



K. R. MANGALAM UNIVERSITY

THE COMPLETE WORLD OF EDUCATION

SCHOOL OF MEDICAL

AND

ALLIED SCIENCES

Master of Pharmacy- Pharmaceutics

Program Code: 61

Master of Pharmacy- Pharmacology

Program Code: 65

2019-2021

**Approved in the 20th Meeting of Academic Council Held on
16 July 2019**



Registrar

**K.R. Mangalam University
Sohna Road, Gurugram, (Haryana)**



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PREFACE

The KRMU envisions all its programs in the best interest of their students and in this endeavour it offers a new vision to all its courses. Through its programs it aims to provide a focused, student-centric syllabus with an agenda to structure the teaching-learning experiences experientially.

The curriculum strengthens student's experiences and prepares the students for, academia and employability, sustainability and life-long learning.

Each program reflects the promise to accomplish the learning outcomes by studying the courses. The graduate attributes encompass values related to well-being, emotional stability, critical thinking, social justice and also skills for entrepreneurship.

The K.R. Mangalam University hopes the curriculum will help students in making an informed decision at the time of working in the field of pharmacy.

ACKNOWLEDGEMENT

The development of the Curriculum for Post Graduate degree program in Pharmacy is a result of thoughtful deliberations at various stages of dedicated and specialized experts. This curriculum has been framed to meet the expectations of an academically challenging environment, develop problem-solving skills by students, and aligns with current standards and to enrich the students to make them self-enablers and/or match job requirements on successful completion of their degrees.

I wish to acknowledge all our experts who have been involved in the process of developing this outcome-based curriculum for Masters of Pharmacy (M. Pharm). I am thankful to Prof. Manoj M. Gadewar, Dr. Shrestha Sharma, Dr. Urooj A. Khan and Dr. Lakhveer who were devotedly committed towards framing this curriculum.

I am greatly gratified Ms. Manvi Arora for her supervision contribution, guidance, and support throughout the development of this curriculum.

Special thanks and gratitude to Prof. Aditya Malik Vice Chancellor, K.R. Mangalam University, who have been instrumental and encouraging throughout the process of developing this curriculum.

Last, but not the least, I also sincerely thank to Ms. Silky Sethy, Ms. Neha Minocha and Mr. Sanjeev Kumar who have contributed for development of this curriculum.

Dean
School of Medical and Allied Sciences

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1. INTRODUCTION

The K.R. Mangalam Group has made a name for itself in the field of education. The K.R. Mangalam story goes back to the chain of schools that offered an alternative option of world-class education, pitching itself against the established elite schools, which had enjoyed a position of monopoly till then. Having blazed a new trail in school education, the focus of the group was aimed at higher education.

K.R. Mangalam University is the fastest-growing higher education institute in Gurugram, India. K. R. Mangalam University was established under the Haryana Private University Act 2006, received the approval of Haryana Legislature vide Amendment Act # 36 of 2013 and consent of the Hon'ble Governor of Haryana on 11th April 2013, which was published in the Gazette notification vide Leg. No.10/2013, dated 3rd May 2013.

Since its inception in 2013, the University has been striving to fulfil its prime objective of transforming young lives through ground-breaking pedagogy, global collaborations, and world-class infrastructure. Resources at K.R Mangalam University have been continuously upgraded to optimize opportunities for the students. Our students are groomed in a truly interdisciplinary environment where they grow up with integrative skills through interaction with students from engineering, social sciences, management and other study streams.

K. R. Mangalam University is unique because of its

- i. Enduring legacy of providing education to high achievers who demonstrate leadership in diverse fields.
- ii. Protective and nurturing environment for teaching, research, creativity, scholarship, social and economic justice.

2. OBJECTIVES

To impart undergraduate, post graduate and doctoral education in identified areas of higher education.

- To undertake research programmes with industrial interface.
- To integrate its growth with the global needs and expectations of the major stake holders through teaching, research, exchange & collaborative programmes with foreign, Indian Universities/Institutions and MNCs.
- To act as a nodal center for transfer of technology to the industry.
- To provide job oriented professional education to the Indian student community with particular focus on Haryana.

3. ABOUT THE SCHOOL OF MEDICAL AND ALLIED SCIENCES

School of Medical and Allied Sciences mainly focused on training to students for various subjects and practical aspects related to drug formulation and testing along with co-curricular development. School offers Diploma, undergraduate, post graduate courses in pharmacy and Bachelor degree in physiotherapy post. We provide an extra edge to our students by teaching and training by leading pharma industry experts to facilitate industry academia interaction, participation in conferences / workshops / skill development programs, carrier guidance, coaching for GPAT and other competitive examinations. We encourage students to participate in various health camps organized by School of Medical and Allied Sciences to make general awareness amongst people regarding various diseases like diabetes, hypertension, communicable and non-communicable diseases. We provide placement assistance to students for getting jobs in various government and private laboratories. We have tie up with various pharmaceutical industries like Dabur Research Foundation, Sun Pharma, Arbro Pharma, Indian Pharmacopoeial Commission, Catalyst Clinical Services, Suraksha Pharma, Medicamen Biotech , Mankind Pharma etc. which provide various carrier opportunities in pharmaceutical production, pharmaceutical quality control, quality assurance, pharmaceutical sales & distribution, drug information services, health insurance, medical coding, supply chain management, forensic sciences, pharmacovigilance, product management team, clinical trials, clinical data management and in Indian Pharmacopeia Commission.

3.1. School Vision

To contribute towards healthcare needs of the society by producing a skilled, motivated and accessible workforce dedicated towards achieving health for all.

3.2 School Mission

M1: To produce self-motivated, self-reliant and socially sensitive young healthcare professionals catering to the needs of academia, industry and research.

M2: To create a center of excellence for learning and research in the field of pharmaceutical and allied health sciences with inter-disciplinary approach in emerging area of science and technology with focus on industry-academia interaction.

M3: To nurture transformational research for the benefit of the society.

M4: To interlink pharmaceutical and allied health sciences with interdisciplinary life sciences.

3.3 Aims of Master Degree Program

Since 2018 the School of Medical and Allied Sciences strives to foster and maintain a creative environment with a deep commitment to inculcate excellence in academics and contribute towards students' development. The Master's programme is designed to provide a sound knowledge and training to students to prepare students for high-level research and leadership positions in pharmaceutical and biotechnology companies. The School of Medical and Allied Sciences offers Masters Programs in Pharmaceutics and Pharmacology that are designed to prepare exceptional students for productive and successful careers in pharmaceutical industry, academia, and research.

4. POST GRADUATE PROGRAMS OFFERED BY SCHOOL OF MEDICAL AND ALLIED SCIENCES

SMAS offers M. Pharmacy degree course which is duly approved by the Pharmacy Council of India (F.No.01.106/2020-PCI, minutes of 109th central council meeting on 08-09 April, 2020, Item No. HR-17/2020-21). The curriculum has been specifically designed so as to impart latest knowledge and skills relevant to Pharmaceutical Sciences including Industrial Visits / Training / Guest Lectures of Experts from Industry and Academia. School of Medical and Allied Sciences offers various courses in Pharmacy, namely:

4.1 M. Pharm (Pharmaceutics)

4.2 M. Pharm (Pharmacology)

4.1 M. PHARM (PHARMACEUTICS) PROGRAM

M. Pharm (Pharmaceutics) program is designed to provide a sound knowledge of principles and applications in the field of pharmaceutics. It develops the ability to analyze the problems related to drug delivery and to come up with Novel Drug Formulation.

4.1.1 Eligibility Criteria

The student should pass in the following examinations:

- B. Pharmacy degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India (PCI) and has scored not less than 55% of the maximum marks (aggregate of 4 years of B.Pharmacy).
- Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

4.1.2 Course Outline

Modern Pharmaceutical Analytical Techniques, Modern Pharmaceutics, Drug delivery system, Regulatory affairs, Molecular Pharmaceutics (Nano Tech and Targeted DDS), Advanced Biopharmaceutics & Pharmacokinetics, Computer Aided Drug Delivery System, Cosmetics and Cosmeceuticals, Research Methodology and Biostatistics, Pharmaceutics Practical, Seminar/Assignment, Discussion / Presentation (Proposal Presentation), Journal Club, Research work.

4.1.3 Career Opportunities

Academics/Research and development/ Pharmacovigilance/ Clinical Research/ Preclinical data analyst/ Medical writing/ Medical coder/ Toxicology/ Analytical R& D/ Formulation Development/ Drug Regulatory Affairs/ Product Marketing/ Sales and Marketing/ Drug inspectors/ Drug Safety Associate/ Overseas opportunity(GRE).

4.2 M. PHARM (PHARMACOLOGY) PROGRAM

M. Pharm (Pharmacology) Program 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. It will impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development.

4.2.1 Eligibility Criteria

The student should pass in the following examinations:

- B. Pharmacy degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India (PCI) and has scored not less than 55% of the maximum marks (aggregate of 4 years of B.Pharmacy).
- Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

4.2.2 Course Outline

Modern Pharmaceutical Analytical Techniques, Advanced Pharmacology, Pharmacological and Toxicological Screening Methods, Cellular and Molecular Pharmacology, Pharmacology Practical, Principles of Drug Discovery, Research Methodology and Biostatistics Seminar/Assignment, Discussion / Presentation (Proposal Presentation), Journal Club, Research work.

4.2.3 Career Opportunities

Academics/ Research and development/ Pharmacovigilance/ Clinical Research/ Preclinical data analyst /Medical writing/ Medical coder/ Toxicology/ Analytical R& D/ Formulation Development/ Drug Regulatory affairs/ Product Marketing/ Sales and Marketing/ Drug inspectors/ Drug Safety Associate/Overseas opportunity(GRE).

5. CLASS TIMINGS

The class will be held from Monday to Friday from 9.10 A.M. to 4.10 P.M.

6. PROGRAM DURATION

The program duration of Bachelor of Education is

Name of the Program	Duration
Master of Pharmacy	2 Years / 4 Semester

7. PROGRAM SCHEME

The syllabi of the M. Pharm programme offered by School of Medical and Allied Sciences are given in the following pages:

TWO YEAR M.PHARM COURSE AT A GLANCE

	Semester I	Semester II	Semester III	Semester IV	Total
Courses	6	6	4	3	18
Credits	26	26	21	20	93

7.1 SCHEME OF STUDIES FOR M.PHARM (PHARMACEUTICS) PROGRAMME

Semester I				
S.No.	Course Code	Course Title	Credits	Hours /week
1	MPH101T	Modern Pharmaceutical Analytical Techniques	4	4
2	MPH102T	Drug Delivery System	4	4
3	MPH103T	Modern Pharmaceutics	4	4
4	MPH104T	Regulatory Affairs	4	4
5	MPH105P	Pharmaceutics Practical I	6	12
6	MPH106S	Seminar	4	7
		TOTAL	26	35

Semester II				
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S.No.	Course Code	Course Title	Credits	Hours /week
1	MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4
2	MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4
3	MPH203T	Computer Aided Drug Delivery System	4	4
4	MPH204T	Cosmetic and Cosmeceuticals	4	4
5	MPH205P	Pharmaceutics Practical II	6	12
6	MPH206S	Seminar/Assignment	4	7
		TOTAL	26	35

Semester III				
S.No	Course Code	Course Title	Credits	Hours /week
1	MRM301T	Research Methodology and Biostatistics	4	4
2	MPH302S	Journal Club	1	1
3	MPH303S	Discussion / Presentation (Proposal Presentation)	2	2
4	MPH304P	Research Work	14	28
		TOTAL	21	35

Semester IV				
S.No.	Course Code	Course Title	Credits	Hours /week
1	MPH401S	Journal Club	1	1
2	MPH402P	Research Work	16	31
3	MPH403S	Discussion / Final Presentation	3	3
		TOTAL	20	35

7.2 SCHEME OF STUDIES FOR M.PHARM (PHARMACOLOGY) PROGRAM

Semester I				
S.No.	Course Code	Course Title	Credits	Hours /week
1	MPL101T	Modern Pharmaceutical Analytical Techniques	4	4

2	MPL102T	Advanced Pharmacology-I	4	4
3	MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4
4	MPL104T	Cellular and Molecular Pharmacology	4	4
5	MPL105P	Pharmacology Practical I	6	12
6	MPL106S	Seminar/Assignment	4	7
		TOTAL	26	35

Semester II				
S.No.	Course Code	Course Title	Credits	Hours /week
1	MPL201T	Advanced Pharmacology II	4	4
2	MPL 202T	Pharmacological and Toxicological Screening Methods-II	4	4
3	MPL203T	Principles of Drug Discovery	4	4
4	MPL204T	Experimental Pharmacology practical- II	4	4
5	MPL205P	Pharmacology Practical II	6	12
6	MPL206S	Seminar/Assignment	4	7
		TOTAL	26	35

Semester III				
S.No	Course Code	Course Title	Credits	Hours /week
1	MRM301T	Research Methodology and Biostatistics	4	4
2	MPL302S	Journal Club	1	1
3	MPL303S	Discussion / Presentation (Proposal Presentation)	2	2
4	MPL304P	Research Work	14	28
		TOTAL	21	35

Semester IV				
S.No.	Course Code	Course Title	Credits	Hours /week
1	MPL401S	Journal Club	1	1
2	MPL402P	Research Work	16	31

3	MPL403S	Discussion / Final Presentation	3	3
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M. Pharma (Pharmaceutics)

Course code	Course Title	L	T	P	C
MPH101T	MODERN PHARMACEUTICAL ANALYSIS	4	0	0	4

Course Teacher (s):

Course Objectives:

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

1. The analysis of various drugs in single and combination dosage forms
2. Theoretical and practical skills of the instruments

Course Syllabus:

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.

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

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy:

Principle, Instrumentation, Interferences and Applications.

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.

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

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

- a) Paper chromatography
- b) Thin Layer chromatography
- c) Ion exchange chromatography
- d) Column chromatography
- e) Gas chromatography
- f) High Performance Liquid chromatography
- g) Affinity chromatography

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.

6 Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.

Text book [TB]:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

Reference book(s) [RB]:

1. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
2. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
3. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
4. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
5. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional	1 Hr.	15	
3	End-Term Examination	3 Hr.	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPH102T	DRUG DELIVERY SYSTEM	4	0	0	4

Course Teacher (s):

Course Objectives:

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

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of
3. The formulation and evaluation of Novel drug delivery systems..

Course Syllabus:

1. **SR/CR formulation:** Introduction & basic concepts, advantages/ disadvantages,

factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers :introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

2. Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, PH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals

3. Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

4. Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

5. Trans Dermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation

6. Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

7. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

Text book [TB]:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.

Reference book(s) [RB]:

1. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
2. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
3. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional	1 Hr.	15	
3	End-Term Examination	3 Hr.	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPH103T	MODERN PHARMACEUTICS	4	0	0	4

Course Teacher (s):

Course Objectives:

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

1. To understand the elements of preformulation studies.
2. To understand the Active Pharmaceutical Ingredients and Generic drug Product development
3. To learn Industrial Management and GMP Considerations.
4. To understand Optimization Techniques & Pilot Plant Scale Up Techniques
5. To study Stability Testing, sterilization process & packaging of dosage forms.

Course Syllabus:

1. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing.

Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability

Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation

2. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

3. Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, , Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities

4. cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management

5. Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.

6. Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plats, Similarity factors – f2 and f1, Higuchi and peppas plot, Linearity Concept of significance, Standard deviation , chi square test , student T-test , Anova test.

Text book [TB]:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.

3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.

Reference book(s) [RB]:

1. Remington's Pharmaceutical Sciences.
2. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
3. Physical Pharmacy; By Alfred martin
4. Bentley's Textbook of Pharmaceutics – Rawbins.
5. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
6. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
7. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
8. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
9. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
9. Pharmaceutical Preformulations; By J.J. We

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional	1 Hr.	15	
3	End-Term Examination	3 Hr.	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPH104T	REGULATORY AFFAIRS	4	0	0	4

Course Teacher (s):

Course Objectives:

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

1. The Concepts of innovator and generic drugs, drug development process
2. The Regulatory guidance's and guidelines for filing and approval process
3. Preparation of Dossiers and their submission to regulatory agencies in different countries
4. Post approval regulatory requirements for actives and drug products
5. Submission of global documents in CTD/ eCTD formats
6. Clinical trials requirements for approvals for conducting clinical trials
7. Pharmacovigilance and process of monitoring in clinical trials.

Course Syllabus:

1. Documentation in pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction

, Hatch- Waxman act and amendments , CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro ,ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO

2. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

3. CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q,S E,M. Regulatory requirements of EU, MHRA, TGA and ROW countries

4. Non clinical drug development: Global submission of IND,NDA,ANDA.Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

5. Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

Text book [TB]:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufner,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.

Reference book(s) [RB]:

1. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
2. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
3. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
4. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional	1 Hr.	15	
3	End-Term Examination	3 Hr.	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPH105P	Pharmaceutics Practical I	0	0	12	6

<u>Course Teacher (s):</u>				
<u>Course Objectives:</u> Upon completion of the course, student shall be able to understand countries				
<ol style="list-style-type: none"> 1. The analysis of various drugs in single and combination dosage forms 2. Theoretical and practical skills of the formulation & development. 				
<u>Course Syllabus:</u>				
<ol style="list-style-type: none"> 1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer 2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry 3. Experiments based on HPLC 4. Experiments based on Gas Chromatography 5. Estimation of riboflavin/quinine sulphate by fluorimetry 6. Estimation of sodium/potassium by flame photometry 7. To perform <i>In-vitro</i> dissolution profile of CR/ SR marketed formulation 8. Formulation and evaluation of sustained release matrix tablets 9. Formulation and evaluation osmotically controlled DDS 10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS 11. Formulation and evaluation of Muco adhesive tablets. 12. Formulation and evaluation of trans dermal patches. 13. To carry out preformulation studies of tablets. 14. To study the effect of compressional force on tablets disintegration time. 15. To study Micromeritic properties of powders and granulation. 16. To study the effect of particle size on dissolution of a tablet. 17. To study the effect of binders on dissolution of a tablet. 18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors. 				
<u>Text book [TB]:</u>				
<ol style="list-style-type: none"> 1. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998. 				
<u>Reference book(s) [RB]:</u>				
<ol style="list-style-type: none"> 1. Instrumental methods of analysis – Willards, 7th edition, CBS publishers. 2. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997. 3. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series 				
<u>Evaluation Scheme:</u>				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		20	
2	Sessional	6 Hr.	30	
3	End-Term Examination	6 Hr.	100	
		Total	150	

Course code	Course Title	L	T	P	C
MPH106P	Seminar and Assignment	0	0	7	4

Course code	Course Title	L	T	P	C
MPH201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	4	0	0	4

<u>Course Teacher (s):</u>				
<u>Course Objectives:</u> Upon completion of the course, student shall be able to understand countries				
<ol style="list-style-type: none"> 1. The various approaches for development of novel drug delivery systems. 2. The criteria for selection of drugs and polymers for the development of NTDS 3. The formulation and evaluation of novel drug delivery systems. 				
<u>Course Syllabus:</u>				
<ol style="list-style-type: none"> 1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. 2. Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation 3. Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. 4. Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation 5. Veterinary Drug Delivery Systems 				
<u>Text book [TB]:</u>				
<ol style="list-style-type: none"> 1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel 47 Dekker, Inc., New York, 1992. 				
<u>Reference book(s) [RB]:</u>				
<ol style="list-style-type: none"> 1. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002. 2. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001). 				
<u>Evaluation Scheme:</u>				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	

2	Sessional	1 Hr.	15	
3	End-Term Examination	3 Hr.	75	
		Total	<u>100</u>	

Course code	Course Title	L	T	P	C
MPH202T	ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS	4	0	0	4

Course Teacher (s):

Course Objectives:

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

1. The basic concepts in biopharmaceutics and pharmacokinetics.
2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
3. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
4. The design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. The potential clinical pharmacokinetic problems and apply basic pharmacokinetic

Course Syllabus:

1. Drug Absorption From The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH-partition theory of drug absorption. Factors affecting drug absorption: physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: 48

Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, Drug Product Performance, *In Vitro*: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products. *In Vitro-In Vivo* Correlation, Dissolution

Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product, Drug Product Considerations.

3. Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extravascular. Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation K_{max} and V_{max} . Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

4. Drug Product Performance, In Vivo: Bioavailability and

Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process. Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapy

Text book [TB]:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991 49
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmanekar and Sunil B.J. Aiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982

Reference book(s) [RB]:

1. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
2. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
3. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
4. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
5. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
6. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
7. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J

Breen, pharmaceutical press, RPS Publishing, 2009.

8. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional	1 Hr.	15	
3	End-Term Examination	3 Hr.	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPH203T	COMPUTER AIDED DRUG DEVELOPMENT	4	0	0	4

Course Teacher (s):

Course Objectives:

Upon completion of the course, student shall be able to understand
History of Computers in Pharmaceutical Research and Development

1. Computational Modeling of Drug Disposition
2. Computers in Preclinical Development
3. Optimization Techniques in Pharmaceutical Formulation
4. Computers in Market Analysis
5. Computers in Clinical Development
6. Artificial Intelligence (AI) and Robotics
7. Computational fluid dynamics(CFD)

Course Syllabus:

1. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameter Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

2. Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

3. Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in

Pharmaceutical Research, Computers in Market analysis
4. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation
 Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations
Computer Simulations in Pharmacokinetics and Pharmacodynamics:
 Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems
5. Artificial Intelligence (AI), Robotics and Computational fluid dynamics:
 General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

Text book [TB]:
 1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.

Reference book(s) [RB]:
 1. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
 2. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional	1 Hr.	15	
3	End-Term Examination	3 Hr.	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPH204T	COSMETICS AND COSMECEUTICALS	4	0	0	4

Course Teacher (s): Dr. Rajiv Sighla

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

1. The key ingredients used in cosmetics and cosmeceuticals.
2. The key building blocks for various formulations.
3. The current technologies in the market
4. The various key ingredients and basic science to develop cosmetics and cosmeceuticals
5. The scientific knowledge to develop cosmetics and cosmeceuticals with

desired Safety, sensory, stability, and efficacy.

Course Syllabus:

1. Formulations approaches and Requirements

Definition of cosmetic products as per EU guidelines. Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor.

Structure of hair and hair growth cycle. Common problems associated with oral cavity.

Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arms. Formulation requirements for ethnic needs.

2. Plant Lay out, factory requirements and commonly used cosmetics raw materials

Building blocks for different product formulations of cosmetics/cosmeceuticals.

Surfactants- Classification and application. Emollients rheological additives: classification and application. Antimicrobials used as preservatives, their merits and demerits.

Factors affecting microbial preservative efficacy. Building blocks for formulation of a cream, shampoo and toothpaste.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

3. Design of special purpose cosmeceutical products

Sun protection, sunscreens classification and regulatory aspects. addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor. Dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth.

3. Herbal Cosmetics

Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

4. Formulation of Lip care products and Cosmetic Safety

Chemistry and formulation of paraphylene diamine based hair colorants. Soaps and syndet bars Labelling requirements for cosmetics Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI). Review of the list of ingredients on the labels of cosmetics, cosmeceuticals, baby care and men's range of the products in the market and conduct comparative study of the formulations.

Text book [TB]:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.

Reference book(s) [RB]:

1. Remington's Pharmaceutical Sciences.
2. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
3. Physical Pharmacy; By Alfred martin
4. Bentley's Textbook of Pharmaceutics – Rawbins.
5. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.

6. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
7. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
8. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
9. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
10. Pharmaceutical Preformulations; By J.J. We

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional	1 Hr.	15	
3	End-Term Examination	3 Hr.	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPH205P	Pharmaceutics Practical-II	0	0	12	6

Course Teacher (s):

Course Objectives:
 Upon completion of the course, student shall be able to understand countries

1. The analysis of various drugs in single and combination dosage forms
2. Theoretical and practical skills of the formulation & development.

Course Syllabus:

1. To study the effect of temperature change , non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes
5. Formulation and evaluation of niosomes
6. Formulation and evaluation of spheruls
7. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
8. Comparison of dissolution of two different marketed products /brands
9. Protein binding studies of a highly protein bound drug & poorly protein bound drug
10. Bioavailability studies of Paracetamol.
11. Pharmacokinetic and IVIVC data analysis by WinnolineR software
12. *In vitro* cell studies for permeability and metabolism
13. DoE Using Design Expert® Software
14. Formulation data analysis Using Design Expert® Software
15. Quality-by-Design in Pharmaceutical Development
16. Computer Simulations in Pharmacokinetics
17. Computer Simulations Pharmacodynamics
18. Computational Modeling Of Drug Disposition

19. To develop Clinical Data Collection manual
20. To carry out Sensitivity Analysis, and Population Modeling.
21. Development and evaluation of Creams
22. Development and evaluation of Shampoo and Toothpaste base
23. To Incorporate herbal and chemical actives to develop products
24. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

Text book [TB]:

1. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

Reference book(s) [RB]:

1. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
2. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
3. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		20	
2	Sessional	6 Hr.	30	
3	End-Term Examination	6 Hr.	100	
		Total	150	

Course code	Course Title	L	T	P	C
MRM 301T	Research Methodology and Biostatistics	4	0	0	4

Course Teacher (s):

Course Objectives:

1. Explain the objective, hypothesis, type of research work.
2. Know about the research data presentation.
3. Know about clinical research proposal, type, objectives, criterion to remove bias, sampling.
4. Know about the CPCSEA guidelines for animal experimentation.
5. Understand the biostatistics principle and analysing the experimental and clinical data.
6. Know the research work writing and correlating.

Course Syllabus:

UNIT – I

12 hrs.

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

12 hrs.

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 (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

12 hrs.

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

12

hrs.

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

12 hrs.

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

Text book [TB]:

1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney -Theresa L. White “Research Methods” (Cengage learning India Pvt. Ltd)

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Reference book(s) [RB]:

1. Remington's Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional exams	1 hours	15	
3	End-Term Examination	3 hours	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPH302S	Journal Club	0	0	0	1

Course Teacher (s):

Course Objectives:

- To promote the soft skills for the scientific program
- To develop the critical think for the pharmaceutical sector

Course Syllabus:

Text book [TB]:

- 1.
-
- 2.
- 1.
-
- 2.

Reference book(s) [RB]:

- 1.
-
- 2.
- 1.
-
- 2.
- 1.
- 2.

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode			
2	Sessional exams			
3	End-Term Examination		25	
		Total	25	

Course code	Course Title	L	T	P	C
MPH 303S	Discussion / Presentation (Proposal Presentation)	0	0	0	2

Course Teacher (s):

Course Objectives:

- To develop the review literature skills
- To promote the scientific temperament in the young researcher

Course Syllabus:

Text book [TB]:

- 1.
- 2.

Reference book(s) [RB]:

- 1.
- 2.
- 3.

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode			
2	Sessional exams			
3	End-Term Examination		50	
		Total	50	

Course code	Course Title	L	T	P	C
MPH304P	Research work	0	0	28	14

Course Teacher (s):

Course Objectives:

- To promote research skills
- To develop the critical think for the pharmaceutical sector
- To develop the review literature skills

Course Syllabus:

As per the supervisor and researcher interest

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Text book [TB]: Not applicable

1.

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2.

1.

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2.

Reference book(s) [RB]:

1.

Not applicable

2.

1.

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2.

1.

2.

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode			
2	Sessional exams			
3	End-Term Examination			
		Total	350	

Course code	Course Title	L	T	P	C
MPH401S	Journal Club	0	0	0	1

Course Teacher (s):

Course Objectives:

1. To promote the soft skills for the scientific program
2. To develop the critical think for the pharmaceutical sector
3. To promote research skills

Course Syllabus:

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<p style="font-size: 2em;"> </p>

Text book [TB]:

3.

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4.

3.

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4.

Reference book(s) [RB]:

3.

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4.

3.

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4.

3.

4.

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode			
2	Sessional exams			
3	End-Term Examination		25	
		Total	25	

Course code	Course Title	L	T	P	C
MPH402P	Research work	0	0	31	16

Course Teacher (s):

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Course Objectives:

1. To promote research skills
2. To develop the critical think for the pharmaceutical sector
3. To develop the review literature skills

Course Syllabus:

As per the supervisor and researcher interest

Text book [TB]: Not applicable

3.

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4.

3.

—

4.

Reference book(s) [RB]:

3.

Not applicable

4.

3.

—

4.

3.

4.

Evaluation Scheme:				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode			
2	Sessional exams			
3	End-Term Examination			
		Total	350	

Course code	Course Title	L	T	P	C
MPH403S	Discussion /Final Presentation	0	0	0	3

<u>Course Teacher (s):</u>				
<u>Course Objectives:</u>				
<ol style="list-style-type: none"> 1. To develop the review literature skills 2. To promote the scientific temperament in the young researcher 3. To promote research skills 				
<u>Course Syllabus:</u>				
<u>Text book [TB]:</u>				
<ol style="list-style-type: none"> 1. 2. 				
<u>Reference book(s) [RB]:</u>				
<ol style="list-style-type: none"> 1. 2. 3. 				
<u>Evaluation Scheme:</u>				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode			
2	Sessional exams			
3	End-Term Examination		75	
		Total	75	

M. Pharma (Pharmacology)

Course code	Course Title	L	T	P	C
MPL101T	MODERN PHARMACEUTICAL ANALYSIS	4	0	0	4

Course Teacher (s):

Course Objectives:

1. Chemicals and Excipients
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

Course Syllabus:

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. **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. **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.

12 Hrs

2

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

12 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

12 Hrs

4

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

- a) Paper chromatography
- b) Thin Layer chromatography
- c) Ion exchange chromatography
- d) Column chromatography
- e) Gas chromatography
- f) High Performance Liquid chromatography
- g) Affinity chromatography

12 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.

12 Hrs

Text book [TB]:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

Reference book(s) [RB]:

1. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
2. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional exams	1 hours	15	
3	End-Term Examination	3 hours	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPL 102T	ADVANCED PHARMACOLOGY-I	4	0	0	4

Course Teacher (s):

Course Objectives:

1. Discuss the pathophysiology and pharmacotherapy of certain diseases.
2. Explain the mechanism of drug actions at cellular and molecular level.
3. Understand the adverse effects, contraindications.
4. Clinical uses of drugs used in treatment of diseases.

Course Syllabus:

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. 06 hrs
- 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. 06 hrs

UNIT-II

12 Hrs

Neurotransmission

- a. General aspects and steps involved in neurotransmission.
- b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
- c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].
- d. Non adrenergic non cholinergic transmission (NANC). 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
84

a. Autonomic Pharmacology

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

UNIT-III

12 Hrs

Central nervous system Pharmacology

General and local anesthetics 02 hrs
Sedatives and hypnotics, drugs used to treat anxiety. 02 hrs
Depression, psychosis, mania, epilepsy, neurodegenerative diseases. 05 hrs
Narcotic and non-narcotic analgesics. 03 hrs

UNIT-IV

Cardiovascular Pharmacology

12 Hrs

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. 07 hrs

Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs 05 hrs

UNIT- V

Autocoid Pharmacology

12 Hrs

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins
Opioid autocoids Pharmacology of antihistamines, 5HT antagonists.

Text book [TB]:

1.Pharmacology by H.P. Rang and M.M. Dale.

Reference book(s) [RB]:

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.

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional exams	1 hours	15	
3	End-Term Examination	3 hours	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPL 103T	Pharmacological and Toxicological Screening Methods-I	4	0	0	4

Course Teacher (s):

Course Objectives:

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

Course Syllabus:

Unit-I

12 Hrs

Laboratory Animals

Common lab 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.

Unit-II

12 Hrs

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

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

Unit-III

12 Hrs

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.

Unit-IV

12 hrs

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

Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antihyperlipidemic, and agents. Anti cancer agents

Unit V

12 hrs

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

Immunosuppressants and immunomodulators

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.

Text book [TB]:

1. Fundamentals of experimental Pharmacology by M.N.Ghosh
2. Preclinical evaluation of new drugs by S.K. Gupta

Reference book(s) [RB]:

1. Drug discovery and Evaluation by Vogel H.G

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional exams	1 hours	15	
3	End-Term Examination	3 hours	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPL 104 T	Cellular and Molecular Pharmacology	4	0	0	4

Course Teacher (s):

Course Objectives:

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

Course Syllabus:

Unit I

12 Hrs

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 II

12Hrs

Cell signaling

Intercellular and intracellular signaling pathways.
 Classification of receptor family and molecular structure ligand gated ion channels; Gprotein coupled receptors, tyrosine kinase receptors and nuclear receptors.
 Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-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 III

12Hrs

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 IV

12Hrs

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

Unit V

12Hrs

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

Unit VI

Biosimilars

Text book [TB]:

1. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al

Reference book(s) [RB]:

1. Current protocols in molecular biology vol I to VI edited by Frederick M. Ausuvel et la.

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional exams	1 hours	15	
3	End-Term Examination	3 hours	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPL 105 P	Pharmacology Practical I	0	0	12	6

Course Teacher (s):

Course Syllabus: 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 Bradford/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.

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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)

Text book [TB]:

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. Spectrometric Identification of Organic compounds - Robert M Silverstein

Reference book(s) [RB]:

1. Drug discovery and Evaluation by Vogel H.G.

Evaluation Scheme:

	Evaluation Component	Durat ion	Weig htage (%)	Date, Time & Venue
1	Continuous mode		20	
2	Sessional exams	6 hours	30	
3	End-Term Examination	6 hours	100	
		Total	150	

Course code	Course Title	L	T	P	C
MPL 106 S	SEMINAR / ASSIGNMENT	0	0	7	4

Course Teacher (s):

Course Syllabus: NA

Text book [TB]:

NA

Reference book(s) [RB]:

NA

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode	-	-	-
2	Sessional exams	-	-	-
3	End-Term Examination	-	-	-
		Total	100	

Course code	Course Title	L	T	P	C
MPL 201 T	Advanced Pharmacology II	4	0	0	4

Course Teacher (s):

Course Objectives:

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

Course Syllabus:

Endocrine Pharmacology 12 Hrs

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

UNIT-II

Chemotherapy 12 Hrs

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

UNIT-III 12 Hrs

Chemotherapy 06 Hrs

Drugs used in Protozoal Infections

Drugs used in the treatment of Helminthiasis

Chemotherapy of cancer

Immunopharmacology 06 Hrs

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants

UNIT-IV

GIT Pharmacology 08 Hrs

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology 04 Hrs

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT-V

Free radicals Pharmacology 04 Hrs

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: 08 Hrs

Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

Text book [TB]:

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.

Reference book(s) [RB]:

1. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
2. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional exams	1hr	15	
3	End-Term Examination	3 hr	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPL 202 T	Pharmacological and Toxicological Screening Methods-II	4	0	0	4

Course Teacher (s):

Course Objectives:

1. Upon completion of the course, the student shall be able to, Explain the various types of toxicity studies.
2. Appreciate the importance of ethical and regulatory requirements for toxicity studies.
3. Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Course Syllabus:

Unit I 12 Hrs

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 II 12 Hrs

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 III 12 Hrs

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II)
Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies)
In vivo carcinogenicity studies

Unit IV 12 Hrs

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 V 12 Hrs

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics
Importance and applications of toxicokinetic studies.
Alternative methods to animal toxicity testing.

Text book [TB]:

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.

Reference book(s) [RB]:

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

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional exams	1 hour	15	
3	End-Term Examination	3 hours	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPL 203 T	Principles of Drug Discovery	4	0	0	4

Course Teacher (s):**Course Objectives:**

1. Upon completion of the course, the student shall be able to, Explain the various stages of drug discovery.
2. Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
3. Explain various targets for drug discovery.
4. Explain various lead seeking method and lead optimization
5. Appreciate the importance of the role of computer aided drug design in drug discovery .

Course Syllabus:**Unit-I 12 Hrs**

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-II 12 Hrs

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-III 12 Hrs**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-IV 12 Hrs

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-V 12 Hrs

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

Text book [TB]:

1. MouldySioud. 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. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols.
4. Springer New York Dordrecht Heidelberg London

Reference book(s) [RB]:

1. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
2. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., Hoboken, New Jeney

Evaluation Scheme:				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional exams	1 hour	15	
3	End-Term Examination	3 hours	75	
		Total	100	

Course code	Course Title	L	T	P	C
MPL 204 T	Clinical Research & Pharmacovigilance	4	0	0	4

Course Teacher (s):
<p>Course Objectives:</p> <p>Upon completion of the course, the student shall be able to, Explain the regulatory requirements for conducting clinical trial</p> <ol style="list-style-type: none"> 1. Demonstrate the types of clinical trial designs 2. Explain the responsibilities of key players involved in clinical trials 3. Execute safety monitoring, reporting and close-out activities 4. Explain the principles of Pharmacovigilance 5. Detect new adverse drug reactions and their assessment 6. Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance
<p>Course Syllabus:</p> <p>UNIT-I 12 hours</p> <p>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</p> <p>UNIT- II 12 hours</p> <p>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</p> <p>UNIT- III 12 hours</p>

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-IV 12 hours

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-V 12 hours

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.

UNIT-VI

Pharmacoeconomics, Dermatology, safety pharmacology

Text book [TB]:

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. 230
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.

Reference book(s) [RB]:

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. 230

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.

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional exams	1 hour	15	
3	End-Term Examination	3 hours	75	
		Total	<u>100</u>	

Course code	Course Title	L	T	P	C
MPL 205 P	Experimental Pharmacology II	0	0	12	6

Course Teacher (s):

Course Objectives:

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

Course Syllabus:

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue

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

Text book [TB]:

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 Thomse

Reference book(s) [RB]:

1. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
2. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		20	
2	Sessional exams	6 hours	30	
3	End-Term Examination	6 hours	100	
		Total	150	

Course code	Course Title	L	T	P	C
MPL 106 S	SEMINAR / ASSIGNMENT	0	0	7	4

<u>Course Teacher (s):</u>				
<u>Course Syllabus: NA</u>				
<u>Text book [TB]:</u>				
NA				
<u>Reference book(s) [RB]:</u>				
NA				
<u>Evaluation Scheme:</u>				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode	-	-	-
2	Sessional exams	-	-	-
3	End-Term Examination	-	-	-
		Total	100	

Course code	Course Title	L	T	P	C
MRM 301T	Research Methodology and Biostatistics	4	0	0	4

<u>Course Teacher (s):</u>	
<u>Course Objectives:</u>	
<ul style="list-style-type: none"> ● Explain the objective, hypothesis, type of research work. ● Know about the research data presentation. ● Know about clinical research proposal, type, objectives, criterion to remove bias, sampling. ● Know about the CPCSEA guidelines for animal experimentation. ● Understand the biostatistics principle and analysing the experimental and clinical data. ● Know the research work writing and correlating. 	
<u>Course Syllabus:</u>	
UNIT – I	12 hrs.

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

12 hrs.

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 (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

12 hrs.

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

12 hrs.

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

12 hrs.

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

Text book [TB]:

1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney -Theresa L. White “Research Methods” (Cengage learning India Pvt. Ltd)

Reference book(s) [RB]:

1. Remington’s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications

<u>Evaluation Scheme:</u>				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode		10	
2	Sessional exams	1 hours	15	
3	End-Term Examination	3 hours	75	
		Total	<u>100</u>	

Course code	Course Title	L	T	P	C
MPL 302S	Journal club	0	0	0	1

<u>Course Teacher (s):</u>
<u>Course Objectives:</u> <ul style="list-style-type: none"> • To promote the soft skills for the scientific program • To develop the critical think for the pharmaceutical sector
<u>Course Syllabus:</u> <u>As per the supervisor and researcher interest</u>
<u>Text book [TB]: Not applicable</u> <u>NA</u>
<u>Reference book(s) [RB]:</u>

<u>Evaluation Scheme:</u>				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode	-	-	-
2	Sessional exams	-	-	-
3	End-Term Examination	-	-	-
		Total	<u>25</u>	

Course code	Course Title	L	T	P	C
MPL 303 S	Discussion / Presentation (Proposal Presentation)	0	0	0	2

Course Teacher (s):

Course Objectives:

- To develop the review literature skills
- To promote the scientific temperament in the young researcher

Course Syllabus:

NA

Text book [TB]:

A

Reference book(s) [RB]:

NA

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode	-	-	-
2	Sessional exams	-	-	-
3	End-Term Examination	-	-	-
		-	-	-
		Total	50	-

Course code	Course Title	L	T	P	C
MPL 304 P	Research Work	0	0	28	14

Course Teacher (s):

Course Objectives:

- To promote research skills

Course Syllabus:

NA

<u>Text book [TB]:</u>				
<u>Reference book(s) [RB]:</u> NA				
<u>Evaluation Scheme:</u>				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode	-	-	-
2	Sessional exams	-	-	-
3	End-Term Examination	-	-	-
		-	-	-
		Total	350	-

Course code	Course Title	L	T	P	C
MPL 401 S	Journal Club	0	0	0	1

<u>Course Teacher (s):</u>				
<u>Course Objectives:</u>				
<ol style="list-style-type: none"> To promote the soft skills for the scientific program To develop the critical think for the pharmaceutical sector 				
<u>Course Syllabus:</u>				
NA				
<u>Text book [TB]:</u>				
<u>Reference book(s) [RB]:</u> NA				
<u>Evaluation Scheme:</u>				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode	-	-	-
2	Sessional exams	-	-	-
3	End-Term Examination	-	-	-
		-	-	-

		Total	25	-
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Course code	Course Title	L	T	P	C
MPL 402 P	Research Work	0	0	31	16

<u>Course Teacher (s):</u>				
<u>Course Objectives:</u>				
<u>Course Syllabus:</u>				
<u>NA</u>				
<u>Text book [TB]:</u>				
<u>Reference book(s) [RB]:</u>				
<u>NA</u>				
<u>Evaluation Scheme:</u>				
	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode	-	-	-
2	Sessional exams	-	-	-
3	End-Term Examination	-	-	-
		-	-	-
		Total	400	-

Course code	Course Title	L	T	P	C
MPL 403 S	Discussion /Final Presentation	0	0	0	3

<u>Course Teacher (s):</u>				
<u>Course Objectives:</u>				
<u>Course Syllabus:</u>				
<u>NA</u>				

Text book [TB]:

Reference book(s) [RB]:

NA

Evaluation Scheme:

	Evaluation Component	Duration	Weightage (%)	Date, Time & Venue
1	Continuous mode	-	-	-
2	Sessional exams	-	-	-
3	End-Term Examination	-	-	-
		-	-	-
		Total	75	-