Department of Pharmacy

Programme: Master of Pharmacy (Pharmaceutics)

Central University of Rajasthan
NH-8, Bandarsindri,
Kishangarh-305817, Dist. Ajmer

Department of Pharmacy
Central University of Rajasthan

Master of Pharmacy (Pharmaceutics)

Vision of the Department

To be a centre of excellence in the domain of pharmaceutical teaching and research, and to train the young minds to meet the changing needs of pharmaceutical sector. .

Mission of the Department

MS1. To train the students to recognize the professional needs of the profession and community and carry out professional obligations ethically and in keeping with the objectives of the National Health Policy / National Drug Policy;

MS2. The pass-outs should have mastered most of the competencies pertaining to the speciality that are required to be practiced in the various facets of pharmacy profession;

MS3. The students should be aware of the contemporary advances and developments in the discipline concerned;

MS4. The students should have acquired a spirit of scientific inquiry and are oriented to the principles of research methodology;

MS5. The students should have acquired the basic skills in teaching of the pharmacy and other health professionals

2. Qualification descriptors for Master of Pharmacy

The qualification descriptors for Master of Pharmacy programme in the Department of Pharmacy may include the following:

QD1. Demonstrate (i) Comprehensive knowledge and understanding of the principle, underlying concepts and experimental finding in Pharmaceutical Sciences, its different learning areas and applications, and its linkages with related disciplinary areas/subjects; (ii) know-how about different types of professionals related to Pharmaceutical Sciences, including research and development, teaching and government and public service and pharmaceutical industry; (iii) skills in areas of Pharmaceutical Sciences and its subfields and current developments in the academic field.

QD2. Implement knowledge, understanding and skills for critical assessment of wide range of ideas; identifying problems and issues relating to Pharmaceutical Sciences.

QD3. Connect the results of studies undertaken accurately in a range of different contexts using the main concepts, constructs and techniques of the subject(s);

QD4. Satisfy the learning needs, drawing on a range of current research and development work and professional materials;

QD5. Showcase subject knowledge and transferable skills to new/unfamiliar contexts to identify and analyse problems and issues and solve complex problems with appropriate solutions.

QD6. Exhibit subject-related and transferable skills that are relevant to Pharmaceutical Sciences-related job trades and employment opportunities

Mapping Qualification Descriptors (QDs) with Mission Statement (MS)

	MS1	MS2	MS3	MS4	MS5
Q1	3	3	3	3	3
QD2	3	3	2	3	3
QD3	3	3	3	2	3
QD4	3	3	3	3	3
QD5	3	2	3	3	3
QD6	3	3	3	3	3

3= High level mapping; 2=Medium level mapping and 1=Low-level mapping

Program learning outcomes (PLOs) for Master of Pharmacy (Pharmaceutics)

The programme learning outcomes relating to Master of Pharmacy in Pharmaceutics include the following:

PLO1. Demonstrate (i) in-depth knowledge and understanding concepts, principles and processes underlying the academic field of Pharmaceutics, and its linkages with interdisciplinary areas/subjects; (ii) procedural knowledge that creates different types of professionals in the field of Pharmaceutics and related domains of pharmacy discipline; (iii) skills related to specialisation areas within Pharmaceutics as well as within subfields of Pharmacy.

PLO2. Understanding of the principles of drug and excepient identification, characterization and estimation techniques and implement the know-how for academia and industry. Exposure to the solid states, complexation, preformulation and vital pharmaceutical technologies.

PLO3. Pharmacokinetic, molecular and patient-oriented design and development of various dosage forms, drug delivery vehicles and genetic vectors. The imparted knowledge will assist the student in strategic understanding of the materials, process, promises and hurdles in the evolving domains of novel drug delivery systems and cosmetics/cosmeceuticals.

PLO4. Training on the computer-aided drug delivery and formulation optimization aspects, resulting in prediction of quality attributes, release pattern and disposition, the knowledge gained can be implemented to develop safer and effective carriers for various pharmacologically active molecules.

PLO5. Undertake hands on lab work and practical activities which develop problem solving abilities required for successful career in pharmaceutics and related industries, teaching, research, consumer goods industry, food products, cosmetics industry, analytical laboratories etc.

PLO6. Use of relevant techniques and drug regulations pertinent to academia and pharmaceutical industries, generic and professional skills, global competencies including knowledge and skills that enable students to undertake further studies/employment/entrepreneurship in the field of pharmaceutics.

PLO7. Strengthening of speaking and discussion skills, develop general computer proficiency, group discussions and personality development. Skills related to scientific publications and their framing, analysis to identify promising new directions and apply in academic, industrial, economic, environmental and social context.

PLO8. Able to carry out substantial research-based project leading to findings, conclusion and recommendation arising from the project; and to develop critical thinking and acquire leadership skills so as to handle the scientific research project independently

Mapping of PLOs with QDs for M. Pharm. (Pharmaceutics)

	QD1	QD2	QD3	QD4	QD5	QD6
PLO1	3	3	3	3	3	3
PLO2	3	3	3	2	3	3
PLO3	3	3	3	2	3	3
PLO4	3	3	3	2	3	3
PLO5	3	3	3	2	2	3
PLO6	3	3	3	3	2	
PLO7	3	3	3	3	2	
PLO8	3	3	3	3	2	2

SEMESTER WISE DISTRIBUTION OF THE COURSES

Semester I

Code	Title of Course	Type of Course	Credit
MPH101T	Modern Pharmaceutical Analytical Techniques	DE	4
MPH102T	Drug Delivery Systems	C	4
MPH103T	Modern Pharmaceutics	C	4
MPH104T	Regulatory Affair	C	4
MPH105P	Pharmaceutics Practical I	Lab	6
MPH106S	Seminar/Assignment	DE	2

Total Credit: 24

C-Core Courses; DE-Discipline Elective Course; E-Elective Course

Semester II

Code	Title of Course	Type of Course	Credit
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	C	4
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	C	4
MPH203T	Computer Aided Drug Delivery Systems	C	4
MPH204T	Cosmetic and Cosmeceuticals	C	4
MPH205P	Pharmaceutics Practical II	Lab	6
MPH206S	Seminar/Assignment	DE	2

Total Credit: 24

C-Core Courses; DE-Discipline Elective Course; E-Elective Course

Semester III

Code	Title of Course	Type of Course	Credit
MRM 301T	Research Methodology and Biostatistics	E	4
MPH302JC	Journal club	DE	2
MPH303PP	Discussion / Presentation (Proposal Presentation)	C	4
MPH304RW	Research Work	C	14

C-Core Courses; DE-Discipline Elective Course; E-Elective Course

Total Credit: 24

Semester IV

Code	Title of Course	Type of Course	Credit
MPH401JC	Journal Club	DE	2
MPH402RW	Research Work	C	18
MPH403FP	Discussion/Final Presentation	C	4

C-Core Courses; DE-Discipline Elective Course; E-Elective Course; S-Societal Course
Total Credit: 24

Summary:

Semester	No. of Courses	Credits
I	**6**	**24**
II	**6**	**24**
III	**4**	**24**
IV	**3**	**24**
Total	**18**	**96**

Course-level learning outcomes to Master of Pharmacy in Pharmaceutics

MPH 101T: Modern Pharmaceutical Analytical Techniques

Course Learning Outcomes (CLOs):

CLO1. Understanding theory, instrumentation applications of spectroscopic techniques like UV, IR, Raman, NMR, ESR, Mass, X-ray spectroscopy
CLO2. Pharmaceutical applications of various thermo gravimetric, chromatographic and electrophoresis techniques
CLO3. Concepts of Optical Rotatory dispersion and Circular Dichroism and their applications.
CLO4. Spectral analysis of Chemicals and Excipients
CLO5. The analysis of various drugs in single and combination dosage forms
CLO6. Theoretical and practical skills of the instruments
CLO7. The analysis of various APIs, chemicals and analysis of various drugs in single and combination dosage form
CLO8. Theoretical and practical skills of the commonly used analytical instruments

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3	3						3
CLO2	3	3						3
CLO3	3	3						3
CLO4	3	3						3
CLO5	3	3						3
CLO6	3	3						3
CLO7	3	3						3
CLO8	3	3						3

Detailed Syllabus:

Unit	Details	Contact Hours
I	a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible 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 b. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. c. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	11
II	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.	11
III	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	11
IV	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e)Gas chromatography f)High Performance Liquid chromatography g) Affinity chromatography	11
V	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction.	11

VI	Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5

Suggested Readings

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, Volume 11, Marcel Dekker Series

MPH 102T: Drug Delivery Systems

Course Learning Outcomes (CLOs)

CLO1. The various approaches for development of novel drug delivery systems.

CLO2. The criteria for selection of drugs and polymers for the development of delivery systems

CLO3. The formulation and evaluation of novel drug delivery systems.

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3		3			3		3
CLO2	3		3			3		3
CLO3	3		3			3		3

Detailed Syllabus:

Unit	Details	Contact Hours
I	Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	10
II	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
III	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
IV	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	6
V	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10
VI	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	8
VII	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	6
Suggested Readings 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 Wiley Interscience 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

MPH 103: Modern Pharmaceutics
Course Learning Outcomes (CLOs)

CLO1. The need and importance of the pre-formulation studies.

CLO2. Importance of the active pharmaceutical ingredients and generic drug product development.

CLO3. The industrial management, GMP considerations, pilot-plant scale up and change

CLO4. The formulation optimization techniques, complexation, rheology and solid state pharmaceutics.

CLO5. Stability testing, sterilization process & packaging of dosage forms.

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3	3				3		3
CLO2	3	3				3		3
CLO3	3	3				3		3
CLO4	2	3				3		3
CLO5	3	3				3		3

Detailed Syllabus

Unit	Details	Contact Hours
I	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
II	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
III	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	10
IV	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10
V	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

Suggested Readings

1. 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.

MPH 104T: Regulatory Affairs

Course Learning Outcomes (CLOs)

CLO1. The Concepts of innovator and generic drugs, drug development process
CLO2. The Regulatory guidance's and guidelines for filing and approval process
CLO3. Preparation of Dossiers and their submission to regulatory agencies in different countries
CLO4. Post approval regulatory requirements for actives and drug products
CLO5. Submission of global documents in CTD/ e CTD formats
CLO6. Clinical trials requirements for approvals for conducting clinical trials
CLO7. Pharmacovigilence and process of monitoring in clinical trials.

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3					3		3
CLO2	3					3		3
CLO3	3					3		3
CLO4	3					3		
CLO5	3					3		
CLO6	3					3		
CLO7	3					3		

Detailed Syllabus:

Unit	Details	Contact Hours
I	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
II	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
III	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12
IV	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12

Suggested Readings

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

MPH 105P/106P/205P/206P: Pharmaceutics Lab.-I-IV

Course Learning Outcomes:

At completion of this course it is expected that students will be able to understand:
CLO1. The analytical methods for drug estimation;
CLO2. Mechanistic understanding of the drug dissolution process;
CLO3. Preparation of the drug delivery systems;
CLO4. Characterization of the drug delivery systems;
CLO5. The challenges faced in the drug product development;
CLO6. Computational and regulatory aspects of drug delivery;
CLO7. Drug release mechanisms;
CLO8: Pharmacokinetics of drug products

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3				3	3		3
CLO2	3				3	3		3
CLO3	3				3	3		3
CLO4	3				3	3		3
CLO5	3				3	3		3
CLO6	3				3	3		3
CLO7	3				3	3		3
CLO8	3				3	3		3

Detailed Syllabus:

MPH 105P/106P
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 onHPLC 4. Experiments based on GasChromatography 5. Estimation of riboflavin/quinine sulphate byfluorimetry 6. Estimation of sodium/potassium by flamephotometry 7. To perform *In-vitro* dissolution profile of CR/ SR marketedformulation 8. Formulation and evaluation of sustained release matrixtablets 9. Formulation and evaluation osmotically controlled DDS 10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS 11. Formulation and evaluation of Muco adhesivetablets. 12. Formulation and evaluation of trans dermalpatches. 13. To carry out 20reformulation studies oftablets. 14. To study the effect of compressional force on tablets disintegrationtime. 15. To study Micromeritic properties of powders andgranulation. 16. To study the effect of particle size on dissolution of atablet. 17. To study the effect of binders on dissolution of atablet. 18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.
MPH 205P/206P
1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsulespreparation 2. Preparation and evaluation of Alginate beads 3. Formulation and evaluation of gelatin/albuminmicrospheres 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 bounddrug 9. Bioavailability studies of Paracetamol in animals. 10. Pharmacokinetic and IVIVC data analysis by Winnoline^{R}software 11. *In vitro* cell studies for permeability andmetabolism

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 PopulationM odeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Tooth paste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

MPH 201: Molecular Pharmaceutics (Nano Tech and Targeted DDS)

Course learning outcomes (CLOs) that a student is required to demonstrate after completion of this course are indicated below:
CLO1. The genesis of the concept of novel drug delivery systems
CLO2. Understanding the various approaches for development of novel drug delivery systems.
CLO3. The criteria for selection of drugs and polymers for the development of nanotech and targeted drug delivery systems
CLO4. The formulation and evaluation of novel drug delivery systems

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3					3		3
CLO2	3					3		3
CLO3	3					3		3
CLO4	3					3		3

Detailed syllabus:

Unit	Details	Contact Hours
I	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specificdelivery.	12
II	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation andevaluation	12
III	Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes,Electrosomes.	12
IV	Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation andevaluation.	12
V	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 deliverysystems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12

Suggested Readings

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, VallabhPrakashan, New Delhi, First edition2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in2001).

MPH 202T: Advanced Pharmacokinetics and Biopharmaceutics

Course Learning Outcomes (CLOs)

CLO1. Learning and understanding the basic concepts in biopharmaceutics and pharmacokinetics.
CLO2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
CLO3. The critical evaluation of bio-pharmaceutic studies involving drug product equivalency.
CLO4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and bio-pharmaceutic parameters.
CLO5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3		3			3		3
CLO2	3		3			3		3
CLO3	3		3			3		3
CLO4	3		3			3		3
CLO5	3		3			3		3

Detailed syllabus:

Unit	Details	Contact Hours
I	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
II	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 testingperformance of drug products. *In vitro–in vivo* correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drugproduct.	12
III	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: cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max}. Drug interactions: introduction, the effect of protein- binding interactions,the effect of tissue-binding interactions,cytochrome p450-based drug interactions,drug interactions linked totransporters.	12
IV	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 in bioavailability and bioequivalence studies, generic substitution.	12
V	Application of Pharmacokinetics: Modified-Release Drug Products,	12

	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), Genetherapies.	

Suggested Readings

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, LeaandFebiger, Philadelphia,1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York andBasel,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,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPSPublishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons,Inc,2003.

MPH 203T: Computer Aided Drug Delivery Systems

Course learning outcomes (**CLOs)** that a student is required to demonstrate after completion of this course are indicated below:

CLO1. History and need of computers in pharmaceutical research and development
CLO2. Computational modelling of drug disposition
CLO3. Computers in preclinical development
CLO4. Optimization techniques in pharmaceutical formulation
CLO5. Computers in market analysis
CLO6. Computers in clinical development including the need of artificial intelligence (AI) and robotics and computational fluid dynamics (CFD)

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3			3				
CLO2	3			3				
CLO3	3			3				
CLO4	3			3				
CLO5	3			3				
CLO6	3			3				

Detailed syllabus:

Unit	Details	Contact Hours
I	a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, PopulationModeling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	12
II	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
III	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 Marketanalysis	12
IV	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, Biowaiverconsiderations 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
V	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and FutureDirections.	12

Suggested Readings

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, WoodheadPublishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York,1996.

MPH 204T: Cosmetics and Cosmeceuticals

Course Learning Outcomes (CLOs):

CLO1. Introduction to the evolving concept of cosmeceuticals
CLO2. Key ingredients used in cosmetics and cosmeceuticals
CLO3. Key building blocks for various cosmetic formulations
CLO4. Current technologies and federal guidelines for these products
CLO5. Scientific knowledge to develop cosmetics and cosmeceuticals with desired safety, stability and efficacy

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3					3		
CLO2	3					3		
CLO3	3					3		
CLO4	3					3		
CLO5	3					3		

Detailed Syllabus:

Unit	Details	Contact Hours
I	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
II	Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	12
III	Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – 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 andsyndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane	12
IV	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 cosmeceuticalformulations.	12
V	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 herbalcosmetics.	12

Suggested Readings

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.Payeand H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent supplierscatalogue.
6. CTFA directory.

MRM 301T: Research Methodology

Course Learning Outcomes (CLOs)

CLO1. Understand some basic concepts of research and its methodologies
CLO2. Understanding the sojourn of research since its conception till compilation
CLO3. Understanding of journals, metrics and criteria for journal selection
CLO4. Statistical analysis of the data collected
CLO5. Writing a research report, thesis and research proposals for fellowships and grants
CLO6. Introduction to intellectual property rights, the governing laws and the process of patenting in India

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3				3	3		
CLO2	3				3	3		
CLO3	3				3	3		
CLO4	3				3	3		
CLO5	3				3	3		
CLO6	3				3	3		

Detailed Syllabus:

Unit	Details	Contact Hours
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.	12
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.	12
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.	12
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.	10
V	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	12

MPH302JC/ MPH 401JC Journal Club

Course Learning Outcomes (CLOs)

CLO1. The presentation skills on a particular research topic
CLO2. How to discuss the work of others effectively
CLO3. What makes research presentations effective?
CLO4. About how papers are refereed and published.
CLO5. Evaluate research and review papers.
CLO6. How papers are referred and published.
CLO7. Read research papers critically and efficiently.
CLO8. Understanding a new field in the absence of text book.
CLO9. Summarize and review research articles.
CLO10. Effective use of ICT tools.

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3						3	
CLO2	3						3	
CLO3	3						3	
CLO4	3						3	
CLO5	3						3	
CLO6	3						3	
CLO7	3						3	
CLO8	3						3	
CLO9	3						3	
CLO10	3						3	

MPH303PP/ MPH304RW/ MPH402RW/ MPH 403FP: Research Project/Discussion Final Presentation

Course Learning Outcomes (CLOs)

CLO1. Attitudes including communication skills, critical thinking to address a research problem
CLO2. Undertake an individual research topic in discussion with the assigned supervisor and submit a thesis at the end for evaluation
CLO3. Develop research skills through individual research project, and time-management and planning skills
CLO4. Undertaking subjective research independently
CLO5. Development of interpersonal skills for collaborative approach
CLO6. Acquire theoretical knowledge, practical /clinical skills, thesis compilation and writing scientific reports.

	PLO1	PLO2	PLO3	PLO4	PLO5	PLO6	PLO7	PLO8
CLO1	3	3	3	3	3	3	3	3
CLO2	3	3	3	3	3	3	3	3
CLO3	3	3	3	3	3	3	3	3
CLO4	3	3	3	3	3	3	3	3
CLO5	3	3	3	3	3	3	3	3
CLO6	3	3	3	3	3	3	3	3