Department of Pharmacy

Programme: Master of Pharmacy (Pharmaceutics)

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

1. ABOUT THE PROGRAMME

Among the many branches in Pharmacy, Pharmaceutics can be regarded as the important basic streams of Pharmacy. However, unlike other basic sciences, these programmes have appeared as interdependent scientific offshoots amalgamating the principles of various scientific domains. This program provides pharmacy students with a comprehensive understanding of the formulations, the relationship between the pharmacokinetics and pharmacodynamics, about the different novel drug delivery systems including the nanotechnological tools in drug delivery and the technology behind these. An understanding of the chemical basis of drug action coupled with understanding of its pharmacokinetics give pharmacy students the ability to answer rationally the "why" and "how" of drug action, and to modulate the activity by fine tuning various attributes of the drugs. This knowledge puts the pharmacist in a unique position among the various health care professionals. By imparting an exclusive knowledge base, the courses offered play a vital role in providing critical thinking and evidence-based problem-solving skills to pharmacy students, enabling them to make optimal decisions in this area of pharmacy.

2. PROGRAM OBJECTIVES (PO)

PO1	Appreciation of deeper insights for basics and advances including modern knowledge of pharmaceutics and in-particular to different formulations aspects.
PO2	Building foundation for higher studies as well as capable to get suitable employmentin the area of Pharmaceuticals.
PO3	Development of positive attitudes to realize the importance of hard work, commitment, ethics and excellence.
PO4	Development of better scientific attitude, analytical and rational thinking among students.
PO5	Developing confidence for independent pursuit of projects, start-ups and entrepreneurship in the students.

3. APPROVED INTAKE: 15 (Fifteen)

4. MINIMUM ELIGIBILITY FOR ENTRY

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%

(50% for the candidate belonging to SC/ST/OBC/PWD/EWS category) of the maximum marks (aggregate of four years of B. Pharm).

b. Every student should have obtained Registration with the State Pharmacy Council or should obtain the same within one month from the date of his admission, failing which the admission of the candidate shall be cancelled. A candidate with valid GPAT Score will be given preference for admission; however such candidate has to register for CUCET 2020.

5. COURSE STRUCTURE

Core Courses (C)	**Course Code**
Drug Delivery System	MPH102T
Modern Pharmaceutics	MPH103T
Molecular Pharmaceutics (Nano Tech and Targeted DDS)	MPH201T
Advanced Biopharmaceutics & Pharmacokinetics	MPH202T
Computer Aided Drug Delivery System	MPH203T
Cosmetic and Cosmeceuticals	MPH204T
Discussion / Presentation (Proposal Presentation)	MPH303PP
Research Work	MPH304RW& MPH402RW
Discussion/Final Presentation	MPH403FP
Discipline Elective Courses (D)	
Modern Pharmaceutical Analytical Techniques	MPH101T
Seminar/Assignment	MPH 106S & MPH 206S
Regulatory Affair	MPH104T
Journal Club	MPH302JC&MPH401JC
Elective Courses (Ex-discipline; E)	
Research Methodology and Biostatistics	MRM 301T
Elective 2	
Elective 3	
Lab Courses	
Pharmaceutics Practical I	MPH105P
Pharmaceutics Practical II	MPH205P

SEMESTER WISE DISTRIBUTION OF THE COURSES

Semester I

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

Total Credit: 24

C-Core Courses; D-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	L	6
MPH206S	Seminar/Assignment	D	2

Total Credit: 24

C-Core Courses; D-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	D	2
MPH303PP	Discussion / Presentation (Proposal Presentation)	C	4
MPH304RW	Research Work	C	14

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

Total Credit: 24

Semester IV

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

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

Central University of Rajasthan
Department of Pharmacy

Semester-wise structure for the
M. Pharm. in Pharmaceutics (MPH) Programme
Semester I

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/D/E/L		L	I.L	P	T	P	IA-I	IA-II	
1.	MPH 101T	Modern Pharmaceutical Analytical Techniques	D	4	3	1	-	3	-	20	20	60
2.	MPH 102T	Drug Delivery Systems	C	4	3	1	-	3	-	20	20	60
3.	MPH 103T	Modern Pharmaceutics	C	4	3	1	-	3	-	20	20	60
4.	MPH 104T	Regulatory Affair	C	4	3	1	-	3	-	20	20	60
5.	MPH 105P	Pharmaceutics Practical I	L	6	-	-	12	-	6	20	20	60
7.	MPH 106S	Seminar/Assignment	D	2	-	2	-	1	-	-	-	100

Total Credits: Semester I–24 Credits

CIE: Continuous Internal Evaluation; **ESE:** End Semester Examination; **IA:** Internal Assessment, **L:** Lectures, **I. L:** Integrated Learning involving Tutorials, Group Discussions, Assignments, Field Work; **L**:Practicals, Lab. work, Project, **C:** Core, **E:** Elective, **D:** Discipline Elective Course.

The guide will be chosen based on mutual consent of the student and faculty member. After selection of the research guide the student will formulate his/her Seminar topic (MPH106S).

Semester II

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/DE/E/L		L	I.L	P	T	P	IA-I	IA-II	
1	MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	C	4	3	1	-	3	-	20	20	60
2	MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	C	4	3	1	-	3	-	20	20	60
3	MPH 203T	Computer Aided Drug Delivery Systems	C	4	3	1	-	3	-	20	20	60
4	MPH 204T	Cosmetic and Cosmeceuticals	C	4	3	1	-	3	-	20	20	60
6	MPH 205P	Pharmaceutics Practical II	L	6	-	-	12	-	6	20	20	60
7	MPH 206S	Seminar/Assignment	D	2	-	2	-	1	-	-	-	100

Total Credits: Semester II –24

CIE: Continuous Internal Evaluation; **ESE:** End Semester Examination; **IA:** Internal Assessment, **L:** Lectures, **I. L:** Integrated Learning involving Tutorials, Group Discussions, Assignments, Field Work; **L**: Practicals, Lab. work, Project, **C:** Core, **E:** Elective, **D:** Discipline Elective Course.

Semester III

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/D/E/L		L	I.L	P	T	P	IA-I	IA-II	
1	MRM 301	Research Methodology and Biostatistics	E	4	3	1	-	3	-	20	20	60
2	MPH 302JC	Journal Club	DE	2	1	1	-	3	-	-	-	100
3	MPH 303PP	Discussion / Presentation (Proposal Presentation)	C	4	-	4	-	1	-	-	-	100
4	MPH 304RW	Research Project	C	14	-	-	-	1	-	-	-	100

Total Credits: Semester III –24

The research work will commence this Semester. The students will submit a progress report and present seminar(s) based on the progress of his/her research work that should be attended by all students in the department, the research guide, the HOD, and other faculty of the Department. The student will be evaluated by an external expert. The progress report should be handed in by the student the next day after the delivery of the seminar.

*During this semester, the student is free to opt one open elective course of his/her interest, offered by any department of the University, however, the subject will appear in the Marks Sheet (if examination is qualified), but credits will not be accumulated.

Semester IV

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/D/E/Lab		L	I.L	P	T	P	IA-I	IA-II	
1	MPH 401JC	Journal Club	D	2	-	2	-	1	-	-	-	100
2	MPH 402RW	Research Work	C	18	-	4	-	1	-	-	-	100*
3	MPH 403FP	Discussion / Presentation (Final Presentation)	C	4	-	-	-	1	-	-	-	100

Total Credits: Semester IV –24

This Semester is devoted totally to research which will culminate in the submission of a thesis. The student will deliver a pre-submission seminar before submission of his/her thesis at a date and time fixed by the department, that should be attended by all students in the department, the research guide, the HOD and other faculty of the Department. The Seminar will be followed by a discussion.

* MPH 402RW will be evaluated by an external subject expert.

Strong emphasis should be placed on the novelty/IPR aspects of the plagiarism free research work, beside publications in peer reviewed journals of good impact factors. Students should be encouraged to attend conferences, seminars where they will present their research work.

Semester I

MPH101T Modern Pharmaceutical Analytical Techniques Credit: 4

Course Outcome

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosageforms
- Theoretical and practical skills of theinstruments

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- Visiblespectroscopy. 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 IRspectroscopy c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescencespectrophotometer. d. 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 NMRspectroscopy.	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 thefollowing: a) Paper chromatography b) Thin Layerchromatography c) Ion exchange chromatography d) Column chromatography e)Gas chromatography f)High Performance Liquid	11

	chromatography g) Affinity chromatography	
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 electricfocusing 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, Bioluminescenceassays.	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, CBSpublishers.
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 DekkerSeries

MPH 102T	Drug Delivery Systems	Credit: 4

Course Outcome

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

- ✓ The various approaches for development of novel drug delivery systems.
- ✓ The criteria for selection of drugs and polymers for the development of delivering system
- ✓ The formulation and evaluation of Novel drug delivery systems.

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	8

	and Evaluation of delivery systems of proteins and other macromolecules.	
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 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

MPH 103T	MODERN PHARMACEUTICS	Credit: 4

Course Outcome

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

- The elements of pre-formulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMPConsiderations.
- Optimization Techniques & Pilot Plant Scale UpTechniques
- Stability Testing, sterilization process & packaging of dosageforms.

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 andevaluation. 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. offacilities.	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 QualityManagement.	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 , ANOVAtest.	10

Suggested Readings

1. 1. Theory and Practice of Industrial Pharmacy ByLachmann andLibermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by LeonLachmann.

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 PharmaceuticalSciences.
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, NewDelhi.
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 andWilliams.
17. Encyclopaedia of Pharmaceutical technology, Vol I –III.

MPH 104T	REGULATORY AFFAIRS	Credit: 4

Course Outcome

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in differentcountries
- Post approval regulatory requirements for actives and drugproducts
- Submission of global documents in CTD/ eCTDformats
- Clinical trials requirements for approvals for conducting clinicaltrials
- Pharmacovigilence and process of monitoring in clinicaltrials.

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 foreigndrugs	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 ROWcountries.	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 clinicaltrials.	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 carePublishers.

3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the PharmaceuticalSciences,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, DavidMantus.
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	PHARMACEUTICS PRACTICALS – I	Credit: 6

Details
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 adhesive tablets. 12. Formulation and evaluation of trans dermalpatches. 13. To carry out preformulation studies of tablets. 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.

Semester II

MPH 201TMOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS) Credit: 4

Course Outcome

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug deliverysystems.

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 202 ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICSCredit: 4

Course Outcome

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics andpharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism andelimination.
- The critical evaluation of biopharmaceutic studies involving drug productequivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics ofpharmacokinetic

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 –	12

	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.	
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, 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.	12

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 DEVELOPMENTCredit: 4

Course Outcome

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research andDevelopment
- Computational Modeling of DrugDisposition
- Computers in PreclinicalDevelopment
- Optimization Techniques in PharmaceuticalFormulation
- Computers in MarketAnalysis
- Computers in ClinicalDevelopment
- Artificial Intelligence (AI) andRobotics
- Computational fluiddynamics(CFD)

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	12

	Management, Regulation of Computer Systems	
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	Credit: 4

Course Outcome

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

- Key ingredients used in cosmetics andcosmeceuticals.
- Key building blocks for variousformulations.
- Current technologies in themarket
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, andefficacy.

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.

MPH 205P	PHARMACEUTICS PRACTICALS – II	Credit: 6

Details
1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsulespreparation 2. Preparation and evaluation of Alginatebeads 3. Formulation and evaluation of gelatin /albuminmicrospheres 4. Formulation and evaluation of liposomes/niosomes 5. Formulation and evaluation ofspherules 6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersiontechnique. 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 inanimals. 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 PharmaceuticalDevelopment 15. Computer Simulations in Pharmacokinetics andPharmacodynamics 16. Computational Modeling of DrugDisposition 17. To develop Clinical Data Collectionmanual 18. To carry out Sensitivity Analysis, and PopulationModeling. 19. Development and evaluation ofCreams 20. Development and evaluation of Shampoo and Toothpastebase 21. To incorporate herbal and chemical actives to developproducts 22. To address Dryskin,acne,blemish,Wrinkles, bleeding gums and dandruff

Semester III

MRM 301T Research Methodology & BiostatisticsCredit: 4

Course Outcome

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

- Key ingredients used in cosmetics andcosmeceuticals.
- Key building blocks for variousformulations.
- Current technologies in themarket
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, andefficacy.

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