Learning Outcome-based Curriculum Framework for M. Pharm (Pharmacology)

[NEP-2020]

Department of Pharmaceutical Sciences

CENTRAL UNIVERSITY OF HARYANA

Jant-Pali, Mahendergarh, Haryana-123031, India

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1. Background

1.1. Introduction to Department of Pharmaceutical Sciences

The Department of Pharmaceutical Sciences was established in 2020 as a flagship department of Central University of Haryana to provide quality education and training to pharmacy graduates to become highly skilled and caring healthcare professionals and create new knowledge through excellence in basic and translational pharmaceutical research. The department is currently offering **M. Pharm. (Pharmacology)** course for Pharmacy graduates duly approved by Pharmacy Council of India (PCI), New Delhi. The department has engaged experienced, vibrant and well-qualified faculties involved in both teaching and research work. The faculty members have published a substantial number of research papers in journals of national and International repute.

The department is focussed to train the students/scholars in emerging fields of pharmacy catering to pharmaceutical industry and R&D. We have a vision to train and nurture the students towards fundamental & advanced research in pharmacy leading to technological innovation and entrepreneurship. Having collaborations with prominent national and international institutions in future, the department aims to carry out collaborative research in thrust areas of health and medicines.

The department also plans to initiate the research in the field of Natural products in future with focus to identify novel targets and explore their pharmacological benefits in the treatment of various ailments/disorders. The Department of Pharmaceutical Sciences aims at identifying and characterising both new biologically active natural products and their semisynthetic derivatives and at understanding their interactions with human targets on a molecular level using in silico, in vitro, and in vivo models. Based on this knowledge, new lead compounds and disease-relevant targets will be investigated and novel delivery systems for pharmaceutical active ingredients will be developed. Main areas of research include:

a) Ethnopharmacology of Indigenous medicinal plants
b) Development of Nanoformulations of selected Natural Products and their evaluation
c) Standardization and characterization of Ayurvedic/Homeopathic/Unani herbal formulations
d) Neuropharmacology
e) Pharmacovigilance

M. Pharm. (Pharmacology) provides unprecedented opportunities in Pharmaceutical industries focussed on preclinical and clinical research & development, regulatory aspects, Medical writing, and Intellectual property rights (IPR).

1.2.Vision of the Department

- To contribute in the innovation and leadership of healthcare system through superior dissemination of Pharmaceutical knowledge.

1.3.Mission of the Department

- To nurture the young minds towards fundamental & advanced Pharmaceutical research that contribute to the technological innovation and entrepreneurship.
- To provide an integrated and rigorous coursework to fulfill the needs of Pharmaceutical industry and society.
- To create a center of excellence by building collaborations with industry and research institutions.

2. Program Educational Objectives (PEOs)

- **PEO-1:** The Postgraduate students will have a comprehensive knowledge of designing, conducting, analysis, reporting and documentation of the preclinical and clinical research.
- **PEO-2:** The Postgraduate students will integrate basic Pharmacology knowledge and skills with healthcare requirements of the society.
- **PEO-3:** The Postgraduate students will become competent by applying their technical, and leadership skills in pharmaceutical research.

3. Program Outcomes

PO-1: Basic and applied knowledge: Interdisciplinary knowledge to find solution for the complex biological problems

PO-2: Problem analysis: Ability to analyse society related/ applied research problem, design and execute experiments to find relevant solutions

PO-3: Advanced Usage of Technology: Apply advanced instrumentation tools, online resources with an understanding of the troubleshooting and limitations

PO-4: Ethics: Commitment towards professional ethics and responsibilities as a social endeavour to bring harmony with nature

PO-5: Lifelong learning: Scientific skills for industrial applications and entrepreneurship

4. Programme Specific Outcomes (PSOs)

- **PSO-1:** To provide the efficient knowledge of fundamental concepts of Pharmacology.
- **PSO-2:** Analysis and problem solving capability in the field of pharmaceutical sciences.
- **PSO-3:** To develop the professional skills in the area of pharmacological sciences to meet global demand and look for opportunities in Pharmaceutical industries.
- **PSO-4:** To give exposure of latest tools and techniques utilized in preclinical and clinical pharmacology
- **PSO-5:** To give an immersive professional experience to adapt in a globe of constantly developing trend.
- **PSO-6:** To inculcate professional ethics, communication skills, and leadership skills.
- **PSO-7:** To develop students' ability to provide advice on the utilization of medicines and the promotion of drug safety.

5. Postgraduate Attributes

- Pharmacy Knowledge
- Problem analysis
- Design and conduct the investigations of complex problems
- Modern tool usage
- Pharmacist and Society
- Leadership skills
- Communication skills
- Environment and sustainability
- Life-long learning
- Research ethics

6. Structure of Course (M. Pharm. Pharmacology)

Semester-I							
Core Course	**Course Code**	**Course**	**Credit Points**	**L**	**T**	**P**	**S**
1	MPL 101T	Modern Pharmaceutical Analytical Techniques	4	4	0	0	0
2	MPL 102T	Advanced Pharmacology-I	4	4	0	0	0
3	MPL 103T	Pharmacological and Toxicological Screening Methods-I	4	4	0	0	0
4	MPL 104T	Cellular and Molecular Pharmacology	4	4	0	0	0
5	MPL 105P	Pharmacology Practical-I	6	0	0	12	0
6	MPL 106S	Seminar/Assignment	4	0	0	0	7

Semester-II

Core Course	**Course Code**	**Course**	**Credit Points**	**L**	**T**	**P**	**S**
7	MPL 201T	Advanced Pharmacology II	4	4	0	0	0
8	MPL 202T	Pharmacological and Toxicological Screening Methods-II	4	4	0	0	0
9	MPL 203T	Principles of Drug Discovery	4	4	0	0	0
10	MPL 204T	Clinical Research and Pharmacovigilance	4	4	0	0	0
11	MPL 205P	Pharmacology Practical II	6	0	0	12	0
12	MPL 206S	Seminar/Assignment	4	0	0	0	7

Semester-III				
Core Course	**Course Code**	**Course**	**Credit Hours**	**Credit Points**
13	MPL 301T	Research Methodology and Biostatistics	4	4
14	MPL 302	Journal club	1	1
15	MPL 303	Discussion / Presentation (Proposal Presentation)	2	2
16	MPL 304	Research Work	28	14

Semester-IV

Core Course	Course Code	Course	Credit Hours	Credit Points
17	MPL 401	Journal club	1	1
18	MPL 402	Research Work	31	16
19	MPL 403	Discussion/Final Presentation	3	3

7. Learning Outcome Index (Core Courses)

PSO	PSO-1	PSO-2	PSO-3	PSO-4	PSO-5	PSO-6	PSO-7
CC-1		✓	✓	✓	✓		
CC-2	✓	✓	✓		✓	✓	✓
CC-3	✓	✓	✓	✓	✓	✓	✓
CC-4	✓	✓	✓	✓	✓		✓
CC-5	✓	✓	✓	✓	✓	✓	
CC-6	✓				✓	✓	
CC-7	✓	✓	✓		✓	✓	✓
CC-8	✓	✓	✓	✓	✓		✓
CC-9		✓	✓	✓	✓		✓
CC-10		✓	✓	✓	✓	✓	✓
CC-11	✓	✓	✓	✓	✓	✓	
CC-12	✓				✓	✓	
CC-13		✓	✓	✓	✓		
CC-14		✓		✓	✓	✓	✓
CC-15		✓	✓		✓	✓	✓
CC-16		✓	✓	✓	✓	✓	✓
CC-17		✓		✓	✓	✓	✓
CC-18		✓	✓	✓	✓	✓	✓
CC-19		✓	✓		✓	✓	✓

8. Semester wise credits distribution

Semester	Credit Points
M. Pharm.-I	26
M. Pharm.-II	26
M. Pharm.-III	21
M. Pharm.-IV	20
Co-curricular Activities ▪ Attending Conference [01 credit], ▪ Scientific Presentations & other Scholarly Activities [01 credit]	02
Total Credit Points =	**95**

9. Course-level Learning Outcomes

9.1.Core Courses

Core Course-1: Modern Pharmaceutical Analytical Techniques (MPL 101T)

Subject name and code	Modern Pharmaceutical Analytical Techniques (MPL 101T)
Scope	This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.
Learning outcomes	After completion of course, the student is able to know about ✓ Chemicals, drugs and Excipients ✓ The analysis of various drugs in single and combination dosage forms ✓Theoretical and practical skills of the instruments
Unit-1	UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
Unit-2	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.
Unit-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.

Unit-4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: i. Thin Layer chromatography ii. High Performance Thin Layer Chromatography iii. Ion exchange chromatography iv. Column chromatography v. Gas chromatography vi. High Performance Liquid chromatography vii. Ultra High Performance Liquid chromatography viii. Affinity chromatography ix. Gel Chromatography
Unit-5	Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.
Unit-6	Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

Core Course-2: Advanced Pharmacology - I (MPL 102T)

Subject name and code	Advanced Pharmacology - I (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
Learning outcomes	After completion of course student is able to know about,

	✓ Discuss the pathophysiology and pharmacotherapy of certain diseases ✓ Explain the mechanism of drug actions at cellular and molecular level ✓ Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases
Unit-1	General Pharmacology a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.
Unit-2	Neurotransmission 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 (NANC). Cotransmission Systemic Pharmacology A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems Autonomic Pharmacology Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction
Unit-3	Central nervous system Pharmacology General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.
Unit-4	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs
Unit-5	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.

Core Course-3: Pharmacological and Toxicological Screening Methods-I (MPL 103T)

Subject name and code	Pharmacological and Toxicological Screening Methods-I (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
Learning outcomes	After completion of course student is able to know about, ✓ 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
Unit-1	Laboratory Animals Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, scope and limitations and methods
Unit-2	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's and multiple sclerosis. Drugs acting on Autonomic Nervous System.
Unit-3	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti-allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: anti-ulcer, anti - emetic, antidiarrheal and laxatives.
Unit-4	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

	Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods
Unit-5	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Iimmunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans

Core Course-4: Cellular and Molecular Pharmacology (MPL 104T)

Subject name and code	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.
Learning outcomes	After completion of course student is able to know about, ✓ Explain the receptor signal transduction processes. ✓ Explain the molecular pathways affected by drugs. ✓ Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process. ✓ Demonstrate molecular biology techniques as applicable for pharmacology
Unit-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.
Unit-2	Cell signaling Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand

	gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.
Unit-3	Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.
Unit-4	Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice
Unit-5	A. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry B. Biosimilars

Core Course-5: Pharmacological Practical - I (MPL 105P)

PART-A:

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 Handling of laboratory animals.

PART-B:

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using software
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

Core Course-6: Advanced Pharmacology II (MPL 201T)

Subject name and code	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
Learning outcomes	✓ 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
Unit-1	Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation
Unit-2	Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.
Unit-3	Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants
Unit-4	GIT Pharmacology Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer
Unit-5	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

Core Course-7: Pharmacological and Toxicological Screening Methods-II (MPL 202T)

Subject name and code	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.
Learning outcomes	✓ 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.
Unit-1	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development
Unit-2	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies
Unit-3	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies
Unit-4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies
Unit-5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

Core Course-8: Principles of Drug Discovery (MPL 203T)

Subject name and code	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
Learning outcomes	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 for drug discovery. ✓ Explain various lead seeking method and lead optimization ✓ Appreciate the importance of the role of computer aided drug design in drug discovery
Unit-1	An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and Validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.
Unit-2	Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure: Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction
Unit-3	Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening
Unit-4	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.
Unit-5	QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug Design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

Core Course-9: Clinical Research and Pharmacovigilance (MPL 204T)

Subject name and code	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.
Learning outcomes	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
Unit-1	Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process
Unit-2	Clinical Trials: Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management
Unit-3	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

Unit-4	Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance
Unit-5	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, Pharmacoeconomics, Safety pharmacology

Core Course-10: Pharmacology Practical II (MPL 205P)

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 uitable 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

9.2. Elective Courses for other Departments

GEC-1: Clinical Research

Subject name	Clinical Research
Scope	The subject will impart the fundamental knowledge on the clinical drug development process of drugs.
Learning outcomes	The students shall be able to learn the ✓ Different aspects of clinical trial ✓ Ethics in clinical research ✓ Regulatory Perspectives of Clinical Trials ✓ types of clinical trial designs ✓ responsibilities of key players involved in clinical trials
Unit-1	Clinical Drug Development Process Different types of Clinical Studies, Phases of clinical trials, Clinical Trial protocol, Phase 0 studies, Phase I Phase II studies, Phase III studies, Phase IV studies (Post Marketing Studies; PSUR) 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
Unit-2	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
Unit-3	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

GEC-2: Pharmacovigilance

Subject name	Pharmacovigilance
Scope	The subject will impart advanced knowledge on methods, tools and significance of Pharmacovigilance
Learning outcomes	The students shall be able to learn the ✓ Explain the principles of Pharmacovigilance ✓ Detect new adverse drug reactions and their assessment ✓ Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance
Unit-1	Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects
Unit-2	WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance
Unit-3	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.
Unit-4	Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

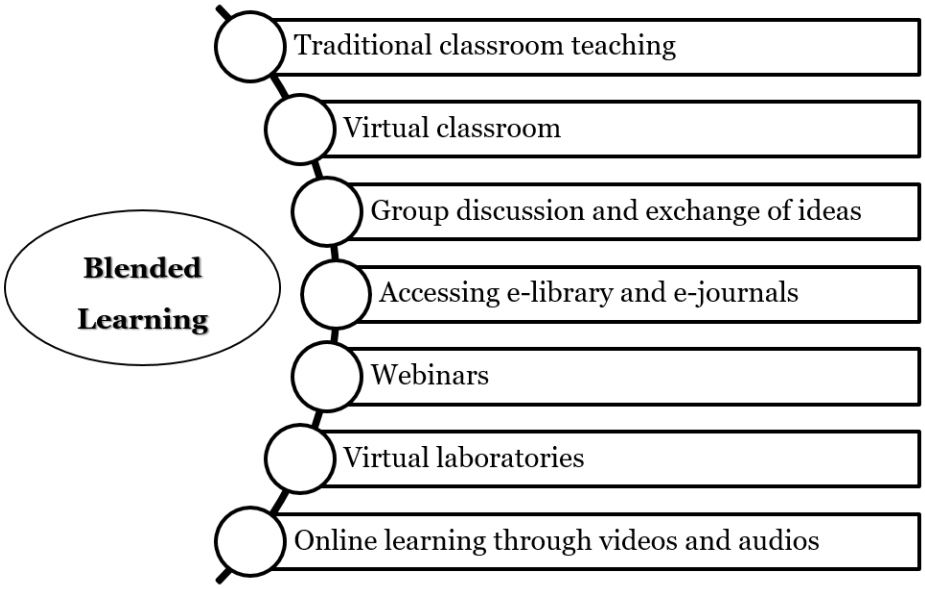
10.Teaching-Learning Process

1. Classroom Lectures
2. Interactive sessions
3. Animation and videos demonstration
4. Quizzes
5. Flipped classroom
6. Group discussions

7. Seminars
8. Electronic learning
9. Tutorials
10. Laboratory demonstrations
11. Collaborative Learning
12. Self-assessed or peer-assessed assignments

11.Blended Learning

A concept that includes framing teaching learning process and incorporates both face to face teaching and teaching supported by ICT. Blended learning incorporates direct as well as indirect instruction, collaborative teaching learning, and individualized computer-assisted learning.



12.Assessment and Evaluation

Internal assessment: Continuous mode

Subject type	Criteria	Maximum Marks
Theory	Attendance	8
	Student – Teacher interaction	2
	Total	**10**
Practical	Attendance	10

	Based on Practical Records, Regular viva voce, etc.	10
	Total	**20**

Scheme for awarding internal assessment: Continuous mode

Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

- Mid-semester and Comprehensive End-term Examination of courses
- Continuous evaluation in the form of
    - ✓ Class work,
    - ✓ Check-in assessment
    - ✓ Periodical quizzes,
    - ✓ Group discussions
    - ✓ Surprise tests,
    - ✓ Tutorials,
    - ✓ Laboratory work evaluation
- Collaborative Assignments
- Open book learning to assess problem solving and analytical abilities
- Oral presentations
- Multiple choice examination
- Problem solving exercises in groups

13.Keywords

- NEP-2020
- Blended Learning
- Programme Educational Objectives (PEOs)
- Learning Outcomes
- Programme Outcomes
- Postgraduate Attributes

- Continuous Mode
- Programme Specific Outcomes
- Course-level Learning Outcomes
- Learning Outcome Index
- Teaching-Learning Process

14. References

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