SHRI GURU RAM RAI UNIVERSITY

[Estd. by Govt. of Uttarakhand, vide Shri Guru Ram Rai University Act no. 03 of 2017 & recognized by UGC u/s (2f) of UGC Act 1956]

SCHOOL OF PHARMACEUTICAL SCIENCES

PROGRAM: M. PHARM (PHARMACOLOGY)

OUTCOME BASED EDUCATION

COURSE OUTCOMES, PROGRAM OUTCOMES, PROGRAM SPECIFIC OUTCOMES

&

ARTICULATION MATRIX

SHRI GURU RAM RAI UNIVERSITY

SCHOOL OF PHARMACEUTICAL SCIENCES

PROGRAM: M.Pharm (Pharmacology)

CO, PO, PSO & CO-PO-PSO Articulation Matrix

Dean
School of Pharmaceutical Sciences
SGRR University, Dehradun (Uttarakhand)

Program Outcomes- M.Pharm. (Pharmacology)

P01	**Advanced Knowledge:** Possess advanced scientific knowledge of the pharmacy profession so as to apply the learning's in providing solutions for complex issues of the Pharmaceutical field.
P02	**Scientific and Technical Skills:** Develop analytical skills for effective scientific writing/presentation, data compilation & interpretation. Obtain erudite technical skills for applying in research and development for improvement of pharmaceutical process and products.
P03	**Multidisciplinary Collaborative Research:** Develop interdisciplinary research with other health care communities to provide innovative solutions.
P04	**Regulatory Professional Skills** Comply and work on rules and regulations involved in the drug discovery & development, manufacture and other allied area of the field.
P05	**Critical Thinking:** Apply critical thinking skills, including investigation, application, analysis, and creativity, evaluation of information, data and documents related to research.
P06	**Problem based learning:** Develop problem-based learning approach and analytical thinking in his/her academic and professional life.
P07	**Professional Identity:** Demonstrate the ability to plan and implement professional activities.
P08	**Leadership Skills:** Leadership qualities of motivation, team building, time management, organizational skills so as to take lead and responsibilities in order to face the challenges of pharmaceutical sector.
P09	**Ethical practice and societal concern:** Exercise ethical practices and moral values in personal and professional endeavours.
P010	**Innovations Leading Skills:** Development of novel analytical techniques for identification, characterization and quantification of drugs, formulation, Pharmacological, Pharmacognostical, and regulatory aspects of drugs and biomolecules.
P011	**Lifelong learning:** Tackle professional challenges through lifelong learning attitude.
P012	**Expertise on Medications:** The student should be able to provide an expert opinion on medications to health care professionals on safe and effective medication-use, relevant policies and procedures based on available evidences.

Program Specific Outcomes- M.Pharm. (Pharmacology)

PSO1	**Pharmacological Knowledge and skill:** Understand and apply, cellular and molecular pharmacology, pathophysiology and pharmacotherapy in treatment of diseases.
PSO2	**Drug Discovery and Development:** Application of acquired scientific knowledge of *in-vitro* and *in-vivo* efficacy and safety studies for Drug Discovery and Development. Apply principles of Anatomy, Physiology, Pharmacology, Pathophysiology, Biochemistry, Cellular and Molecular Biology and Bioinformatics in the core and allied fields of Pharmaceutical Sciences.
PSO3	**Design and Analysis:** Understand and apply the principles and techniques of pharmaceutical analysis for target and lead optimization in designing and quantification of drugs using modern analytical instruments.
PSO4	**Clinical Research and Pharmacovigilance Competence:** Apply knowledge of clinical research **and Pharmacovigilance** in designing, monitoring, auditing, and documentation of clinical trials, medical writing including protocol writing, feasibility studies, narratives, publication of clinical studies, and post-marketing surveillance, detection and reporting of adverse drug reactions for accountable healthcare.

Course Outcomes- M.Pharm. (Pharmacology)

Semester-I	
COURSE NAME: Modern Pharmaceutical Analytical Techniques	
COURSE CODE: MPL101T	
MPL101T: CO 1	Understand the fundamentals of pharmaceutical analytical techniques.
MPL101T: CO 2	Learn about the general principle & theory of pharmaceutical analytical techniques.
MPL101T: CO 3	Explain about the advanced instruments its techniques and applications in drug analysis.
MPL101T: CO 4	Develop in depth knowledge of instruments in modern pharmaceutical analytical techniques.
MPL101T: CO 5	Appraise various applications of Modern Pharmaceutical Instruments.
MPL101T: CO 6	Attain skills in problem solving, critical thinking & analytical reasoning as applied in pharmaceutical analysis.

Articulation matrix:

	Semester –I															
	COURSE NAME: Modern Pharmaceutical Analytical Techniques															
	COURSE CODE: MPL101T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	3	3	2	3	2	3	2	0	0	3	3	1	1	1	1	0
CO 2	3	3	2	3	2	3	2	0	0	3	3	1	1	1	1	0
CO 3	3	3	2	3	2	3	2	0	1	3	3	1	1	1	1	0
CO 4	3	3	2	3	2	3	2	0	1	3	3	1	1	1	1	0
CO 5	3	3	3	3	3	3	2	0	1	3	3	1	1	1	1	1
CO 6	3	3	3	3	3	3	2	2	1	3	3	1	1	1	1	0

Semester-I	
COURSE NAME: Advanced Pharmacology-I	
COURSE CODE: MPL102T	
MPL102T: CO 1	Define/describes the terminology and basic knowledge in the field of pharmacology.
MPL102T: CO 2	Explains the pharmacology of drugs and their relevance in the treatment of different diseases.
MPL102T: CO 3	Demonstrate an understanding of the classifications, pharmacological actions, indications, uses of drugs
MPL102T: CO 4	Illustrates the different autacoids and Neurohumoral transmission and Non adrenergic non cholinergic transmission (NANC)
MPL102T: CO 5	Explains the pharmacokinetics and mechanism of drug actions at cellular and molecular level.
MPL102T: CO 6	Compiles the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases and designs to impart recent advances in the drugs used for the treatment of various diseases.

Articulation matrix:

	Semester –I															
	COURSE NAME: Advanced Pharmacology-I															
	COURSE CODE: MPL102T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	1	1	1	0	1	1	1	0	0	1	3	1	2	0	0	0
CO 2	3	3	3	1	3	2	2	0	0	3	3	3	3	0	0	0
CO 3	3	3	2	1	2	1	2	0	0	2	3	2	3	0	0	0
CO 4	3	2	3	1	1	1	1	0	0	1	1	1	1	0	0	0
CO 5	2	2	2	0	1	1	1	0	0	1	1	2	2	0	0	0
CO 6	3	3	2	0	1	0	1	0	0	1	2	1	1	0	0	0

Semester-I	
COURSE NAME: Pharmacological and Toxicological Screening Methods-I	
COURSE CODE: MPL103T	
MPL103T: CO 1	Define/describes the terminology, anaesthesia & euthanasia of laboratory animals, transgenic animals and basic knowledge in the field of Pharmacological and Toxicological Screening Methods.
MPL103T: CO 2	Explain the regulations/ethical requirement and good laboratory practices for the care and use of experimental animals, bioassays, general principles of preclinical screening, limitations of animal experiments and alternate of animal experiments
MPL103T: CO 3	Applies preclinical screening of new substances as CNS pharmacological agents and drugs used for neurodegenerative disorders
MPL103T: CO 4	Illustrates preclinical screening of new substances as respiratory pharmacological agents, reproductive pharmacological agents, NSAIDs and gastro intestinal drugs
MPL103T: CO 5	Evaluates preclinical screening of new substances as cardiovascular pharmacological agents, anticancer agents and drugs used for metabolic disorder
MPL103T: CO 6	Plans preclinical screening of new substances as immunomodulators and general principles of immunoassay & immunoassay methods. Extrapolation of invitro data to preclinical and preclinical data to humans.

Articulation matrix:

	Semester –I															
	COURSE NAME: Pharmacological and Toxicological Screening Methods-I															
	COURSE CODE: MPL103T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	2	2	1	1	1	1	1	0	2	1	2	1	2	1	0	0
CO 2	2	3	2	3	3	2	2	1	3	2	3	1	3	3	1	0
CO 3	3	3	3	3	3	2	2	1	3	3	3	1	3	3	1	0
CO 4	3	3	3	3	3	2	2	1	3	3	3	1	3	3	1	0
CO 5	3	3	3	3	3	2	2	1	3	3	3	1	3	3	1	0
CO 6	3	3	3	3	3	2	2	1	3	3	3	1	3	3	1	0

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Semester-I	
COURSE NAME: Cellular and Molecular Pharmacology	
COURSE CODE: MPL104T	
MPL104T: CO 1	Define/describe various terminology used in Cellular and Molecular Pharmacology
MPL104T: CO 2	Explains various aspects of cell biology including genome organization, gene expression, cell cycle and apoptosis.
MPL104T: CO 3	Demonstrates the receptor signal transduction processes, molecular pathways affected by drugs.
MPL104T: CO 4	Illustrates basic principles and applications of genomics/ proteomics, recombinant DNA technology and gene therapy
MPL104T: CO 5	Explains the principles and applications of pharmacogenomics. Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
MPL104T: CO 6	Categorizes cell culture techniques and biosimilars. Explains molecular biology techniques as applicable for pharmacology.

Articulation matrix:

	Semester –I															
	COURSE NAME: Cellular and Molecular Pharmacology															
	COURSE CODE: MPL104T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	2	1	1	1	1	1	3	1	1	2	3	2	3	2	1	1
CO 2	3	2	1	3	2	2	2	1	1	0	3	1	3	3	1	2
CO 3	2	2	1	2	2	2	2	1	1	0	3	2	3	3	1	0
CO 4	2	2	3	3	3	3	3	1	1	3	3	2	3	3	1	2
CO 5	2	1	2	1	2	2	2	1	1	1	3	2	3	3	1	2
CO 6	3	3	3	3	3	2	2	1	2	3	3	2	3	3	2	2

Semester-I	
COURSE NAME: Pharmacology Practical- I	
COURSE CODE: MPL105P	
MPL105P: CO 1	Analysis of pharmacopoeial compounds by advanced analytical techniques.
MPL105P: CO 2	Perform routes of drug administration, blood sampling techniques, anaesthesia and euthanasia of experimental animals.
MPL105P: CO 3	Pharmacokinetic studies and data analysis of drugs given by different routes of administration using software.
MPL105P: CO 4	Perform screening of antiulcer, analgesic, diuretic, CNS stimulant/depressant, muscle relaxant, anti-anxiety, anti- inflammatory drugs.

Articulation matrix:

	Semester –I															
	COURSE NAME: Pharmacology Practical- I															
	COURSE CODE: MPL105P															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	2	2	1	1	1	2	1	0	1	3	2	1	0	0	3	0
CO 2	1	1	1	1	1	1	1	0	3	1	2	1	0	2	0	0
CO 3	1	2	1	0	0	0	0	0	1	0	1	2	1	1	0	1
CO 4	3	3	3	3	3	3	2	0	3	3	3	3	3	3	0	1

Semester-II	
COURSE NAME: Advanced Pharmacology II	
COURSE CODE: MPL201T	
MPL201T: CO 1	Define/describes the terminology and basic knowledge in the field of pharmacology.
MPL201T: CO 2	Explains the pharmacology of drugs and their relevance in the treatment of different diseases.
MPL201T: CO 3	Demonstrate an understanding of the classifications, pharmacological actions, indications, uses of drugs. Applies chronopharmacology/chronotherapy in various diseases
MPL201T: CO 4	Illustrates Free radicals Pharmacology and Recent Advances in Treatment of Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus.
MPL201T: CO 5	Describes the pharmacology of drugs acting on endocrine system and its relevance in the treatment of different diseases.
MPL201T: CO 6	Explains the pharmacokinetics and mechanism of drug actions at cellular and molecular level, adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

Articulation matrix:

	Semester –II															
	COURSE NAME: Advanced Pharmacology II															
	COURSE CODE: MPL201T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	2	1	1	1	1	1	1	1	1	1	3	2	2	2	1	1
CO 2	3	1	2	2	2	2	3	1	2	2	3	3	3	2	1	2
CO 3	2	1	2	1	1	2	2	1	1	2	3	3	3	3	1	2
CO 4	3	1	2	2	2	1	2	1	1	2	3	3	3	3	1	2
CO 5	3	1	2	1	1	2	2	1	1	2	3	3	3	3	2	1
CO 6	3	1	2	1	2	2	3	1	1	2	3	3	3	3	2	1

Semester-II	
COURSE NAME: Pharmacological and Toxicological Screening Methods-II	
COURSE CODE: MPL202T	
MPL202T: CO 1	Define/describes the terminology and basic knowledge in the field of Pharmacological and Toxicological Screening Methods.
MPL202T: CO 2	Explains the various types of toxicity studies. Appreciate the importance of ethical and regulatory requirements for toxicity studies. OECD principles of GLP
MPL202T: CO 3	Demonstrate acute, subacute and chronic-oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies and test item characterization
MPL202T: CO 4	Illustrates reproductive, teratogenicity, genotoxicity and carcinogenicity studies
MPL202T: CO 5	Describes IND and Safety pharmacology studies.
MPL202T: CO 6	Designs the toxicokinetic approach in the preclinical research and plan alternative methods to animal toxicity testing including of in-silico based studies.

Articulation matrix:

	Semester –II															
	COURSE NAME: Pharmacological and Toxicological Screening Methods-II															
	COURSE CODE: MPL202T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	2	2	1	1	1	1	1	0	2	1	2	1	2	1	0	0
CO 2	2	2	3	3	3	3	2	1	3	2	3	1	2	3	1	0
CO 3	2	3	3	3	3	3	2	1	3	2	3	1	2	3	1	0
CO 4	2	3	3	3	3	3	2	1	3	2	3	1	2	3	1	0
CO 5	3	3	2	3	3	3	3	1	3	2	3	2	3	3	1	0
CO 6	3	3	3	3	3	3	3	1	3	2	3	2	3	3	1	0

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Semester-II	
COURSE NAME: Principles of drug discovery	
COURSE CODE: MPL203T	
MPL203T: CO 1	Define the basic terminology used in drug discovery.
MPL203T: CO 2	Understand the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
MPL203T: CO 3	Demonstrate the stages of the modern drug discovery process.
MPL203T: CO 4	Illustrates the targets of drug discovery.
MPL203T: CO 5	Describes the various lead-seeking methods and lead optimization.
MPL203T: CO 6	Compiles the importance of the role of computer-aided drug design in drug discovery.

Articulation matrix:

	Semester –II															
	COURSE NAME: Principles of drug discovery															
	COURSE CODE: MPL203T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
CO 2	3	3	2	2	2	2	1	0	2	2	2	1	1	3	3	2
CO 3	2	2	1	2	2	3	1	0	2	2	2	1	1	3	3	1
CO 4	3	3	3	2	2	2	2	0	2	2	2	1	2	3	3	3
CO 5	3	3	3	2	2	3	1	2	2	2	3	1	1	3	3	2
CO 6	3	3	3	3	3	2	2	0	1	2	3	1	2	3	3	1

Semester-II	
COURSE NAME: Clinical Research and Pharmacovigilance	
COURSE CODE: MPL204T	
MPL204T: CO 1	Defines/describes the basic terminology used in clinical trials, Pharmacovigilance and adverse drug reactions.
MPL204T: CO 2	Explain the regulatory requirements in addition to types, design & documentation for conducting clinical trials
MPL204T: CO 3	Demonstrate the types of clinical trial designs and the responsibilities of key players involved in clinical trials.
MPL204T: CO 4	Illustrates principles of Pharmacovigilance and execute safety monitoring, reporting and close-out activities.
MPL204T: CO 5	Evaluates and detect new adverse drug reactions, assessment and management of adverse drug reactions
MPL204T: CO 6	Designs the adverse drug reaction reporting systems and communication in Pharmacovigilance with concept of safety pharmacology, pharmacoepidemiology & pharmacoeconomics

Articulation matrix:

	Semester –II															
	COURSE NAME: Clinical Research and Pharmacovigilance															
	COURSE CODE: MPL204T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	1	1	1	1	0	0	1	0	0	1	1	0	0	0	0	2
CO 2	3	2	3	3	3	2	2	1	3	3	2	2	0	0	0	3
CO 3	3	3	2	2	2	1	2	3	2	1	3	1	0	0	0	3
CO 4	2	1	2	2	1	2	1	0	3	1	2	2	0	0	0	2
CO 5	2	2	1	1	1	2	1	1	1	1	1	1	0	0	0	2
CO 6	2	1	2	2	1	1	1	1	1	2	2	1	0	0	0	2

Semester-II	
COURSE NAME: Pharmacology Practical- II	
COURSE CODE: MPL205P	
MPL205P: CO 1	Record of dose response curve of agonist using suitable isolated tissue preparation.
MPL205P: CO 2	Determination of strength of unknown sample by different bioassay procedure using isolated tissue preparations.
MPL205P: CO 3	Perform oral toxicity studies as per OECD guidelines.
MPL205P: CO 4	Design of clinical trials protocols and ADR monitoring reporting protocols.

Articulation matrix:

	Semester –II															
	COURSE NAME: Pharmacology Practical- II															
	COURSE CODE: MPL205P															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	2	2	0	1	1	1	1	0	2	2	3	2	1	1	0	0
CO 2	2	2	1	2	2	2	2	0	2	2	3	2	1	1	0	0
CO 3	2	2	2	3	2	3	2	0	2	1	2	2	1	1	0	1
CO 4	2	2	2	3	2	2	2	0	3	0	2	2	1	1	0	3

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Semester-III	
COURSE NAME: Research Methodology & Biostatistics	
COURSE CODE: MRM301T	
CO 1	Understand the various aspects of research methodology and the use of biostatistics in research.
CO 2	Compare the various statistical techniques and their applications.
CO 3	Select and perform the appropriate parametric/ non parametric tests as per the data, manually as well as using statistical software.
CO 4	Elaborate with examples the ethics involved in medical research.
CO 5	Comprehend the guidelines for the experimentation on animals.
CO 6	Know about the genesis of bioethics with special reference to Helsinkl declaration.

Articulation matrix:

	Semester –III															
	COURSE NAME: Research Methodology & Biostatistics															
	COURSE CODE: MRM301T															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	3	3	3	0	2	2	3	0	1	1	3	1	3	0	2	0
CO 2	3	2	0	0	2	2	3	2	1	1	3	1	3	1	3	1
CO 3	1	3	0	0	2	2	3	0	1	1	3	0	3	2	3	1
CO 4	1	1	0	0	2	1	1	0	3	0	0	0	0	2	2	2
CO 5	3	1	0	0	2	1	1	0	3	0	0	0	0	0	0	3
CO 6	1	1	0	0	2	1	1	0	3	0	0	1	0	0	1	2

Semester-III & IV	
COURSE NAME: Journal Club	
COURSE CODE:	
CO 1	Search articles from various scientific databases.
CO 2	Critically appraise scientific articles and assess the quality.
CO 3	Develop a report on the critically appraised article.
CO 4	Prepare a technical presentation for a small audience.
CO 5	Deliver a presentation and address related queries.

Articulation matrix:

	Semester –III & IV															
	COURSE NAME: Journal Club															
	COURSE CODE:															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	2	0	3	0	1	2	1	1	1	1	3	3	3	0	1	0
CO 2	2	2	2	2	2	3	3	2	2	2	3	3	2	1	2	2
CO 3	3	2	1	1	3	2	2	2	3	1	3	3	2	1	1	3
CO 4	1	2	2	0	2	2	3	3	3	1	3	3	3	1	3	1
CO 5	2	1	1	0	1	2	3	3	2	2	3	3	3	1	3	1

Semester-III	
COURSE NAME: Research Work	
COURSE CODE:	
CO 1	Gain an understanding to identify the research question.
CO 2	Developing skills to define & determine the research problem with the peers to achieve the desired outcome.
CO 3	Gain understanding to establish the research objectives.
CO 4	Developing skills for establishing a suitable methodology to answer the research problem.
CO 5	Gain an understanding to develop a protocol & plan of work to answer the research problem.
CO 6	Demonstration of the plan of work & critically appraised research problem in appropriate forum.

Articulation matrix:

	Semester –III															
	COURSE NAME: Research Work															
	COURSE CODE:															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	2	3	2	2	3	2	1	1	0	2	2	2	3	0	1	0
CO 2	3	2	2	1	3	3	2	2	0	2	2	3	2	1	2	2
CO 3	3	0	2	1	3	1	1	1	0	2	1	3	2	1	1	3
CO 4	2	2	2	2	2	2	1	1	2	2	2	2	3	1	3	1
CO 5	2	2	2	2	2	1	1	1	2	1	2	3	3	1	3	1
CO 6	2	2	2	2	2	3	1	2	2	3	2	3	3	2	3	1

Semester-IV	
COURSE NAME: Research Work & Colloquium	
COURSE CODE:	
CO 1	Ability to review scholarly articles critically to collect and formulate the data.
CO 2	Developing skills to conduct research for achieving research objectives.
CO 3	Gain understanding to stratify the collected data and formulate into the research findings.
CO 4	Ability to statistically analyse the critically formulated data and generate the research outcome.
CO 5	Developing skills to propose new ideas or outcomes for the defined research question and create research document of the findings.
CO 6	Appraise and defend the research findings with evidence-based observations.

Articulation matrix:

	Semester –IV															
	COURSE NAME: Research Work & Colloquium															
	COURSE CODE:															
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO 1	3	3	2	1	1	2	1	2	3	2	2	3	1	2	3	1
CO 2	3	3	2	2	2	2	1	2	3	2	3	2	3	2	3	1
CO 3	3	2	2	1	2	2	1	1	2	2	2	2	3	3	3	2
CO 4	2	3	3	2	2	2	1	2	2	2	1	3	2	1	3	0
CO 5	3	3	3	2	2	2	1	2	2	3	1	1	3	3	3	1
CO 6	3	2	2	2	2	2	2	1	2	2	1	1	3	3	3	1

Dean
School of Pharmaceutical Sciences
SGRR University, Dehradun (Uttarakhand)

PHARMACOLOGY (MPL)

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.

Objectives

After completion of course student is able to know about,

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

THEORY 60 Hrs

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. 10 Hrs

   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 (Characterestics 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.

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. 10 Hrs

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: j) Thin Layer chromatography k) High Performance Thin Layer Chromatography l) Ion exchange chromatography m) Column chromatography n) Gas chromatography o) High Performance Liquid chromatography p) Ultra High Performance Liquid chromatography q) Affinity chromatography r) Gel Chromatography	10 Hrs
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.	10 Hrs
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.	10 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

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

Objectives

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

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

THEORY 60 Hrs

1. General Pharmacology 12 Hrs

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

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

2 Neurotransmission 12 Hrs

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting
neuromuscular junction

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.	12 Hrs
4	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs	12 Hrs
5	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	12 Hrs

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.

10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications - Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

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

Objectives

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

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

THEORY 60 Hrs

1. Laboratory Animals 12 Hrs

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

Transgenic animals: Production, maintenance and applications
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

2 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and

depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

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, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.	12 Hrs
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.	12 Hrs
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	12 Hrs

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

CELLULAR AND MOLECULAR PHARMACOLOGY
(MPL 104T)

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Objectives:

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

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

THEORY		60 Hrs
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.	12 Hrs
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.	12 Hrs

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.	12 Hrs
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	12 Hrs
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	12 Hrs

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGICAL PRACTICAL - I
(MPL 105P)

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.

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

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

ADVANCED PHARMACOLOGY - II
(MPL 201T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Objectives

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

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

	THEORY	60 Hrs
1.	Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation	12 Hrs
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.	12 Hrs
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	12 Hrs

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	12 Hrs
5	Free radicals Pharmacology Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12 Hrs

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

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

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

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

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

	THEORY	60 Hrs
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	12 Hrs
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	12 Hrs
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	12 Hrs
4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.	12 Hrs

	Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	
5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12 Hrs

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp-handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY
(MPL 203T)

Scope:

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

Objectives:

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

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets 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

THEORY		60 Hrs
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.	12 Hrs
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	12 Hrs
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	12 Hrs

	Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,	
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.	12 Hrs
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	12 Hrs

REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markelln. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MPL 204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

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

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

	THEORY	60 Hrs
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	12 Hrs
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	12 Hrs

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.	12 Hrs
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	12 Hrs
5	Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	12 Hrs
6	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	12 Hrs

REFERENCES

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

PHARMACOLOGICAL 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 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 PA_2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

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

UNIT – IV

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

UNIT – V

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