaluation | n | | | | | |
|---------|------------|-----|-----------|--|-----|-------|--|
| M | ISE | CA | | | ESE | Total | |
| MSE1 | MSE2 | CA1 | CA2 (ATT) | | | | |
| 60 | 60 | 2 | 8 | | | | |
| Conver | ted to 15 | 10 | | | 75 | 100 | |
| | | | | | | | |



| Course Code: MPL204T | Course Pharmaco | Name: ovigilance | Clinical | Research | and | L | Т | P | С |
|--|--------------------|---------------------|----------|----------|-----|---|---|---|---|
| Course Offered in: KIET School of Pharmacy | | | | | | | | 0 | 4 |

Course Objectives: Upon completion of the course, students shall be able to understand-

- Explain the regulatory requirements for conducting clinical trials.
- 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.

Course Outcome: After completion of the course, the student will be able to-

- 1. Elaborate the regulatory perspectives of Clinical trials.
- 2. Explore the types of Clinical Trial designs and the roles of stakeholders involved in Clinical trials.
- 3. Apply the various guidelines for preparation of regulatory documents of Clinical trials and management of adverse drug reactions.
- 4. Illustrate the establishment and scope of Pharmacovigilance in India and global with emphasis on WHO International Drug Monitoring Programme.
- 5. Analyze various ADR reporting systems and the concepts of Pharmacoepidemiology, Pharmacoeconomics and Safety Pharmacology.

| CO-PO Mapping (Scale) | CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High) | | | | | | | | | | |
|------------------------------|--|----------|-----|-----|-----|-----|-----|--|--|--|--|
| CO-PO Mapping | | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 | | | | |
| CO1 | | 1 | 1 | 2 | ı | 3 | 1 | | | | |
| CO2 | | 1 | 1 | 2 | - | 3 | 1 | | | | |
| CO3 | | 1 | 1 | 2 | - | 3 | 1 | | | | |
| CO4 | | 1 | 1 | 2 | - | 3 | 1 | | | | |
| CO5 | | 1 | 1 | 2 | 2 | 3 | 1 | | | | |
| Unit 1 | Regulato | 12 hours | | | | | | | | | |

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

Unit 2 Clinical Trials types and Responsibilities of CT personnel 12 hours

Types and design experimental study- RCT and non RCT, observation study: Cohort, case control, cross sectional clinical trial study team roles and responsibilities of clinical trial personnel: Investigator, study coordinator, sponsor, contract research organization and its management.

Unit 3 Clinical Trial Documentation 12 hours

Guidelines to the preparation of documents, preparation of protocol, investigator brochure, case report forms, clinical study report. Clinical trial monitoring: Safety monitoring in CT. Adverse drug reactions: Definition and types, detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, management of adverse drug reactions: Terminologies of ADR

Unit 4 Basic Aspects, Terminologies and Establishment of Pharmacovigilance 12 hours

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 centers in hospitals, industry and national programmes related to pharmacovigilance. Roles and responsibilities in pharmacovigilance.

Unit 5 Methods, and Tools in Pharmacovigilance 9 hours

Methods, ADR reporting and tools used in pharmacovigilance international classification of diseases, international nonproprietary names for drugs, passive and active surveillance, comparative observational studies, targeted clinical investigations and vaccine safety surveillance. Spontaneous reporting system and reporting to regulatory authorities, guidelines for ADRs reporting. Argus, Aris G pharmacovigilance, VigiFlow, statistical methods for evaluating medication safety data.



| Unit 6 Pharmacoepidemiology, Safety pharmacology | | | | | |
|--|--|----------|--|--|--|
| Pharmacoepidemiology, ph | narmacoeconomics, safety pharmacology. | | | | |
| Total Lecture Hours | | 60 hours | | | |

Textbook:

- 1. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- 2. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- 3. Handbook of Clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
- 4. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

- 1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
- 2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- 3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

| Mode of | Mode of Evaluation | | | | | | | |
|---------|--------------------|-----|-----------|-----|-----|-------|--|--|
| M | SE | CA | | | ESE | Total | | |
| MSE1 | MSE2 | CA1 | CA2 (ATT) | | | | | |
| 60 | 60 | 2 | 8 | | | | | |
| Conver | onverted to 15 10 | | 75 | 100 | | | | |
| | | | | | | | | |



| Course Code: MPL205P | Course Name: Experimental Pharmacology II (Practical) | L | T | P | C |
|----------------------------|---|---|----|---|---|
| Course Offered in: KIET Sc | 0 | 0 | 12 | 6 | |

Course Objectives: This course aims to:

- Apply fundamental knowledge of the bioassay of various agonists and antagonists using isolated tissues preparation.
- Apply *in-silico* experiments
- Evaluate *in vivo* experiments viz. toxicity studies as per OECD guidelines and recording of BP, heart rate and ECG.

Course Outcome: After completion of the course, the student will be able to-

- 1. Demonstrate proficiency in recording dose-response curves (DRC) and conducting various bioassay methods (matching, interpolation, bracketing, multiple-point) using isolated tissue preparations.
- 2. Evaluate the effects of agonists, antagonists, and potentiating agents on isolated tissues and determine PA₂ values, along with the impact of drugs on isolated heart preparations and cardiovascular parameters (BP, ECG).
- 3. Perform drug absorption studies, and conduct acute and repeated dose toxicity studies in compliance with OECD guidelines, including biochemical, hematological, and histopathological evaluations.
- 4. Apply in-silico techniques such as molecular docking, pharmacophore screening, and QSAR studies to explore drug-receptor interactions and support drug discovery research.
- 5. Design clinical trial protocols, prepare ADR monitoring and reporting systems.

CO-PO Mapping (Scale 1: Low, 2: Medium, 3: High)

| CO-PO Mapping | PO1 | PO2 | PO3 | PO4 | PO5 | PO6 |
|------------------|-----|-----|-----|-----|-----|-----|
| CO1 | 3 | 2 | 3 | 2 | 1 | 1 |
| CO2 | 3 | 2 | 3 | 2 | 1 | 1 |
| CO3 | 2 | 3 | 3 | 2 | 3 | 1 |
| CO4 | 3 | 2 | 3 | 2 | 1 | 1 |
| CO5 | 3 | 2 | 3 | 2 | 2 | 1 |

List of Experiments (Indicative & not limited to)

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

Total Lecture Hours: 12 hrs./week



| Mode of Evaluation | | | | | | | |
|-----------------------------------|------------|-----|-----------|--------------------|-------|--|--|
| MSE | | CA | | ESE | Total | | |
| MSE1 30 | MSE2 30 | CA1 | CA2 10 | CA3 (ATT) 10 | | | |
| Avg. of MSE1 & MSE2 and converted | | | | 100 | 150 | | |
| to 30 | | | 20 | | | | |

Annexure-1

Course Evaluation Structure

The evaluation of the M. Pharm Pharmacology course consists of both theory and lab assessments. The assessments are divided into multiple components as outlined below.

Theory Evaluation Plan

1.Continuous Assessment (CA) of MPL101T, MPL102T, MPL103T, MPL104T, MPL201T, MPL202T, MPL203T, MPL204T - Total Marks: 10

- CA-1: 2 Marks (Based on Assignment/Quiz/Class test/Presentation/GD/Seminar)
- CA-2: 8 Marks (Based on attendance)

2.Mid-Semester and End-Semester Evaluations of MPL101T, MPL102T, MPL103T, MPL104T, MPL201T, MPL202T, MPL203T, MPL204T - Total Marks: 25 Internal, 75 External

- MSE-1: 60 Marks
- MSE-2: 60 Marks Average of MSE and converted to 15 marks
- CA: 10 Marks (Based on continuous assessment)
- ESE: 75 Marks (externally evaluated)

Practical Evaluation Plan

1. Continuous Assessment (CA) of MPL105P & MPL205P - Total Marks: 20

- CA-1: NA
- CA-2: 10 Marks (Regular lab activities, Quiz, Viva and Lab work)
- CA-3: 10 Marks (Based on attendance)

2. Internal and External Marks Distribution of MPL105P & MPL205P: 50 + 100 = 150 Marks

- MSE-1: 30 Marks
- MSE-2: 30 Marks Average of MSE1 and MSE2 30 marks
- CA: 20 Marks
- External: 100 Marks (Practical ESE)

