GANPAT UNIVERSITY

FACULTY OF PHARMACY

TEACHING AND EXAMINATION SCHEME

Program		Master of Pharmacy (M.Pharm)	Branch	Pharmacology	Semester	II	Version	2.0.0.0
Effective from		2018-19	Effective for batches admitted onwards		2018-19			

S. N	Subject Code	Subject Name	Theory / Practical/ Seminar	Teaching Scheme		Examination Scheme			
				Credit	Hours Per Week	Marks			Total Marks
						CE	SE	ES	
1	MPL201T	Advanced Pharmacology II	Theory	4	4	10	15	75	100
2	MPL202T	Pharmacological and Toxicological Screening Methods-II	Theory	4	4	10	15	75	100
3	MPL203T	Principles of Drug Discovery	Theory	4	4	10	15	75	100
4	MPL204T	Clinical Research and Pharmcoviglilance	Theory	4	4	10	15	75	100
5	MPL205P	Pharmacology Practical II	Practical	6	12	20	30	100	150
6	MEL206S	Seminar	Seminar	4	8	-	-	100	100
			Total	26	36	60	90	500	650

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FACULTY OF PHARMACY										
Program	Master of Pharmacy			Branch/Spec.	Pharmacology					
Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPL201T	Subject Name	Advanced Pharmacology II							
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

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 Outcome:

Upon completion of this course, students should be able to:

	Know the mechanism of drug actions at cellular and molecular level with their pharmacology of endocrine drugs.
	Understand the cellular and molecular mechanism of actions and resistance of chemotherapeutic agents.
	Learn the drugs used in the treatment of various cancer and infectious diseases.
	Analyse unwanted effects, contraindications and indication of drugs in selection of appropriate drugs.
	Apply the basic principles of therapeutics in preparing algorithm of treatment.
	Appreciate correlation of pharmacology with related medical sciences.

Syllabus- Theory

Unit	Content	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
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
3	Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemo therapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immuno suppressants and Immunostimulants	12
4	GIT Pharmacology Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer	12
5	Free radicals Pharmacology Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12

Reference books

1	The Pharmacological basis of therapeutics-Goodman and Gillman'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	K.D. 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

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Program	Master of Pharmacy			Branch/Spec.	Pharmacology					
Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPL202T	Subject Name		Pharmacological and Toxicological Screening Methods-II						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

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 Outcome:

Upon completion of this course, students should be able to:

	Know the regulatory aspects for the toxicological evaluation of drugs and chemicals.
	Understand principle and study design of safety evaluation, acute toxicity, repeated dose studies (sub acute and chronic), analysis of safety pharmacological data.
	Learn in-vitro and in-vivo studies including genotoxicity, mutagenicity, carcinogenicity, reproductive toxicity, Safety testing for chemicals
	Analyse the techniques for find out pharmacological activity of new substance, safety assessment, toxicity studies.
	Apply the principles of biological standardization.
	Appreciate and correlate the preclinical data to humans.

Syllabus- Theory

Unit	Content	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
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
3	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12
4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay.Tier2-GI,renal and other studies	12
5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing	12

Reference books

1	Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphandbook.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/ guidance compliance regulatory information/guidances/ucm073246.pdf)

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Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPL203T	Subject Name		Principles of Drug Discovery						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

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

Learning Outcome:

Upon completion of this course, students should be able to:

	Know an overview of modern drug discovery process
	Understand various facets of lead identification in drug discovery.
	Learn rational and traditional drug design techniques.
	Demonstrate various tools for insilico screening of drugs.
	Apply several QSAR statistical methods for selection of rationale drug candidates.
	Validate a model helpful in funnelling library of compounds.

Syllabus- Theory

Unit	Content	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
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
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	12
4	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. Denovo 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
5	QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3DQSARapproaches 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

Reference books

1	Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc
2	Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation.2006byTaylor 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 ChemicalSociety:Washington,DC,1999
7	J. Rick Turner. Newdrug development design, methodology and, analysis. JohnWiley&Sons,Inc.,New Jersey

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Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPL204T	Subject Name		Clinical Research and Pharmcoviglilance						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

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 Outcome:

Upon completion of this course, students should be able to:

	Know regulatory perspective of clinical trials.
	Understand designs of clinical trials and roles and responsibilities of clinical research professionals.
	Learn necessary documentation being prepared in clinical trials.
	Analyse data collected from patients and infer some concrete statement.
	Apply pedagogy and tools for ADR reporting.
	Create in-house system for collection, assessment and interpretation of ADR report.

Syllabus- Theory

Unit	Content	Hrs
1	Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization-Good Clinical Practice(ICHGCP)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	10
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	10
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	10
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	10
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.	10
6	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	10

Reference books

1	Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry ofHealth;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;May1996
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 Dayand 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

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Program	Master of Pharmacy			Branch/Spec.	Pharmacology					
Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPL205P	Subject Name		Pharmacology Practical II						
Teaching scheme		Examination scheme								
Credit	6		CE	SE	ES	Total		SE	ES	
Hours	12	Marks	20	30	100	150	Duration	1 hr.	3 hr.	

Pre-requisites	
Nil	
Learning Outcome	
	Know basic requirements to conduct experiments on various isolated tissue preparations.
	Understand several toxicity tests for single, multiple dose, carcinogenicity and genotixicity nature of chemical substance in accordance to OECD guideline.
	Learn to prepare and present protocols for clinical trial and pharmacovigilance.
	Demonstrate several methods for assessment of safety and efficacy of NCEs.
	Apply knowledge of several methods in screening of effect of drugs.
	Create a newer model to enhance drug discovery process.

Syllabus- Practical		
Unit	Content	Hrs
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 isolated tissue preparation.	
4	To determine to the strength of unknown sample by interpolation bioassay by using suitable isolated tissue preparation.	
5	To determine to the strength of unknown sample by bracketing bioassay by using suitable isolated tissue preparation.	
6	To determine to the strength of unknown sample by multiple point bioassay by using suitable isolated 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 to toxicity studies as per OECD guidelines.	
14	Repeated dose t 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.	

Reference books	
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.

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Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MEL206S	Subject Name		Seminar						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	8	Marks	-	-	100	100	Duration	-	3 hr.	
Pre-requisites										
Nil										
Scope and Objectives:										
	• To develop know how of the latest development in the area of pharmaceutical science. • To develop the presentation skill for the information collected and compilated in the form of seminar.									
Learning Outcome:										
	Knowledge of the latest development in the area of Pharmaceutical Sciences.									
	Understand the use of the library and internet resources for the referencing and literature purpose									
	Apply the knowledge of surfing and referencing to collect and compile relevant data in scientific way									
	Analyse the problems and strengthen ability for presentations and defending the viva voce									
	Evaluate the hypothesis, study design, method and results in a systemic manner									
	Develop presentation skill utilizing various tools and techniques for the data analysis and meaningful conclusion									