YENEPOYA
(DEEMED TO BE UNIVERSITY)

REGULATIONS AND CURRICULUM GOVERNING

M.PHARM PROGRAM

(Based on the notification in the Gazette of India No 362, Dated December 11, 2014)

Yenepoya Pharmacy College & Research Centre



Deralakatte, Mangalore, Karnataka.

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NOTIFICATION FROM THEUNIVERSITY

भारतीय भेषजी परिषद्
(स्वास्थ्य एवं परिवार कल्याण मंत्रालय के अंतर्गत सांविधिक निकाय)
भारत सरकार
आई-300, तीसरी मंजिल, टावर-1, वर्ल्ड ट्रेड सेंटर,
नौरोजी नगर, नई दिल्ली-110029
टेलीफोन नंबर 011-65218900-01
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PHARMACY COUNCIL OF INDIA
(Statutory body under Ministry of Health & Family Welfare)
Government of India
I-300, 3rd floor, Tower-I, World Trade Centre,
Nauroji Nagar, New Delhi-110029
Telephone No. 011-65218900-01
E-mail: registrar@pci.nic.in

कामये दु:खतप्तानाम् प्राणिनामार्तिनाशनम्

DECISION LETTER

Institute Name/Inst ID Yenepoya Pharmacy College Research Centre University Road Deralakatte Mangalore 575018 / PCI-2666
State KARNATAKA
District -
Village/Town/City Naringana
Pin Code 575018

Sir/Madam
With reference to the subject cited above i am directed to convey the approval of PCI as per Following Details

Course	Name of Affiliation body/University	Decision	Approval Status	Approval Up to / Academic Session	Intake
D.Pharm	The Controller of Examinations Yenepoya university University Road Deralakatte Mangalore	D.Pharm Extend approval upto 2025-2026 academic session for 60 admissions for D.Pharm course.	Approved	2025-2026	60
B.Pharm	The Controller of Examinations Yenepoya university University Road Deralakatte Mangalore	B.Pharm Extend approval up to 2025-2026 academic session for 60 admissions for B.Pharm course.	Approved	2025-2026	60
M.Pharm Pharmacology	The Controller of Examinations Yenepoya university University Road Deralakatte Mangalore	M.Pharm (Pharmacology)	Approved	2025-2026	15
M.Pharm Pharmacy Practice	The Controller of Examinations Yenepoya university University Road Deralakatte Mangalore	M.Pharm (Pharmacy Practice)	Approved	2025-2026	15
M.Pharm Regulatory Affairs	The Controller of Examinations Yenepoya university University Road Deralakatte Mangalore	M.Pharm (Regulatory Affairs)	Approved	2025-2026	15
M.Pharm	The Controller of	M.Pharm (Pharmaceutics)	Approved	2025-2026	12

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APPROVALS

भारतीय भेषजी परिषद्
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DECISION LETTER

Course	Name of Affiliation body/University	Decision	Approval Status	Approval Up to / Academic Session	Intake
Pharmaceutics	Examinations Yenepoya university University Road Deralakatte Mangalore	M.Pharm (Pharmaceutics)	Approved	2025-2026	12
Pharm.D	The Controller of Examinations Yenepoya university University Road Deralakatte Mangalore	Pharm.D Grant approval for 2025-2026 academic session for the conduct of 4th year for 30 admissions for Pharm.D course. Allow 30 admissions in 2025-2026 academic session in 1st year.	Approved	2025-2026	30

Communication Date: 30 Aug 2025

डॉ नरेन्द्र मु. गोपेकर

For
Registrar-cum-Secretary
PCI

Copy to

i) Registrar of the University

ii) Principal of the college

iii) Secretary/Chairman of the Trust/Society

iv) Guard File (PCI)

Note: Validity of the course details may be verified at pci.gov.in

कामये दुःखतप्तानाम् प्राणिनामार्तिनाशनम्

YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

Office of the Registrar
University Road
Deralakatte, Mangalore – 575 018
Ph: 0824 – 2204667/68/69/70/71
Fax: 0824 - 2203943

NOTIFICATION – 43-ACM/2021 dtd.07.07.2021

Sub: Starting of PG Program (M.Pharm) under the Faculty of Pharmacy

Ref: Resolution of the 43rd Academic Council at its meeting held on 07.07.2021 vide agenda - 16

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The Academic Council at its 43rd meeting held on 07.07.2021 and subsequently the Board of Management at its meeting held on 08.07.2021 have approved the proposal for starting M.Pharm program under the Faculty of Pharmacy from the academic year 2022-23.

REGISTRAR
mj

To:

The Principal, Yenepoya Pharmacy College & Research Centre

Copy to:

1. Controller of Examinations
2. File copy

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1. PREAMBLE

The M. Pharm Program was initiated in Yenepoya (Deemed to be University) held on 07.07.2021 and subsequently the Board of Management held on 08.07.2021 have approved the proposal of starting M. Pharm program under the Faculty of Pharmacy from the academic year 2002-23

2. Eligibility for Admission

M. Pharmacy: Minimum qualification for admission

A. Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B. Pharm.)

b) 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.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B. Pharm.)

3. Duration of the program

The program of study for M. Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Maximum period for completion of program

- **Standard Duration:** The M. Pharm program is a full-time, two-year (four semesters) course.
- **Maximum Limit:** Students are generally allowed a maximum of four years (eight semesters) from the date of initial registration to complete all academic requirements.

5. Aim of the Program

To develop competent, research-oriented professionals who can contribute to the advancement of pharmaceutical sciences and the healthcare needs of the country.

6. Objectives (outcomes of the program)

PROGRAM OUTCOMES

M.PHARM – PHARMACEUTICS

PO 1:	Apply knowledge and skills in filing or documentation or registering of drug products in different countries as per the guidelines.
PO 2:	To understand the use of different software and modern tools to analyse and solve the problems.
PO 3:	Able to understand the theoretical and practical analytical skills of instruments.
PO 4:	To develop the formulation and evaluate the novel drug delivery systems.
PO 5:	Understand the stability testing, optimization and pilot plant scale up techniques.
PO 6:	To know the role of computers in market analysis and clinical development.
PO 7:	Ability to work in a multidisciplinary environment in research, academia and pharmaceutical industry.
PO 8:	To develop cosmetics and cosmeceuticals with desired safety and efficacy.
PO 9:	Able to design and evaluate dosage regimens of using pharmacokinetic and biopharmaceutics parameters.
PO 10:	To understand basic research methodology to carry out the research work.

M.PHARM – REGULATORY AFFAIRS

PO 1:	Exhibit proficiency in pharmaceutical compliance standards governing medicinal product authorization, clinical research protocols, and quality assurance frameworks (GxP systems)
PO 2:	Cultivate proficiency in issue detection, causal investigation, and systematic resolution
PO 3:	Demonstrate proficiency in formulating regulatory compliance frameworks and proposing corrective interventions for regulatory enforcement actions (including FDA-483/Warning Letter scenarios)
PO 4:	Apply specialized knowledge to execute systematic audits and conduct comprehensive evaluations of quality deviations in pharmaceutical production and clinical trial operations
PO 5:	Demonstrate expertise in deploying advanced regulatory technology solutions including electronic submission platforms (e.g., eCTD, RIM systems) and compliance management tools
PO 6:	Develop entrepreneurial acumen to innovate and deliver pharmaceutical solutions that address societal healthcare needs
PO 7:	Analyze the environmental footprint of drug manufacturing processes and implement sustainable green chemistry solutions to minimize ecological impact
PO 8:	Embed ethical principles in clinical trial conduct and pharmaceutical regulatory practice to uphold the highest standards of research integrity
PO 9:	Foster compliant teamwork and cross-functional synergy in regulatory practice, employing problem-based learning to advance pharmaceutical innovation
PO10:	Formulate research concepts, master technical and interpersonal communication, and synthesize data to construct evidence-based conclusions

PO 11:	Optimize human capital, budgetary allocations, and operational assets to deliver project outcomes aligned with stakeholder expectations
PO 12:	Develop self-directed learning agility to drive innovation, leadership excellence, and adaptive problem-solving in dynamic pharmaceutical landscapes

M.PHARM – PHARMACY PRACTICE

PO 1:	To understand clinical and therapeutic aspects of various diseases
PO 2:	To develop skills in critically evaluating and practicing evidence-based medicine along with managing drug related problems.
PO 3:	Ability to provide patient-centred care and demonstrate effective communication and counselling skills.
PO 4:	Develop an ability to identify and provide solution in the areas of clinical and community pharmacy.
PO 5:	Ability to manage inventory and dispensing of medications in accordance with legal and regulatory requirements
PO 6:	Analyze and interpret the pattern of drug use, effectiveness and safety in populations.
PO 7:	To understand ethical principles and guidelines governing research involving human subjects.
PO 8:	To assess cost effectiveness of pharmaceutical interventions and health policies.
PO 9:	To know various research methodology techniques to carrying out research work.
PO10:	To understand medication safety principles and be able to manage medication-related errors and adverse events.

M.PHARM – PHARMACOLOGY

PO1:	Apply interdisciplinary and pharmacology knowledge in the treatment of diseases.
PO2:	Develop the capacity to formulate, plan, and carry out experiments to identify pertinent remedies to society-related, applied and industrial problems.
PO3:	Conduct pharmacological screening in the models and analyze the significant outcomes that brings about the translational value and benefits the society.
PO4:	Solve a research problem using modern analytical & molecular techniques, softwares & tools, animal models, reasoning & problem-solving skills as per the needs of pharmaceutical industry.
PO5:	Inculcate the ethics and professional principles in animal and clinical research of drug discovery and development according to the regulatory bodies
PO6:	Detect and monitor new toxicities, adverse drug reactions and help avoid human misery by systematic reporting
PO7:	Operate well both individually and as a team member or leader in multicultural and multidisciplinary contexts for team-building exercises.
PO8:	Utilize scientific expertise for consultancy, business ventures and industrial collaboration and use.

PO9:	Develop overall personality by imparting soft skills for efficient communication and presentation of research findings.
PO10:	Demonstrate the knowledge of sustainable development and its importance while comprehending the effects of professional pharmaceutical solutions in societal and environmental contexts.

COURSE OUTCOME

M.PHARM - PHARMACEUTICS

Semester	Course Name	Course Outcomes	
I	Modern Pharmaceutical Analytical Techniques	CO1	Explain the theoretical principles, instrumentation & applications of UV, IR spectroscopy, Fluorimeter and flame photometer.
		CO 2	Understand & apply basic principles and instrumentation of H1 NMR, C13 NMR & Mass.
		CO 3	Understand basic principles involved in TLC, column chromatography and paper chromatography
		CO 4	Remember & understand the theory instrumentation of GC, HPLC, gel chromatography, ion exchange chromatography and affinity chromatography.
		CO 5	Explain Instrumentation and separation of compounds by electrophoresis technique & natural products separation by various chromatographic techniques.
		CO 6	Understand & apply the principles of X-ray refraction and diffraction methods.
	Drug delivery system	CO 1	Select drugs as suitable candidates for various novel drug delivery systems based on their physicochemical properties.
		CO 2	Select polymers, retardants, and other additives based on the requirement and desired characteristics of the drug delivery.
		CO 3	Formulate and design controlled release and sustained-release drugs, protein drugs, and vaccine delivery systems.
		CO 4	Evaluate drug delivery system for physicochemical characteristics, in vitro and in vivo drug release.
		CO 5	Conduct stability studies for dosage forms as per prescribed guidelines
		CO 6	Describe the concepts of personalized medicines and tele pharmacy in the optimization of therapy in patients.
	Modern Pharmaceutics	CO 1	Students will be able to remember the concepts and importance of pre formulation studies, large volume and small volume parenterals.
		CO 2	Students will be able to understand the theories of pharmaceutical dispersions, concept of optimization process and their applications in pharmaceutical industries.
		CO 3	Students will apply the statistical design in the development of different formulations.

			CO 4	Students will be able to analyze the validation process for different dosage forms, ICH and WHO guidelines for calibration and validation of equipment.
			CO 5	Students will be able to evaluate the GMP and cGMP considerations involved in pharmaceutical industries
			CO 6	Students will be able to learn and create inventory management and control.
		Regulatory affairs	CO 1	Students will be able to remember the CFR and ICH guidelines for Q S E M.
			CO 2	Students will be able to understand the concept of innovator, generic drug and documentation requirements.
			CO 3	Students will apply the guidelines of SUPAC and principles involved in outsourcing of BA & BE to CRO.
			CO 4	Students will be able to analyze the pharmacovigilance and its process in monitoring the clinical trials.
			CO 5	Students will be able to evaluate the regulatory guidelines for filing the approval process.
			CO 6	Students will be able to learn and create the dossiers and their submissions to regulatory agency.
	II	Molecular Pharmaceutics (Nano tech and targeted DDS)	CO 1	Students will be able to remember the concept of designing drug delivery systems for targeting drugs to tumours and to the brain.
			CO 2	Students will be able to understand how to select drugs, polymers in designing microspheres/ microcapsules.
			CO 3	Students will apply the strategies for improving nasal absorption in the design of nasal drug delivery systems.
			CO 4	Students will be able to analyze how to optimize pulmonary delivery by designing suitable aerosols, nebulizers and dry powder inhalers.
			CO 5	Students will be able to evaluate how to formulate aquasomes, niosomes, phytosomes and electrosomes for various applications in drug targeting.
			CO 6	Students will be able to learn and create to apply gene therapy in the treatment of cancer and inherited diseases.
		Advanced Biopharmaceutics & Pharmacokinetics	CO 1	Explain mechanism of drug absorption & various factors affecting drug absorption.
			CO 2	Learn various biopharmaceutics factors affecting drug bioavailability.
			CO 3	Learn various method of dissolution testing and in vitro - in vivo correlation dissolution data.
			CO 4	Understand basic considerations of pharmacokinetic models.
			CO 5	Understand different compartment model and non-compartment model.

		CO 6	Explain the design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutics parameters.
	Computer aided drug development	CO 1	Students will be able to remember the ICH Q8 guidelines.
		CO 2	Students will be able to understand the statistical modeling in pharmaceutical research and development.
		CO 3	Students will apply the concepts of optimization and optimization parameters in formulation development.
		CO 4	Students will be able to analyze the in vitro dissolution and in vivo correlation.
		CO 5	Students will be able to evaluate the computer simulations in pharmacokinetics and pharmacodynamics.
		CO 6	Students will be able to learn and create the Factorial design for formulations.
	Cosmetics & Cosmeceuticals	CO 1	Students will be able to remember the definition of cosmetic products as per Indian regulation and Indian regulatory requirements for cosmetics.
		CO 2	Students will be able to understand the common problems associated with oral cavity and skin.
		CO 3	Students will apply the concepts of building blocks for different product formulations of cosmetics/cosmeceuticals.
		CO 4	Students will be able to analyze the challenges in formulating herbal cosmetics.
		CO 5	Students will be able to evaluate the factors affecting microbial preservative efficacy.
		CO 6	Students will be able to learn and create design and formulations of cosmetics, cosmeceuticals and herbal cosmetics.
III	Research Methodology & Biostatistics	CO 1	Students will be able to remember the CPCSEA guidelines for laboratory animal facility and ethics guidelines.
		CO 2	Students will be able to understand the study design and types of studies in general research methodology.
		CO 3	Students will be able to apply the concepts of statistical tests of significance, null hypothesis and interpretation of 'P' values.
		CO 4	Students will analyze the basic principles involved in medical research and medical care.
		CO 5	Students will be able to evaluate the parametric and non-parametric tests.
		CO 6	Students will be able to create and carry out crossover design study.

M.PHARM REGULATORY AFFAIRS

Semester	Course Name	Course Outcomes

Good Regulatory Practices	CO1	Students will be able to understand the principles and implementation of Current Good Manufacturing Practices (cGMP).
	CO 2	Students will be able to analyze the components and requirements of Good Laboratory Practices (GLP).
	CO 3	Students will be able to remember the key elements and procedures involved in Good Automated Laboratory Practices (GALP).
	CO 4	Students will be able to evaluate the scope and application of Good Distribution Practices (GDP) in pharmaceutical logistics.
	CO 5	Students will be able to apply the core concepts of a Quality Management System (QMS) in regulatory and industrial settings.
	CO 6	Students will be able to learn the structure and purpose of checklists and Standard Operating Procedures (SOPs) used in regulated environments.
Documentation and Regulatory Writing	CO1	Students will be able remember the documentation pertaining to drugs in pharmaceutical Industry.
	CO 2	Students will be able to understand the basics of dossier preparation.
	CO 3	Students will apply the regulatory guidelines for the audits.
	CO 4	Students will be able to analyze the root cause analysis & CAPA during inspections.
	CO 5	Students will be able to evaluate and follow up the submissions and post approval document requirements.
	CO 6	Students will be able to learn and create and assemble the regulation submission as per the requirements of agencies.
Clinical Research Regulations	CO1	Students will be able to understand the History, origin, and ethics of clinical and biomedical research and evaluation
	CO 2	Students will be able to evaluate the concept of Clinical drug, medical device development process, different types and phases of clinical trials
	CO 3	Students will be able to apply knowledge the regulatory requirements and guidance for the conduct of clinical trials and research.
	CO 4	Students will be able to evaluate the clinical and ethical principles, including the informed consent form, its process, and documentation.
	CO 5	Students will be able to remember the key principles of Indian GCP, CDSCO, and ICMR guidelines applicable to biomedical research.

	Regulations and Other Legislation in India and Intellectual Property Rights	CO1	Students will be able to create a comprehensive overview of the approval processand regulatory requirements for drugs & cosmetics, medical devices, biologicals, herbals, and food & nutraceuticals in India.
		CO 2	Students will be able to evaluate the Indian Pharmacopoeial and Bureau of Indian Standards (BIS) for quality and compliance in pharmaceutical products.
		CO 3	Students will be able to analyze the guidelines for drug testing in animals, focusing on ethical considerations, regulatory expectations, and scientific validation.
		CO 4	Students will be able to apply the core principles of Intellectual Property Rights (IPR) in pharmaceutical and healthcare product development.
		CO 5	Students will be able to understand the various acts and guidelines governing drugs & cosmetics, medical devices, biologicals, herbals, and nutraceuticals in the Indian regulatory landscape.
		CO6	Students will be able to remember the foundational regulations and protocols related to preclinical animal testing and their application in drug development.

M.PHARM PHARMACY PRACTICE

Semester	Course Name	Course Outcomes	
I	Modern Pharmaceutical Analytical Techniques	CO1	Explain the theoretical principles, instrumentation & applications of UV, IR spectroscopy, Fluorimeter and flame photometer.
		CO 2	Understand & apply basic principles and instrumentation of H1 NMR, C13 NMR & Mass.
		CO 3	Understand basic principles involved in TLC, column chromatography and paper chromatography
		CO 4	Remember & understand the theory instrumentation of GC, HPLC, gel chromatography, ion exchange chromatography and affinity chromatography.
		CO 5	Explain Instrumentation and separation of compounds by electrophoresis technique & natural products separation by various chromatographic techniques.
		CO 6	Understand & apply the principles of X-ray refraction and diffraction methods.

Clinical Pharmacy Practice	CO1	Demonstrate the ability to conduct a thorough patient assessment and develop a comprehensive medication therapy plan.
	CO 2	Apply principles of evidence-based medicine to make clinical decisions.
	CO 3	Communicate effectively with healthcare team members, patients, and caregivers.
	CO 4	Evaluate and monitor medication therapy for efficacy and safety.
	CO 5	Identify and manage medication-related problems.
	CO 6	Demonstrate knowledge of pharmacokinetics, pharmacodynamics, and pharmacogenomics aspects of a drug.
Pharmacotherapeutics-I	CO1	Demonstrate knowledge of the pharmacological principles of drug action and the mechanisms of drug interactions.
	CO 2	Understand basic principles of drug utilization evaluation.
	CO 3	Explain the pharmacokinetics and pharmacodynamics aspects of the drugs.
	CO 4	Develop skills in the selection and monitoring of drug therapy.
	CO 5	Understand and apply legal and ethical aspects of drug therapy.
	CO 6	Develop skills in patient counseling and medication therapy management.
Hospital & Community Pharmacy	CO1	Remember and understand the concept of medication use process in hospital and community pharmacy settings.
	CO 2	Able to communicate effectively with healthcare team members, patients, and caregivers.
	CO 3	Remember and apply principles of medication safety to prevent errors and adverse events.
	CO 4	Manage inventory and dispensing of medications in accordance with legal and regulatory requirements.
	CO 5	Develop skills to provide patient counseling on medication therapy and disease management.
	CO 6	Understand and apply the different pharmaceutical care services including compounding, infusion therapy, and medication therapy management.
Clinical Research	CO1	Remember and describe the basic principles of clinical research design and methodology.
	CO 2	Understand and identify appropriate study endpoints and outcome measures.
	CO 3	Develop study protocols and obtain regulatory approval.

		CO 4	Understand the concept of various study design and analyze data using appropriate statistical methods.
		CO 5	Develop skills to interpret study results and draw conclusions.
		CO 6	Communicate study findings through written reports and presentations.
II	Principles of Quality Use of Medicines	CO1	Describe the principles of safe and effective medication use.
		CO 2	Develop skills to identify factors that contribute to medication-related problems.
		CO 3	Apply principles of medication safety to prevent errors and adverse events.
		CO 4	Understand and develop strategies to promote medication adherence.
		CO 5	Evaluate the impact of medication therapy on patient outcomes.
		CO 6	Communicate effectively with healthcare team members, patients, and caregivers regarding medication use.
	Pharmacotherapeutics-II	CO1	Develop and implement appropriate treatment plans for complex disease states.
		CO 2	Evaluate the efficacy and safety of medication therapy for complex disease states.
		CO 3	Develop skills to identify and manage drug interactions and adverse effects in complex disease states.
		CO 4	Understand and apply principles of pharmacogenomics to personalize medication therapy.
		CO 5	Discuss the role of non-pharmacologic therapies in the management of complex disease states.
		CO 6	Communicate effectively with healthcare team members, patients, and caregivers regarding complex medication regimens.
	Pharmacotherapeutics-II	CO1	Develop and implement appropriate treatment plans for complex disease states.
		CO 2	Evaluate the efficacy and safety of medication therapy for complex disease states.
		CO 3	Develop skills to identify and manage drug interactions and adverse effects in complex disease states.
		CO 4	Understand and apply principles of pharmacogenomics to personalize medication therapy.
		CO 5	Discuss the role of non-pharmacologic therapies in the management of complex disease states.

		CO 6	Communicate effectively with healthcare team members, patients, and caregivers regarding complex medication regimens.
	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	CO1	Describe the principles of pharmacokinetics and pharmacodynamics.
		CO 2	Apply pharmacokinetic principles to individualize medication dosing.
		CO 3	Interpret therapeutic drug monitoring results and adjust medication doses accordingly.
		CO 4	Identify factors that can affect drug metabolism and elimination.
		CO 5	Evaluate the impact of renal and hepatic dysfunction on medication therapy.
		CO 6	Communicate effectively with healthcare team members, patients, and caregivers regarding medication dosing and monitoring.
	Pharmacoepidemiology & Pharmacoeconomics	CO1	Describe the principles of pharmacoepidemiology and pharmacoeconomics.
		CO 2	Evaluate the cost-effectiveness of medication therapy.
		CO 3	Develop skills to identify factors that contribute to medication non-adherence.
		CO 4	Apply principles of medication safety to prevent errors and adverse events.
		CO 5	Evaluate the impact of medication therapy on healthcare utilization and costs.
		CO 6	Effective communication with healthcare team members, patients, and caregivers regarding medication costs and adherence.
III	Research Methodology & Biostatistics	CO 1	Students will be able to remember the CPCSEA guidelines for laboratory animal facility and ethics guidelines.
		CO 2	Students will be able to understand the study design and types of studies in general research methodology.
		CO 3	Students will be able to apply the concepts of statistical tests of significance, null hypothesis and interpretation of ‘P’ values.
		CO 4	Students will analyze the basic principles involved in medical research and medical care.
		CO 5	Students will be able to evaluate the parametric and non-parametric tests.
		CO 6	Students will be able to create and carry out crossover design study.

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M.PHARM PHARMACOLGY

Semester	Course Name	Course Outcomes	
I	Modern Pharmaceutical Analytical Techniques	CO1	Explain the theoretical principles, instrumentation & applications of UV, IR spectroscopy, Fluorimeter and flame photometer.
		CO 2	Understand & apply basic principles and instrumentation of H1 NMR, C13 NMR & Mass.
		CO 3	Understand basic principles involved in TLC, column chromatography and paper chromatography
		CO 4	Remember & understand the theory instrumentation of GC, HPLC, gel chromatography, ion exchange chromatography and affinity chromatography.
		CO 5	Explain Instrumentation and separation of compounds by electrophoresis technique & natural products separation by various chromatographic techniques.
		CO 6	Understand & apply the principles of X-ray refraction and diffraction methods.
	Advanced Pharmacology I	CO1	Apply the basic pharmacological knowledge in the prevention and treatment of various diseases
		CO 2	Explain the mechanism of drug action at organ system or subcellular or macromolecule and Molecular levels
		CO 3	Understand the pharmacological actions, and its relevance in the treatment of different diseases in different categories of drugs
	Pharmacological and Toxicological Screening Methods -I	CO1	Appraise the regulations and ethical requirement for the usage of experimental animals.
		CO 2	Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals.
		CO 3	Describe the various newer screening methods involved in the drug discovery process.
		CO4	Appreciate and correlate the preclinical data to humans.
	Cellular and Molecular Pharmacology	CO1	Explain various cellular events, functions, pathways and transduction mechanisms and how is gene is expressed
		CO 2	Differentiate cell signaling pathways based on receptors and secondary messengers in the cell
		CO 3	Apply the various principles of immune-therapeutics and omics tool in gene therapy and DNA technology
		CO4	Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
		CO5	Demonstrate molecular biology techniques as applicable for Pharmacology
II	Advanced Pharmacology-II	CO1	Explain the mechanism of drug actions at cellular and molecular level

		CO 2	Discuss the Pathophysiology and pharmacotherapy of certain diseases
		CO 3	Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases
	Pharmacological And Toxicological Screening Methods-II	CO1	Explain the various types of toxicity studies.
		CO 2	Appreciate the importance of ethical and regulatory requirements for toxicity studies.
		CO3	Demonstrate the practical skills required to conduct the preclinical toxicity studies.
	Clinical Research and Pharmacovigilance	CO1	Explain the regulatory requirements for conducting clinical trial
		CO 2	Demonstrate the types of clinical trial designs
		CO 3	Explain the responsibilities of key players involved in clinical trials
		CO4	Execute safety monitoring, reporting and close-out activities
		CO5	Explain the principles of Pharmacovigilance
		CO6	Detect new adverse drug reactions and their assessment
		CO7	Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance
	Principles of Drug Discovery	CO1	Explain the various stages of drug discovery
		CO 2	Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
		CO 3	Explain various targets of drug discovery
		CO4	Explain various lead seeking method and lead optimization.
		CO5	Appreciate the importance of the role of computer aided drug discovery
III	Research Methodology &Biostatistics	CO 1	Students will be able to remember the CPCSEA guidelines for laboratory animal facility and ethics guidelines.
		CO 2	Students will be able to understand the study design and types of studies in general research methodology.
		CO 3	Students will be able to apply the concepts of statistical tests of significance, null hypothesis and interpretation of 'P' values.
		CO 4	Students will analyze the basic principles involved in medical research and medical care.
		CO 5	Students will be able to evaluate the parametric and non-parametric tests.
		CO 6	Students will be able to create and carry out crossover design study.

Attendance

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

Grading and classification

Marks Range (%)	Grade Point	Letter Grade	Description	
90 & Above	10	O	Outstanding	First Class with Distinction
80-89.9	09	A	Excellent	
75-79.9	08	B	Very Good	
60-74.9	07	C	Good	First Class
55-59.9	06	D	Fair	Second Class
50-54.9	05	E	Average	Pass
Less than 50	0	F	Fail	Fail
Absent	0	AB	Fail	Fail

A student who remains absent for any semester end examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

The Semester grade point average (SGPA):

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4G4}{-C1 + C2 + C3 + C4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4* ZERO}{-C1 + C2 + C3 + C4}$$

Cumulative Grade Point Average (CGPA):

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$CGPA = \frac{C1S1 + C2S2 + C3S3 + C4S4}{C1 + C2 + C3 + C4}$$

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S1,S2, S3,….is the SGPA of semester I,II,III,…. .

Declaration of class

The class shall be awarded to those who pass the examination in first attempt on the basis of CGPA as follows:
First Class with Distinction : CGPA 7.50 and above First Class : CGPA 6.00 to 7.49
Second Class: CGPA 5.00 to 5.99
Candidates who pass the examination in more than one attempt shall be declared as passed in "pass" class irrespective of the percentage of marks secured.

An attempt means the appearance of a candidate for one or more courses either in part or full in a particular examination.

A candidate who fails in main examination and passes one or more subjects or all subjects in the supplementary examination is not eligible for award of class or distinction. Passing in supplementary examination by such candidates shall be considered as attempt.

If a candidate submits application for appearing for the regular examination but does not appear for any of the courses/subjects in the regular University examination, he can appear for supplementary examination provided other conditions such as attendance requirement, internal assessment marks, etc. are fulfilled and his appearing in the supplementary examination shall be considered as the first attempt.

Candidates who pass the subjects in the supplementary examinations are not eligible for the award of Gold Medal or Merit Certificate.

Teaching - Learning methods course-wise for the M. Pharm program

Teaching - Learning method	Courses
Experiential learning	1. Modern Pharmaceutical Analytical Techniques 2. Drug Delivery System 3. Molecular Pharmaceutics 4. Advanced Biopharmaceutics & Pharmacokinetics 5. Cosmetic and Cosmeceuticals 6.Pharmacotherapeutics-I, II 7. Advanced Pharmacology I, II 8. Principles of Drug Discovery
Integrated/Inter-disciplinary learning	1.Computer-Aided Drug Development 2. Cellular and Molecular Pharmacology 3. Research Methodology & Biostatistics
Participatory learning	1. Principles of Quality Use of Medicines 2. Clinical Pharmacokinetics and Therapeutic Drug Monitoring 3.Pharmacological and Toxicological Screening Methods I, II
Problem-solving methodologies	Research work
Self-directed learning	1. Good Regulatory Practices 2. Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights 3. Regulatory Aspects of Drugs & Cosmetics 4. Regulatory Aspects of Herbal & Biologicals 5. Regulatory Aspects of Medical Devices 6. Regulatory Aspects of Food & Nutraceuticals
Patient-centric and Evidence-based learning	1. Clinical Research Regulations 2. Clinical Pharmacy Practice 3. Hospital & Community Pharmacy 4. Clinical Research 5. Pharmacoepidemiology & Pharmacoeconomics
The Humanities	
Project-based learning	Documentation and Regulatory Writing Research work
Role-play Team-work Reflective writing Any other	

Scheme of Examinations / Assessments:

End Semester Examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the university except for the subject with asterisk symbol (*) in table 8 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Schemes for internal assessments and end semester examinations (Pharmaceutics – MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
17MPS11	Modern Pharmaceutical Analytical Techniques	10	15	1½ Hr	25	75	3 Hrs	100
17MPS12	Drug Delivery System	10	15	1½ Hr	25	75	3 Hrs	100
17MPS13	Modern Pharmaceutics	10	15	1½ Hr	25	75	3 Hrs	100
17MPS14	Regulatory Affairs	10	15	1½ Hr	25	75	3 Hrs	100
17MPS15P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
17MPS21	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1½ Hr	25	75	3 Hrs	100
17MPS22	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1½ Hr	25	75	3 Hrs	100
17MPS23	Computer Aided Drug Development	10	15	1½ Hr	25	75	3 Hrs	100
17MPS24	Cosmetic and Cosmeceuticals	10	15	1½ Hr	25	75	3 Hrs	100
17MPS25P	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
17MRA11	Good Regulatory Practices	10	15	1½ Hr	25	75	3 Hrs	100
17MRA12	Documentation and Regulatory Writing	10	15	1½ Hr	25	75	3 Hrs	100
17MRA13	Clinical Research Regulations	10	15	1½ Hr	25	75	3 Hrs	100
17MRA14	Drugs Regulations and other Legislation in India and Intellectual Property Rights	10	15	1½ Hr	25	75	3 Hrs	100
17MRA15P	Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**

Schemes for internal assessments and end semester examinations (Pharmacy Practice - MPP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
17MPP11	Clinical Pharmacy Practice	10	15	1½ Hr	25	75	3 Hrs	100
17MPP12	Pharmacotherapeutics-I	10	15	1½ Hr	25	75	3 Hrs	100
17MPP13	Hospital & Community Pharmacy	10	15	1½ Hr	25	75	3 Hrs	100
17MPP14	Clinical Research	10	15	1½ Hr	25	75	3 Hrs	100
17MPP15P	Pharmacy Practice Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
17MPP21	Principles of Quality Use of Medicines	10	15	1½ Hr	25	75	3 Hrs	100

17MPP22	Pharmacotherapeutics II	10	15	1½ Hr	25	75	3 Hrs	100
17MPP23	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1½ Hr	25	75	3 Hrs	100
17MPP24	Pharmacoepidemiology & Pharmacoeconomics	10	15	1½ Hr	25	75	3 Hrs	100
17MPP25P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Schemes for internal assessments and end semester examinations (Pharmacology - MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
17MPY11	Modern Pharmaceutical Analytical Techniques	10	15	1½ Hr	25	75	3 Hrs	100
17MPY12	Advanced Pharmacology-I	10	15	1½ Hr	25	75	3 Hrs	100
17MPY13	Pharmacological and Toxicological Screening Methods - I	10	15	1½ Hr	25	75	3 Hrs	100
17MPY14	Cellular and Molecular Pharmacology	10	15	1½ Hr	25	75	3 Hrs	100
17MPY15P	Pharmacology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
17MPY21	Advanced Pharmacology-II	10	15	1½ Hr	25	75	3 Hrs	100
17MPY22	Pharmacological and Toxicological Screening Methods – II	10	15	1½ Hr	25	75	3 Hrs	100
17MPY23	Principles of Drug Discovery	10	15	1½ Hr	25	75	3 Hrs	100
17MPY24	Clinical Research and Pharmacovigilance	10	15	1½ Hr	25	75	3 Hrs	100
17MPY25P	Pharmacology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Schemes for internal assessments and end semester examinations
(Semester III & IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1½ Hr	25	75	3 Hrs	100
-	Journal Club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal Presentation)	-	-	-	50	-	-	50
-	Research Work*	-	-	-	-	350	1 Hr	350
Total								**525**
Semester IV								
-	Journal Club				25	-	-	25
-	Discussion / Final Presentation				75	-	-	75
-	Research Work and Colloquium				-	400	1 Hr	400
Total								**500**

*Non University Examination

Eligibility to appear for University Examination

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

Criteria for passing

A candidate shall be declared as pass if he secures 50% of marks (including internal assessment) in each subject in theory and practical examination separately in each semester provided he/she secures a minimum of 40% marks in internal assessment and end semester university examinations.

Theory and practical subjects are considered as independent subjects. The candidate who fails either in theory or practical subject has to appear only in theory or practical as the case may be in the subsequent examinations.

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Program Structure

PHARMACEUTICS (MPS)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(MPH 101T))

Units	Contents	Hours
1	a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice Hrs of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	10
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT NMR and 13C NMR. Applications of NMR spectroscopy.	10
3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10
4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer Chromatography	10

	c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra High Performance Liquid chromatography h. Affinity chromatography i. Gel Chromatography	
5	a. **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the Hrs following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. **X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	10
6	a. **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. b. **Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.	10

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

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

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series

8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

DRUG DELIVERY SYSTEMS (MPH 102T))

Units	Contents	Hours
1	**Sustained Release(SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ Hrs 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.	10
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.	10
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.	10
4	**Occular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers.	06
5	**Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10
6	**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08

7	**Vaccine delivery systems**: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06

References

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.

3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim

4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001)

5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)

2. Indian drugs (IDMA)

3. Journal of controlled release (Elsevier Sciences) desirable

4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

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MODERN PHARMACEUTICS (MPH 103T)

Units	Contents	Hours
1	a. **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. b. **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	10 10
2	**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.	10
3	**cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, Hrs 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.	10
4	**Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10
5	**Study of consolidation parameters:** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10

References:

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.

6. Remington's Pharmaceutical Sciences.

7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.

8. Physical Pharmacy; By Alfred martin

9. Bentley's Textbook of Pharmaceutics – by Rawlins.

10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.

11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.

12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.

13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.

14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.

15. Pharmaceutical Preformulations; By J.J. Wells.

16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

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REGULATORY AFFAIRS (MPH 104T)

Units	Contents	Hours
1	**a. 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. **b. Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.	12
2	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.	12
3	**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12
4	**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 clinical trials.	12

References

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,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.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.

6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm 10.https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS - I ((MPH 105P)

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

MOLECULAR PHARMACEUTICS

(NANO TECHNOLOGY & TARGETED DDS) (NTDS) (MPH 201T)

Units	Contents	Hours
1	**Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Hrs Brain specific delivery.	12

2	**Targeting Methods:** introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12
3	**Micro Capsules / Micro Spheres:** Types, preparation and evaluation, Monoclonal Antibodies: preparation and application, Hrs preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12
4	**Pulmonary Drug Delivery Systems:** Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12
5	**Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12

References

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

(MPH 202 T)

Units	Contents	Hours
1	**Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH– partition theory of drug absorption. Formulation and 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: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	12
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, 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.	12
3	**Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:two compartment - model in brief, non-linear pharmacokinetics: causeof non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. 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.	12
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, methods. Permeability: In- vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns	12

	in bioavailability and bioequivalence studies, generic substitution.	
5	**Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12

References

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., 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
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex

Avdeef, John Wiley & Sons, Inc,2003.

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COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Units	Contents	Hours
1	a. **Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Hrs Pharmaceutical Research and Development. Statistical modelingin Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. **Quality-by-Design in Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	12
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.	12
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	12
4	a. **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 b. **Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. **Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems	12

5	**Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12

References

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick,James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS (MPH 204T)

Units	Contents	Hours
1	**Cosmetics – Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	12
2	**Cosmetics - Biological aspects:** Structure of skin relating to problems like dry skin, acne, pigmentation, prickly hat, 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-arm.	12
3	**Formulation Building blocks:** Building blocks for different 12 product formulations of cosmetics/cosmeceuticals. Surfactants – Hrs Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. **Perfumes:** Classification of perfumes. Perfume ingredients listed as	12

	allergens in EU regulation. **Controversial ingredients:** Parabens, formaldehyde liberators, dioxane.	
4	**Design of 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 through cosmeceutical formulations.	12
5	**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.	12

References

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A. O. Barel, M. Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II (MPH 205P)

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/niosomes
5. Formulation and evaluation of spherules

6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.

7. Comparison of dissolution of two different marketed products /brands

8. Protein binding studies of a highly protein bound drug & poorly protein bound drug

9. Bioavailability studies of Paracetamol in animals.

10. Pharmacokinetic and IVIVC data analysis by Winnoline® Software

11. In vitro cell studies for permeability and metabolism

12. DoE Using Design Expert® Software

13. Formulation data analysis Using Design Expert® Software

14. Quality-by-Design in Pharmaceutical Development

15. Computer Simulations in Pharmacokinetics and Pharmacodynamics

16. Computational Modeling Of Drug Disposition

17. To develop Clinical Data Collection manual

18. To carry out Sensitivity Analysis, and Population Modeling.

19. Development and evaluation of Creams

20. Development and evaluation of Shampoo and Toothpaste base

21. To incorporate herbal and chemical actives to develop products

22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

GOOD REGULATORY PRACTICES (MRA 101T))

Units	Contents	Hours
1	**Current Good Manufacturing Practices:** Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs.	12

2	**Good Laboratory Practices:** Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards	12
3	**Good Automated Laboratory Practices:** Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards	12
4	**Good Distribution Practices:** Introduction to GDP, Legal GDPRequirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards	12
5	**Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.	12

References

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

DOCUMENTATION AND REGULATORY WRITING (MRA102T)

Units	Contents	Hours
1	**Documentation in pharmaceutical industry:** Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).	12
2	**Dossier preparation and submission:** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.	12
3	**Audits:** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.	12
4	**Inspections:** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).	12
5	**Product life cycle management:** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard.	12

References

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications.
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS (MRA103T)

Units	Contents	Hours
1	**Clinical Drug Development Process** • Different types of Clinical Studies • Phases of clinical trials, Clinical Trial protocol • Phase 0 studies • Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points • Phase II studies (proof of concept or principle studies to establish efficacy) • Phase III studies (Multi ethnicity, global clinical trial, registration studies) • Phase IV studies (Post Marketing Studies; PSUR)	12

	Clinical Investigation and Evaluation of Medical Devices & IVDs Different Types of Studies, Key Concepts of Medical Device Clinical Evaluation, Key concepts of Clinical Investigation efficacy) • Phase III studies (Multi ethnicity, global clinical trial, registration studies) • Phase IV studies (Post Marketing Studies; PSUR) **Clinical Investigation and Evaluation of Medical Devices & IVDs** Different Types of Studies, Key Concepts of Medical Device Clinical Evaluation, Key concepts of Clinical Investigation	
2	**Ethics in Clinical Research:** • Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki • Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines. • The ethics of randomized clinical trials • The role of placebo in clinical trials • Ethics of clinical research in special population • Institutional Review Board/Independent Ethics Committee/ Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data • Data safety monitoring boards. • Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research • Ethical principles governing informed consent process • Patient Information Sheet and Informed Consent Form • The informed consent process and documentation	12
3	**Regulations governing Clinical Trials** **India:** Clinical Research regulations in India – Schedule Y & Medical Device Guidance **USA:** Regulations to conduct drug studies in USA (FDA) • NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug) • NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant) • ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product) FDA Guidance for Industry – Acceptance of Foreign Clinical Studies • FDA Clinical Trails Guidance Document: Good Clinical Practice EU: Clinical Research regulations in European Union (EMA)	12

4	**Clinical Research Related Guidelines** • Good Clinical Practice Guidelines (ICH GCP E6) • Indian GCP Guidelines • ICMR Ethical Guidelines for Biomedical Research • CDSCO guidelines GHTF study group 5 guidance documents **Regulatory Guidance on Efficacy and Safety ICH Guidance's** • E4 – Dose Response Information to support Drug Registration • E7 – Studies in support of General Population: Geriatrics • E8 – General Considerations of Clinical Trials • E10 – Choice of Control Groups and Related Issues in Clinical Trials, • E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population General biostatics principle applied in clinical researc	12
5	**USA & EU Guidance** **USA: FDA Guidance** • CFR 21Part 50: Protection of Human Subjects • CFR 21Part 54: Financial Disclosure by Clinical Investigators • CFR 21Part 312: IND Application • CFR 21Part 314: Application for FDA Approval to Market a New Drug • CFR 21Part 320: Bioavailability and bioequivalence requirements • CFR 21Part 812: Investigational Device Exemptions • CFR 21Part 822: Post-market surveillance • FDA Safety Reporting Requirements for INDs and BA/BE Studies • FDA Med Watch • Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment **European Union: EMA Guidance** • EU Directives 2001 • EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use EU Annual Safety Report (ASR) • Volume 9A – Pharmacovigilance for Medicinal Products for Human Use • EU MDD with respect to clinical research ISO 14155	12

References

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams

2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD

3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene

4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.

5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.

6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.

7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA

8. Country Specific Guidelines from official websites.

9. Drugs & Cosmetics Act & Rules and Amendments.

Recommended websites:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc /clinical- eudirective-04-april-01.pdf

2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts /cdrh/cfdocs/cfcfr/cfrsearch.cfm

3. Guidelines of International Conference on Harmonization: http://www. ich.org/products/guidelines.html

4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.html

5. FDA New Drug Application: http://www.fda.gov/regulatoryinformation /legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugs andDevices/ucm108 125.htm

6. Medicinesand Healthcare products Regulatory Agency: http://www.mhra.gov.uk

7. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf

8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in /ethical_guidelines.pdf

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REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA104 T)

Units	Contents	Hours
1	**Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):** 1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA 2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India **Other relevant Acts:** Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.	12
2	**Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals:** CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals Format and contents of Regulatory dossier filing Clinical trial/ investigations	12
3	Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards	12
4	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study **Stability requirements:** ICH and WHO **Guidelines for Drug testing in animals**/Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research	12
5	**Intellectual Property Rights:** Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs	12

References

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India

2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer

3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee

4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.

5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)

6. ICH E6 Guideline — Good Clinical Practice‖by ICH Harmonised Tripartite

7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)

8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO

9. Guidelines for Import and Manufacture of Medical Devices by CDSCO

10. Guidelines from official website of CDSCO

REGULATORY AFFAIRS PRACTICAL - I (MRA 105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software

21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Units	Contents	Hours
1	**USA & CANADA:** Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.	12
2	**European Union & Australia:** Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.	12

3	**Japan:** Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan	12
4	**Emerging Market:** Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) **WHO:** WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product(CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)	12
5	**Brazil, ASEAN, CIS and GCC Countries:** **ASIAN Countries:** Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. **CIS (Commonwealth Independent States):** Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.	12

References:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. 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.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.

6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official website. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2.http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
11. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981- 230-750-7
12. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
13. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
14. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
15. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
16. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
17. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
18. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Institute of South east asian studies, Singapore

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202 T)

Units	Contents	Hours
1	**India :** Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.	12

2	**USA:** Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics	12
3	**European Union:** Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU.	12
4	**Vaccine regulations in India, US and European Union:** Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)	12
5	**Herbal Products:** Quality, safety and legislation for herbal products in India, USA and European Union.	12

References

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India

9. www.cdsco.nic.in

10. www.ema.europa.eu › scientific guidelines › Biologicals

11. www.fda.gov/biologics bloodVaccines/Guidance Compliance Regulatory Information (Biologics)

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Units	Contents	Hours
1	**Medical Devices:** Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices. **IMDRF/GHTF:** Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical DeviceNomenclature (GMDN).	12
2	**Ethics:** Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) **Quality: Quality System Regulations of Medical Devices:** ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device	12
3	**USA:** Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.	12
4	**European Union:** Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.	12

5	**ASEAN, China & Japan:** Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.	12

References

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Units	Contents	Hours
1	**Nutraceuticals:** Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.	12
2	**Global Aspects**: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.	12
3	**India:** Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.	12
4	**USA:** US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S	12
5	**European Union:** European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.	12

References

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)5 36324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL - II (MRA 205P)

1. Case studies
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization

14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

PHARMACY PRACTICE (MPP)

CLINICAL PHARMACY PRACTICE (MPP 101T)

Units	Contents	Hours
1	**Introduction to Clinical Pharmacy:** Definition, evolution and Scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care **Clinical Pharmacy Services:** Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)	12
2	**Clinical Pharmacy Services:** Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services.	12

3	**Patient Data Analysis:** **Patient Data & Practice Skills:** Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services. **Lab Data Interpretation:** Hematological tests, Renal function tests, Liver function tests	12
4	**Lab Data Interpretation:** Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests	12
5	**Medicines & Poison Information Services** **Medicine Information Service:** Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre. **Poison Information Service:** Definition, need, organization and functions of poison information centre.	12

References

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I (MPP 102T)

Units	Contents	Hours
Etiopathogenesis and pharmacotherapy of diseases associated with following systems		
1	**Cardiovascular system:** Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias	12
2	**Respiratory system:** Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases	12
3	**Gastrointestinal system:** Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis	12

4	**Gastrointestinal system:** Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease **Hematological diseases:** Anemia, Deep vein thrombosis, Drug induced hematological disorders	12
5	**Bone and joint disorders:** Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis **Dermatological Diseases:** Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders **Ophthalmology:** Conjunctivitis, Glaucoma	12

References

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

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(DEEMED TO BE UNIVERSITY)

HOSPITAL & COMMUNITY PHARMACY (MPP 103T)

Units	Contents	Hours
1	**Introduction to Hospitals** – Definition, classification, organizational structure **Hospital Pharmacy:** Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management **Hospital Drug Policy:** Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH	12
2	Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management	12
3	**Education and training:** Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. **Community Pharmacy Practice:** Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers. **Community Pharmacy management:** Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.	12
4	**Prescription –** Legal requirements & interpretation, prescription related problems **Responding to symptoms of minor ailments:** Head ache, pyrexia, menstrual pains, food and drug allergy **OTC medication:** Rational use of over the counter medications Medication counseling and use of patient information leaflets Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence Patient referrals to the doctors ADR monitoring in community pharmacies	12
5	**Health Promotion –** Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care **National Health Programs-** Role of Community Pharmacist in Malaria and TB control programs **Home Medicines review program –** Definition, Objectives,	12

	Guidelines, method and outcomes **Research in community pharmacy Practice**	

References

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH (MPP 104T)

Units	Contents	Hours
1	**Drug development process:** Introduction, various approaches to drug discovery, Investigational new drug application submission Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.	12
2	**Types and Designs used in Clinical Research:** Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) **Clinical Trial Study team:** Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.	12

3	**Clinical trial Documents:** Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards **Clinical Trial Start up activities:** Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission	12
4	**Investigational Product:** Procurement and Storage of investigation product **Filing procedures:** Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up **Clinical Trial Monitoring and Close out:** **Preparation and conduct of monitoring visit:** Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up **Close-Out visit:** Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.	12
5	**Quality Assurance and Quality Control in Clinical Trials:** Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management **Data Management:** **Infrastructure and SystemRequirement for Data Management:** Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival **Clinical Trial Data Management:** Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.	12

References

1. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;

2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone

3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

4. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.

5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.

7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.

8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.

10. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I (MPP 105P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)

7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

PRINCIPLES OF QUALITY USE OF MEDICINES (MPP 201T)

Units	Contents	Hours
1	**Introduction to Quality use of medicines (QUM):** Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.	12
2	**Concepts in QUM** **Evidence based medicine:** Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings **Essential drugs:** Definition, need, concept of essential drug, National essential drug policy and list **Rational drug use:** Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.	12
3	**QUM in various settings:** Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. **QUM in special population:** Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients	12
4	**Regulatory aspects of QUM in India:** Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.	12

5	**Medication errors:** Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors **Pharmacovigilance:** Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.	12

References:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors Online: http://medicinesaustralia.com.au/ files/2012/05/MA_QUM_External_Reduced.pdf
   http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
   http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
6. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS II (MPP 202T)

Units	Contents	Hours
1	**Nervous system:** Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.	12
2	**Psychiatric disorders:** Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease	12
3	**Infectious diseases:** General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.	12

4	**Infectious diseases:** Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections **Gynecological disorders:** Dysmenorrhea, Hormone replacement therapy.	12
5	**Oncology:** General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care	12

References

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

(MPP 203T)

Units	Contents	Hours
1	**Introduction to Clinical pharmacokinetics:** Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses **Designing of dosage regimens:** Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.	12

2	**Pharmacokinetics of Drug Interaction:** Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion **Pharmacogenetics:** Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations **Introduction to Pharmacometrics:** Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.	12
3	**Non Linier Mixed Effects Modelling:** The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.	12
4	**Altered Pharmacokinetics:** Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure.	12
5	**Therapeutic Drug monitoring:** Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium,Fluoxetine, Amitriptyline;Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem.	12

References

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.

3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.

4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.

5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.

6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.

7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.

8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.

9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott Williams & Wilkins, USA.

10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.

11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.

12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist, USA.

13. Relevant review articles from recent medical and pharmaceutical literature

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP 204T)

Units	Contents	Hours
1	**Introduction to Pharmacoepidemiology:** Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. **Concept of risk:** Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio	12
2	**Pharmacoepidemiological Methods:** Qualitative models: DrugUtilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology	12
3	**Introduction to Pharmacoeconomics:** Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. **Cost categorization and resources for cost estimation:** Direct costs. Indirect costs. Intangible costs. **Outcomes and Measurements of Pharmacoeconomics:** Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.	12
4	**Pharmacoeconomic evaluations:** Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).	12

5	**Definition, Steps involved, Applications, Advantages and disadvantages of the following:** **Health related quality of life (HRQOL):** Definition, Need for measurement of HRQOL, Common HRQOL measures. **Definition, Steps involved, Applications of the following:** Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.	12

References

1. Rascati K L. Essentials of Pharmacoeconomics, Kluw Woulters Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - II (MPP 205P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics- II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

PHARMACOLOGY (MPY)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Units	Contents	Hours
1	a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice Hrs of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	10
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT NMR and 13C NMR. Applications of NMR spectroscopy.	10
3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10
4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:	10

	a. Thin Layer chromatography b. High Performance Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra High Performance Liquid chromatography h. Affinity chromatography i. Gel Chromatography	
5	a. **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the Hrs following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. **X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	10
6	a. **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. b. **Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.	10

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

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

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series

8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY - I (MPL 102T)

Units	Contents	Hours
1	**General Pharmacology** a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of c. drug receptors interaction and elicited effects.	12
2	**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 **Autonomic Pharmacology:** Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction	12
3	**Central nervous system Pharmacology** General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.	12

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

References

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer- Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.

15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.

16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I (MPL 103T)

Units	Contents	Hours
1	**Laboratory Animals**: Common laboratory Description, handling and animals: applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, Scope and limitations and methods	12
2	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.	12
3	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti-emetic, anti-diarrheal and laxatives.	12
4	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anticancer agents. Hepatoprotective screening methods.	12

5	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** Iimmunomodulators, Immunosuppressants and immunostimulants **General principles of immunoassay:** theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, Objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans	12

References

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

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CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

Units	Contents	Hours
1	**Cell biology**: Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.	12
2	**Cell signaling**: Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.	12
3	**Principles and applications of genomic and proteomic tools:** DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene Basic principles of recombinant DNA technology-Restriction therapy enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	12
4	**Pharmacogenomics:** Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics **Immunotherapeutics**: Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice	12

5	a. **Cell culture techniques**: Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars	12

References:

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

PHARMACOLOGICAL PRACTICAL - I (MPL 105P)

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

Handling of laboratory animals

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

23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

References

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

ADVANCED PHARMACOLOGY - II (MPL 201T)

Units	Contents	Hours
1	**Endocrine Pharmacology:** Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation	12
2	**Chemotherapy:** Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.	12
3	**Chemotherapy:** Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer **Immunopharmacology:** Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants	12

4	**GIT Pharmacology:** Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. **Chronopharmacology:** Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer	12
5	**Free radicals Pharmacology:** Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant **Recent Advances in Treatment:** Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12

References

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

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PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II

(MPL 202T)

Units	Contents	Hours
1	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	12
2	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	12
3	Reproductive toxicology studies, Male reproductive toxicity studies female reproductive studies (segment I and segment III) teratogenecity studies (segment II) Genotoxicity studies (Ames Test in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12
4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	12
5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12

References

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

6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.

7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Units	Contents	Hours
1	**An overview of modern drug discovery process:** Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.	12
2	**Lead Identification-** combinatorial chemistry & high throughputscreening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X- ray crystallography in protein structure prediction	12
3	**Rational Drug Design** Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,	12
4	**Molecular docking:** Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.	12

5	**QSAR Statistical methods –** regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA **Prodrug design-**Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.	12

References

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

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Units	Contents	Hours
1	**Regulatory Perspectives of Clinical Trials:** Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines **Ethical Committee:** Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR **Informed Consent Process:** Structure and content of an Informed Consent Process Ethical principles governing informed consent process	12
2	**Clinical Trials:** Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional **Clinical Trial Study Team** Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	12

3	**Clinical Trial Documentation-** Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT **Adverse Drug Reactions:** Definition and types. Detection and Reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	12
4	**Basic aspects, terminologies and establishment of pharmacovigilance:** History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	12
5	**Methods, ADR reporting and tools used in Pharmacovigilance** International classification of diseases, International Non- proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	12
6	**Pharmacoepidemiology, pharmacoeconomics, safety pharmacology**	12

References

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOLOGICAL PRACTICAL - II (17MPY25P)

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

References

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

Semester III
MRM 301T - Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance

tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non- parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

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

UNIT – IV

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

UNIT – V

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

Annexures

Minimum two sessional exams shall be conducted for each theory/ practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

Question paper pattern for sessional theory examinations

1. Long Answers (Answer 1 out of 2) - 1 x 10 = 10
2. Short Answers (Answer 4 out of 5) - 4 x 5 = 20

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Total = 30 Marks

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Question paper pattern for sessional Practical examinations

1. Synopsis	- 10
2. Experiment – I (Core Subject)	- 25
3. Experiment – II (MPAT)	- 15
4. Viva voce	- 10

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Total = 60 Marks

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Question paper pattern for end semester theory examinations

1. Long Answers (Answer 3 out of 4) - 3 x 10 = 30
2. Short Answers (Answer 9 out of 11) - 9 x 5 = 45

Total =75 Marks

Question paper pattern for end semester Practical examinations

1. Synopsis - 15
2. Experiment – I - 40
3. Experiment – II - 30
4. Viva voce - 15

Total = 100 Marks

Question Paper pattern for **end semester Practical examinations** - Modern Pharmaceutical Analytical Techniques (MPAT)

	Core subject	**MPAT**	**Total**
Synopsis	10	05	15
Experiment 1	30	10	40
Experiment 2	20	10	30
Viva-voce	10	5	15
Total	**70**	**30**	**100**

Question paper pattern for sessional Practical examinations

	Core subject	**MPAT**	**Total**
Synopsis	04	02	06
Experiment 1	12	06	18
Viva-voce	04	02	06
Total	**20**	**10**	**30**