Scheme and Syllabus

M. Pharmacy
Pharmaceutics

Batch 2017 onwards

PTU

ਆਈ. ਕੇ. ਗੁਜਰਾਲ ਪੰਜਾਬ ਟੈਕਨੀਕਲ ਯੂਨੀਵਰਸਿਟੀ

By
Board of Studies Pharmacy
Department of Academics

First Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MPH101T	Modern Pharmaceutical Analytical Techniques	4	-	25	75	100	4
MPH102T	Drug Delivery System	4	-	25	75	100	4
MPH103T	Modern Pharmaceutics	4	-	25	75	100	4
MPH104T	Regulatory Affairs	4		25	75	100	4
MPH105P	Pharmaceutics Practical I	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	-	-	100	4
	Total	**16**	**19**	**150**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Second Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MPH201T	Molecular Pharmaceutics (Nano Tech & Targeted DDS)	4	-	25	75	100	4
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	-	25	75	100	4
MPH203T	Computer Aided Drug Delivery System	4	-	25	75	100	4
MPH204T	Cosmetic & Cosmeceuticals	4		25	75	100	4
MPH205P	Pharmaceutics Practical II	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	-	-	100	4
	Total	**16**	**19**	**150**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Third Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	**External**	**Total**	
MRM301T	Research Methodology & Biostatistics*	4	-	25	75	100	4
-	Journal Club	1	-	25	-	25	1
-	Discussion / Presentation (Proposal Presentation)	2	-	50	-	50	2
-	Research Work*	-	28	-	350	350	14
	Total	**7**	**28**	**100**	**425**	**525**	**21**

- *Non -University Exam

Fourth Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
-	Journal Club	1	-	25	-	25	1
-	Research Work	-	31	-	400	400	16
-	Discussion/Final Presentation	3	-	75	-	75	3
-	Co-curricular Activities	-	-	Satisfactory/Unsatisfactory			2*
Total		**4**	**31**	**100**	**400**	**500**	**22**

**Note: Required credit points 02 for satisfactory; Less than 02 credit points unsatisfactory*

***Credits not included towards calculation of CGPA**

Semester Wise Credits Distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations & Other Scholarly Activities)	02*
Total Credit Points	**93 + 2* = 95**

- *Credit Points for Co-curricular Activities
- *Credits not included towards calculation of CGPA
- *The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University

Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points
Participation in National Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student) OR Academic Award/Research Award from State Level/National Agencies	02
Participation in International Level Seminar/ Conference/ Workshop/ Symposium / Training Programs (related to the specialization of the student) #	02
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)*	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)*$	02

- #International Conference held even in India will be considered for award of Credit Points.
- *Only those research / review publications will be considered which have been published during the tenure of M. Pharm. Course.
- $ International Journal: The Editorial Board outside India.

Academic Work

The department / teaching staff of respective courses shall maintain a regular record of attendance in Theory, Practical, Seminar, Assignment, Journal Club, and Discussion with the supervisor, Research work presentation and Dissertation.

Program Committee

1. M. Pharm. Programme shall have a Programme Committee constituted by the Head of the Institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   a. A teacher at the cadre of Professor shall be the Chairperson
   b. One Teacher from each M. Pharm. Specialization
   c. Four student representatives (two from each academic year), nominated by the Head of the Institution
3. Duties of the Programme Committee:
   a. Periodically review the progress of the classes.
   b. Discuss the problems concerning curriculum, syllabus and the conduct of classes.
   c. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

Sessional Exams

- Two sessional exams shall be conducted for each theory/practical course
- The average marks of two sessional exams shall be computed for internal assessment
- Sessional exam shall be **conducted for 30 marks** for theory and shall be **computed for 15 marks**.
- Sessional exam for practical shall be **conducted for 40 marks** and shall be **computed for 30 marks**.

Question Paper Pattern for Theory Sessional Examinations

Multiple Choice Questions (MCQs) **OR** Objective Type Questions (5 x 2) (Answer all the questions)	10 x 1 = 10 **OR** 05 x 2 = 10
Short Answers (Answer 2 out of 3)	2 x 5 = 10
Long Answers (Answer 1 out of 2)	1 x 10 = 10
Total	**30 Marks**

Question Paper Pattern for Practical Sessional Examinations

Synopsis	10
Experiments	25
Viva voce	05
Total	**40 Marks**

Internal Assessment

- The internal assessment will have two components i.e. **Continuous Mode** and **Sessional Exams**

1. Theory Courses having Internal of 25 Marks the scheme of internal award is:
   - Sessional Exams: 15 Marks
   - Continuous Mode: 10 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	08
Student – Teacher interaction	02
Total	**10**

2. Practical Courses having Internal of 50 Marks the scheme of internal award is:
   - Sessional Exams: 30 Marks
   - Continuous Mode: 20 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

***Guidelines for the Allotment of Marks for Attendance**

Percentage of Attendance	Theory (Maximum Marks 08)	Practical (Maximum Marks 10)
95 – 100	08	10
90 – 94	06	7.5
85 – 89	04	5
80 – 84	02	2.5
Less than 80	0	0

1st SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPH101T	Modern Pharmaceutical Analytical Techniques	4	-	25	75	1	3	4

Scope: This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives: After completion, of course student is able to know

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

Module 01 **11 Hour**

UV-Visible Spectroscopy

- Introduction, Theory, Laws, and Instrumentation associated with UV-Visible spectroscopy
- Choice of solvents and solvent effect
- Applications of UV- Visible spectroscopy

IR Spectroscopy

- Theory, Modes of Molecular vibrations, Sample handling
- Instrumentation of Dispersive and Fourier - Transform IR Spectrometer
- Factors affecting vibrational frequencies
- Applications of IR spectroscopy

Spectroflourimetry

- Theory of Fluorescence
- Factors affecting fluorescence, Quenchers, Instrumentation
- Applications of fluorescence spectrophotometer

Flame Emission Spectroscopy and Atomic Absorption Spectroscopy

- Principle, Instrumentation, Interferences and Applications

Module 02 **11 Hours**

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 ^{13}C NMR
- Applications of NMR spectroscopy

Module 03 **11 Hours**

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
- Applications of Mass spectroscopy

Module 04 **11Hours**

Chromatography

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

- Paper chromatography
- Thin Layer chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Affinity chromatography

Module 05 **11Hours**

Electrophoresis

Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- Paper electrophoresis
- Gel electrophoresis
- Capillary electrophoresis
- Zone electrophoresis
- Moving boundary electrophoresis
- Isoelectric focusing

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

Module 06 **05 Hours**

Immunological Assays

- RIA (Radio immuno assay)

- ELISA
- Bioluminescence assays

Recommended Books (Latest editions)

1. Spectrometric Identification of Organic Compounds - Robert M Silverstein, John Wiley & Sons.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, Eastern press, Bangalore.
3. Instrumental methods of analysis – Willards, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, CBS Publishers, New Delhi.
5. Organic Spectroscopy - William Kemp, ELBS.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPH102T	Drug Delivery Systems	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

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

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

Module 01 **10Hours**

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

Module 02 **10Hours**

Rate Controlled Drug Delivery Systems

- Principles and 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 and Fundamentals

Module 03 **10Hours**

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

Module 04 **06Hours**

Occular Drug Delivery Systems

- Barriers of drug permeation
- Methods to overcome barriers

Module 05 **10Hours**

Transdermal Drug Delivery Systems

- Structure of skin and barriers
- Penetration enhancers
- Transdermal Drug Delivery Systems
- Formulation and evaluation

Module 06 **08 Hours**

Protein and Peptide Delivery

- Barriers for protein delivery
- Formulation and Evaluation of delivery systems of proteins and other macromolecules

Module 07 **06 Hours**

Vaccine Delivery Systems

- Vaccines
- Uptake of antigens
- Single shot vaccines
- Mucosal and transdermal delivery of vaccines

Recommended Books (Latest editions)

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

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

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPH103T	Modern Pharmaceutics	4	-	25	75	1	3	4

Scope: Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries.

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

1. The elements of pre-formulation studies.
2. The active pharmaceutical ingredients and generic drug product development.
3. Industrial management and GMP considerations.
4. Optimization techniques and pilot plant scale up techniques.
5. Stability testing, sterilization process and packaging of dosage forms.

Module 01 **20 Hours**

Pre-formation Concepts

- Drug excipient interactions- different methods, kinetics of stability, Stability testing. Theories of dispersion
- Pharmaceutical dispersion (Emulsion and Suspension, SMEDDS) preparation and stability
- Large and small volume parental– physiological and formulation consideration, manufacturing and evaluation

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

Module 02 **10 Hours**

Validation

- Introduction to pharmaceutical validation, scope and 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

Module 03 **10 Hours**

cGMP and 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

Module 04 **10 Hours**

Compression and Compaction

- Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles
- Solubility

Module 05 **10 Hours**

- Study of consolidation parameters
- Diffusion parameters
- Dissolution parameters
- 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

Recommended Books (Latest editions)

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, 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.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPH104T	Regulatory Affairs	4	-	25	75	1	3	4

Scope: Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance

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

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

Module 01 **12 Hours**

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

Module 02 **12 Hours**

- 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

Module 03 **12 Hours**

Non-Clinical Drug Development

- Global submission of IND, NDA, ANDA
- Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

Module 04 **12 Hours**

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

Recommended Books (Latest editions)

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 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, 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

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPH105P	Pharmaceutics Practical - I	-	12	50	100	6	6	6

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 of 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

2nd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPH201T	Molecular Pharmaceutics (Nano Tech & Targeted DDS)	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

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

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

Module 01 **12 Hours**

Targeted Drug Delivery Systems

- Concepts, events and biological process involved in drug targeting
- Tumor targeting
- Brain specific delivery

Module 02 **12 Hours**

Targeting Methods

- Introduction preparation and evaluation

Nano Particles and Liposomes

- Types, preparation and evaluation

Module 03 **12 Hours**

- Micro Capsules / Micro Spheres: types, preparation and evaluation
- Monoclonal Antibodies: preparation and application
- Preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes

Module 04 **12 Hours**

Pulmonary Drug Delivery Systems

- Aerosols, propellents, Containers types, preparation and evaluation

Intra Nasal Route Delivery Systems

- Types, preparation and evaluation

Module 05 **12 Hours**

Nucleic Acid Based Therapeutic Delivery System

- Gene therapy, introduction (ex-vivo and in-vivo gene therapy)
- Potential target diseases for gene therapy (inherited disorder and cancer)
- Gene expression systems (viral and non-viral gene transfer)

- Liposomal gene delivery systems
- Bio distribution and pharmacokinetics
- Knowledge of therapeutic antisense molecules and aptamers as drugs of future

Recommended Books (Latest editions)

1. Y. W. Chien, Novel Drug Delivery Systems, revised and expanded, Marcel Dekker, Inc., New York.
2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers and Distributors, New Delhi.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

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

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

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

Pharmacokinetics

- Basic considerations, pharmacokinetic models

Compartment Modelling

- One compartment model- IV bolus, IV infusion, extra-vascular
- Multi compartment model: Two compartments - 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, and drug interactions linked to transporters

Module 04 **12 Hours**

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, 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

Module 05 **12 Hours**

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

Recommended Books (Latest editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, Philadelphia, Lea and Febiger.
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, Connecticut Appleton Century Crofts.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book.
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, Marcel Dekker Inc.,New York.
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia.
7. Clinical Pharmacokinetics, Concepts and Applications, by MalcolmRowland and Thom N. Tozer, Lea and Febiger, Philadelphia.
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania.
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, Drug Intelligence Publications, Hamilton, Illinois.
11. Encyclopedia of Pharmaceutical Technology, Vol 13,James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York.
12. Basic Pharmacokinetics , Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPH203T	Computer Aided Drug Delivery System	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

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

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

Module 01 **12 Hours**

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, Population Modeling

Quality-by-Design in Pharmaceutical Development

- Introduction, ICH Q8 guideline, Regulatory and industry views on
- QbD, Scientifically based QbD - examples of application

Module 02 **12 Hours**

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

Module 03 **12 Hours**

Computer-Aided Formulation Development

- Concept of optimization, optimization parameters, factorial design, optimization technology and 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

Module 04 **12 Hours**

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, Bio-waiver considerations

Computer Simulations in Pharmacokinetics and Pharmacodynamics

- Introduction, Computer Simulation
- Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes

Computers in Clinical Development

- Clinical Data Collection and Management, Regulation of Computer Systems

Module 05 **12 Hours**

Artificial Intelligence (AI), Robotics and Computational Fluid Dynamics

- General overview, Pharmaceutical Automation, Pharmaceutical applications
- Advantages and Disadvantages
- Current Challenges and Future Directions

Recommended Books (Latest editions)

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

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPH204T	Cosmetics & Cosmeceuticals	4	-	25	75	1	3	4

Scope: This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

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

1. Key ingredients used in cosmetics and cosmeceuticals.
2. Key building blocks for various formulations.
3. Current technologies in the market.
4. Various key ingredients and basic science to develop cosmetics and cosmeceuticals.
5. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Module 01 **12 Hours**

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

Module 02 **12 Hours**

Cosmetics - Biological Aspects

- Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odour
- 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

Module 03 **12 Hours**

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 and syndetbars

Perfumes

- Classification of perfumes
- Perfume ingredients listed as allergens in EU regulation

Controversial Ingredients

- Parabens, formaldehyde liberators, dioxane

Module 04 **12 Hours**

Design of Cosmeceutical Products

- Sun protection, sunscreens classification and regulatory aspects
- Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odour, dandruff, dental cavities, bleeding gums, mouth odour and sensitive teeth through cosmeceutical formulations

Module 05 **12 Hours**

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

Recommended Books (Latest editions)

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

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPH205P	Pharmaceutics Practical - II	-	12	50	100	6	6	6

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 and poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals
10. Pharmacokinetic and IVIVC data analysis by Winnoline R 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

3rd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MRM301T	Research Methodology & Biostatistics	4	-	25	75	1	3	4

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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

Module 05 **12 Hours**

Declaration of Helsinki

- History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care

Recommended Books (Latest editions)

1. Basic & Clinical Biostatistics, Beth Dawson and Robert G. Trapp. Lange Medical Books/McGraw-Hill Medical Publishing Division.
2. Research Methdology, R. Panneerselvam, PHI Learning Pvt. Limited, Delhi.
3. Methods in Biostatistics, B.K. Mahajan. JAYPEE Brothers Medical Publishers (P) Ltd.
4. CPCSEA Guidelines.
   A Handbook of Applied Statistics in Pharmacology, Katsumi Kobayashi and K. Sadasivan Pillai. CRC Press, Taylor & Francis Group.