Pt. Ravishankar Shukla University,
Raipur (C.G.), India 492010

CURRICULUM & Syllabus
(Based on CBCS & LOCF)

M. Pharm.- Pharmaceutics
(Semester System)

Semester: I-IV

Session: 2025-2027

टीपः– सत्र. 2024-2026 के पाठ्यक्रम को सत्र 2025-2027.....के लिए यथावत प्रभावशील किया जाता है।

Approved by	:	
Board of Studies	:	Pharmacy
Dates	:	16-05-2025
Name of Chairman	:	Dr. S. J. Daharwal
Name of Member's	:	Dr. Preeti K. Suresh
		Dr. Manju Singh
		Dr. Amber Vyas
		Dr. Deependra Singh

M. Pharm in Pharmaceutics

Upon successful completion of the Master of Pharmacy in Pharmaceutics program, students will be able to:

Program Outcomes (POs)

PO-1	**Knowledge:** Acquire knowledge and skills in the areas of preformulation, different pharmaceutical dosage forms, industry management, optimization techniques, computational tools, Quality-by- Design, cGMP, IPR, pilot plant scale up, drug regulation, cosmeceuticals, advanced manufacturing processes, biopharmaceutics and pharmacokinetics
PO-2	**Critical Thinking and Reasoning:** Develop ability for in-depth information and critical thinking in order to design and develop the appropriate dosage forms to overcome the problems of the drugs in connection with bioavailability drug targeting, manufacturing and stability by adapting advanced strategies.
PO-3	**Problem Solving:** Recognize and analyze the problems related to design, development and manufacturing of dosage forms
PO-4	**Advanced Analytical and Computational Skills:** Apply appropriate and modern analytical methods, instrumentation, technologies, and processes such as computational approaches. Develop skills necessary for applying computers in pharmaceutical research and development. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process.
PO-5	**Effective Communication**: Understand, analyze and communicate effectively on academic, research, industry, regulatory, health careissues.
PO-6	**Social/ Interdisciplinary Interaction**: Integrate pharmaceutics concepts and techniques into multidisciplinary context, collaborating effectively with professionals from other fields to address complex problems in pharmaceutical domain. Fill the gap with interdisciplinary health care communities to provide innovative solutions for the purpose of maintain public health.
PO-7	**Self-directed and Life-long Learning**: Cultivate a spirit that would enable individuals to recognise the importance of ongoing professional development and work towards self-driven performance- goals, entrepreneurial endeavours and overall leadership to tackle future challenges through lifelong learning.
PO-8	**Effective Citizenship**: **Leadership and Innovation:** Cultivate the skill and confidence to perform proficiently as an individual, as one of the team members or as a leader of the team in multidisciplinary settings for effective productivity and to provide innovative solutions to emerging challenges in pharmaceutics.
PO-9	**Ethics**: Develop and demonstrate a sense of fair play and sensitivity to pharmaceutical and professional ethics in research, teaching and collaboration, adhering to professional standards and best practices.
PO-10	**Further Education or Employment:** Engage for further academic pursuits, includingPhD programs and post-doctoral research in pharmaceutical sciences and allied fields. Get employment in academia, research institutions, industry, government and other sectors.
PO-11	**Global Perspective**: Empower to recognize the global perspective of pharmaceutical professionals and its impact, appreciating diverse cultural perspectives in various pharmaceutical domains.

PROGRAMME SPECIFIC OUTCOMES (PSOs): At the end of the program, the student will be able to:

PSO1	Understand the development and evaluation of various pharmaceutical dosage forms, with research competencies to work in the domain of pharmaceutical formulation or drug delivery science and technology, and explore the concept in further details.
PSO2	Apply the knowledge of pharmaceutical concepts to Train the Masters' students to gain comprehensive knowledge and skills to deliver services to the pharmaceutical organizations to design, formulate, evaluate and manufacture suitable drug products. To apply the knowledge in interdisciplinary fields and draw the inferences by finding appropriate solutions.
PSO3	Nurture and support an inclination for higher education, pursue research in challenging areas of pharmaceutics and entrepreneurship.
PSO4	Employ confidently the knowledge of the course in solving complex pharmaceutical problems and scientific investigations.
PSO5	Empower and sensitize the Pharmaceutics professionals to serve the Pharmaceutical Industry, Academia, Society, Regulatory Bodies and the Profession.

M. Pharm in Pharmaceutics

Semester-I

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutics**	I	I
Course Code	Course Title		Course Type
MPH 102T	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	--	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the significance of pharmacognosy in the herbal drug industry and explain the principles and practices of cultivation, collection, and conservation of medicinal plants, including regulatory and ethical guidelines.	Ap
2	Describe the techniques for isolation and purification of marine natural products, identify marine toxins, discuss recent advances, and analyze challenges and solutions in marine drug research.	Ap
3	Explain the classification, formulation, standardization, and regulatory guidelines of nutraceuticals; and evaluate the sources, chemical nature, and health benefits of commonly used nutraceutical ingredients.	U
4	Identify and classify important phytopharmaceuticals based on chemical nature, explain their isolation, and evaluate their pharmacological and health-related applications.	An
5	Understand and apply WHO and AYUSH guidelines for safety monitoring of natural medicines, and analyze biodrug interactions and reporting systems with appropriate examples.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	3	1	2	3	3	2	3	2	2	3	1	2	3	2
CO2	3	3	3	3	1	1	3	1	2	3	2	2	3	2	1	2
CO3	3	3	2	3	2	2	2	2	2	3	3	3	3	2	2	3
CO4	3	2	3	3	2	1	3	2	2	3	2	3	3	3	2	2
CO5	3	3	2	1	3	2	3	1	3	2	3	2	2	2	2	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
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, Difference/ Derivative spectroscopy. b) **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy. c) **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	10hrs	1
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.	10hrs	2
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.	10hrs	3
IV	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Affinity chromatography	10hrs	4

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 methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction **Immunological assays** : RIA (Radio immuno assay), ELISA, Bioluminescence assays	10hrs	
VI	**Potentiometry**: Principle, working, Ion selective Electrodes and Application of potentiometry. **Thermal Techniques**: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	10hrs	

Books Recommended:

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. Pharmaceutics - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutics, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

Semester-I

	Subject	Year	Semester
M. Pharm.	Pharmaceutics	I	I
Course Code	Course Title		Course Type
MPH 102T	DRUG DELIVERY SYSTEMS		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	--	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):
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

	Course Outcomes (CO):
CO1	Explain the fundamental concepts, advantages, mechanisms, and formulation strategies of sustained and controlled drug delivery systems, and explore advances like personalized medicines, bioelectronics, and 3D-printed pharmaceuticals.
CO2	Describe and analyze the principles, classification, and mechanisms of various rate-controlled, modulated, and feedback-regulated drug delivery systems..
CO3	Demonstrate understanding of specialized drug delivery systems including gastro-retentive, buccal, ocular, and transdermal systems, along with their barriers and evaluation.
CO4	Analyze formulation strategies and barriers for protein, peptide, and vaccine delivery systems, including novel delivery approaches like mucosal and transdermal routes.
CO5	Integrate advanced drug delivery knowledge with contemporary technologies and regulatory requirements for designing innovative and patient-specific drug delivery systems..

CO-PO/PSO Mapping for the course:

PO-CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	2	2	2	2	2	2	3	3	3	3	2	3	3
CO2	3	3	3	3	2	1	1	1	2	3	2	3	3	2	3	2
CO3	3	3	3	3	2	2	2	2	2	3	2	3	3	2	3	3
CO4	3	3	3	3	2	2	2	2	2	3	2	3	3	3	3	3
CO5	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3

Detailed Syllabus

1.	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, BioelectronicMedicines, 3D printing of pharmaceuticals, Telepharmacy.	10 Hrs
2.	Rate Controlled Drug Delivery Systems: Principles &Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10 Hrs
3.	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10 Hrs
4.	Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs
5.	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6.	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7.	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	07 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyIntersciencePublication, 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,VallabhPrakashan, 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

Semester-I

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutics	I	I
Course Code	Course Title		Course Type
MPH 103T	MODERN PHARMACEUTICS		Core

Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	–	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

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

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand and evaluate preformulation concepts, drug-excipient interactions, dispersion systems, parenteral dosage forms, and apply optimization techniques in formulation and process development.	Ap
2	Demonstrate knowledge of pharmaceutical validation principles, regulatory guidelines, and validation protocols including URS, DQ, IQ, OQ, and PQ for various dosage forms and equipment.	Ap
3	Apply the principles of cGMP and industrial management including production, inventory, quality, cost control, and Total Quality Management in pharmaceutical industries.	U
4	Analyze the physical principles and mechanics of compression and compaction, and their influence on dosage form design and performance.	An
5	Perform and interpret various statistical and kinetic parameters relevant to drug formulation, dissolution, and pharmacokinetics using tools like Heckel plots, similarity factors, and ANOVA.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO-CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	3	2	2	2	2	2	3	2	3	3	2	3	3
CO2	3	3	3	3	2	2	2	2	3	3	2	3	3	2	3	3
CO3	3	2	2	2	3	3	3	3	3	3	3	2	3	2	2	3
CO4	3	3	3	3	2	2	2	2	2	2	2	3	3	2	3	2
CO5	3	3	3	3	2	1	1	1	2	2	2	3	3	3	3	2

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

1.	a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.	10 Hrs 10 Hrs
2.	Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10 Hrs
3.	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 Hrs
4.	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10 Hrs
5.	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckelplots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10 Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutics	I	I
Course Code	Course Title		Course Type
MPH 104T	REGULATORY AFFAIRS		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
04	4	–	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

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 regulatoryimportance
- To learn the documentation requirements for
- To learn the importance and

Objectives:

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

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand and apply documentation practices in pharmaceutical industry including Master Formula Records, DMFs, distribution records, and regulatory submission processes like NDA, ANDA, BE studies, and post-marketing surveillance.	Ap
2	Demonstrate knowledge of national and international regulatory requirements and pathways for drug and biologics approval including USFDA, EMA, MHRA, TGA, and ROW countries.	Ap
3	Analyze regulatory expectations in Chemistry, Manufacturing and Controls (CMC), post-approval changes, medical devices, and CTD/eCTD dossier submissions.	U
4	Evaluate the non-clinical drug development process including regulatory submissions such as IND, NDA, ANDA, IMPD, and Investigator Brochure (IB).	An
5	Understand the design, ethical considerations, and safety monitoring of clinical trials, including protocol development, IRB/IEC processes, informed consent, HIPAA requirements, and pharmacovigilance.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	3	2	2	2	2	3	3	2	3	3	2	3	3
CO2	3	3	3	2	2	2	2	2	3	3	3	3	3	2	3	3
CO3	3	3	3	3	2	2	2	2	3	3	2	3	3	2	3	3
CO4	3	3	3	3	2	2	2	2	2	3	2	3	3	2	3	2
CO5	3	3	3	2	3	2	2	2	3	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus

1.	a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.	12 Hrs
2.	CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3.	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4.	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,MarcelDekker 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, andbiologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to RegulatoryCompliance 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

Semester-I

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutics	1	I
Course Code	Course Title		Course Type
MPH 105P	Pharmaceutics Practical - I		Core

Credit	Hours Per Week (L-T-P)		
	L	T	P
6	–	–	12

Maximum Marks	CIA	ESE
150	50	100

Learning Objective (LO):

This course is designed to gain practical skills on formulation and evaluation of various types of tablets and novel drug delivery systems. This course also includes preformulation and analytical techniques for estimation of pharmaceutical active ingredients and their formulations. Upon completion of this course, the student will be able to –

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Apply spectroscopic and chromatographic techniques (UV-Vis, HPLC, GC, fluorimetry, flame photometry) for qualitative and quantitative analysis of pharmaceutical compounds and formulations.	Ap
2	Perform in-vitro evaluation and comparative dissolution studies of sustained-release and controlled-release drug delivery systems.	Ap
3	Formulate and evaluate various novel drug delivery systems including matrix tablets, osmotically controlled systems, floating DDS, mucoadhesive tablets, and transdermal patches.	U
4	Conduct preformulation studies and analyze the influence of formulation variables (compressional force, particle size, binder concentration, micromeritics) on tablet characteristics and performance.	An
5	Apply mathematical models and kinetic plots (Heckel, Higuchi, Peppas, similarity factors) to interpret drug release data and optimize formulation strategies.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO-CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	3	3	2	1	2	1	3	3	2	3	3	2	3	3
CO2	3	3	3	2	2	2	2	1	2	3	2	3	3	2	3	3
CO3	3	3	3	2	2	2	2	2	2	3	2	3	3	2	3	3
CO4	3	3	3	3	2	1	2	1	2	3	2	3	3	2	3	3
CO5	3	3	3	3	2	1	2	2	2	3	2	3	3	2	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

LIST OF PRACTICALS
1. Analysis of pharmacopoeial compounds and their formulations by UV Visspectrophotometer. 2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry. 3. Experiments based on HPLC. 4. Experiments based on Gas Chromatography. 5. Estimation of riboflavin/quinine sulphate by fluorimetry 6. Estimation of sodium/potassium by flame photometry. 7. To perform In-vitro dissolution profile of CR/ SR marketed formulation. 8. Formulation and evaluation of sustained release matrix tablets. 9. Formulation and evaluation osmotically controlled DDS. 10. Preparation and evaluation of Floating DDS- hydro dynamically balancedDDS. 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 similarityfactors.

M. Pharm in Pharmaceutics

Semester-II

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutics	1	II
Course Code	Course Title		Course Type
MPH201T	MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	–	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

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

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the principles and biological processes involved in targeted drug delivery, with specific focus on tumor and brain targeting.	Ap
2	Describe the preparation, characterization, and evaluation of advanced drug carriers such as nanoparticles and liposomes	Ap
3	Develop knowledge of micro and nano drug delivery systems including microspheres, microcapsules, monoclonal antibodies, and novel vesicular carriers like niosomes, aquasomes, and phytosomes.	U
4	Apply the formulation and evaluation principles for site-specific delivery via pulmonary and intranasal routes using specialized dosage forms like aerosols and inhalers.	An
5	Comprehend the fundamentals of gene therapy and nucleic acid-based drug delivery systems, including their pharmacokinetics, biodistribution, and therapeutic potential using modern vectors.	U

CO-PO/PSO Mapping for the course:

PO-CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	2	2	2	2	1	2	3	2	3	3	2	3	3
CO2	3	3	3	3	2	2	2	1	2	3	2	3	3	2	3	3
CO3	3	3	3	3	2	2	2	1	2	3	2	3	3	2	3	3
CO4	3	2	3	3	2	2	2	1	2	3	2	3	3	2	3	3
CO5	3	3	3	3	2	2	3	2	3	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus

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

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts andadvances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers &Distributors, NewDelhi, First edition 1997 (reprint in 2001).

Semester-II

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutics	I	II
Course Code	Course Title		Course Type
MPH202T	ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	--	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

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.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Explain the physiological and physicochemical factors affecting drug absorption from the gastrointestinal tract and relate them to formulation design and drug dissolution principles.	Ap
2	Evaluate biopharmaceutical factors influencing drug product performance, including in vitro–in vivo correlation (IVIVC), dissolution testing, and drug stability.	Ap
3	Interpret and apply compartmental and non-compartmental pharmacokinetic models including nonlinear pharmacokinetics and drug interactions.	U
4	Analyze in vivo drug performance, bioavailability, bioequivalence, and regulatory considerations in designing and evaluating dosage forms, including biosimilars and BCS classification.	An
5	Understand and apply pharmacokinetic principles to the development of modified-release and targeted drug delivery systems, especially biotechnological products such as proteins, monoclonal antibodies, and gene therapies.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO-CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	3	2	2	2	1	2	3	2	3	3	2	3	3
CO2	3	3	3	3	3	2	2	2	2	3	2	3	3	2	3	3
CO3	3	3	3	3	3	3	3	2	2	3	2	3	3	3	3	3
CO4	3	3	3	3	3	2	3	2	2	3	2	3	3	3	3	3
CO5	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

1.	Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form,Dissolution methods,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	12 Hrs
2.	Biopharmaceutical considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutical 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 drug product.	12 Hrs
3.	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmaxand vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, druginteractions linked to transporters.	12 Hrs
4.	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hrs
5.	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hrs

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankarand Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2ndedition, 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, MarcelDekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics,Swarbrick. J, LeaandFebiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition byMalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, MackPublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expanded by Robert. E. Notari, Marcel Dekker Inc, NewYork and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner andM.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 JBreen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and ChargeState, Alex Avdeef, John Wiley & Sons, Inc,2003.

Semester-II

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutics	I	II
Course Code	Course Title		Course Type
MPH203T	COMPUTER AIDED DRUG DEVELOPMENT		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	–	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

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.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to ;	CL
1	Understand the evolution of computer applications in pharmaceutical R&D and apply statistical and mechanistic modeling principles, including Quality by Design (QbD) frameworks.	Ap
2	Analyze computational models of drug disposition including absorption, distribution, metabolism, excretion, and transporter interactions.	Ap
3	Apply computer-aided formulation and optimization techniques using design of experiments (DoE), and understand legal and ethical implications in R&D computing.	U
4	Evaluate computer-aided biopharmaceutical and pharmacokinetic/pharmacodynamic (PK/PD) modeling tools, including virtual trials and biowaiver-based simulations.	An
5	Understand and assess the use of Artificial Intelligence, robotics, and computational fluid dynamics in pharmaceutical automation and future development.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO-CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	3	3	2	2	2	2	3	2	3	3	2	3	3
CO2	3	3	3	3	3	2	2	2	2	3	2	3	3	3	3	3
CO3	3	3	3	3	3	2	2	3	2	3	3	3	3	3	3	3
CO4	3	3	3	3	3	2	2	3	2	3	3	3	3	3	3	3
CO5	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

1.	a. 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 b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	12 Hrs
2.	Computational Modeling Of Drug Disposition: Introduction,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	12 Hrs
3.	Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis.	12 Hrs
4.	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in vivo correlation, Biowaiver considerations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems.	12 Hrs
5.	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs

REFERENCES

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

Semester-II

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutics	I	II
Course Code	Course Title		Course Type
MPH204T	COSMETICS AND COSMECEUTICALS		Core

Credit	Hours Per Week (L-T-P)		
	L	T	P
06	-	–	12

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):
This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Explain the Indian regulatory framework governing the manufacture, labeling, import, and classification of cosmetic products	Ap
2	Understand the biological aspects of skin, hair, and oral cavity relevant to cosmetic product development and dermatological concerns.	Ap
3	Identify and evaluate formulation building blocks and additives used in various cosmetics/cosmeceuticals, including safety and regulatory concerns	U
4	Design cosmetic and cosmeceutical products targeted at specific dermatological and oral conditions, including sun protection, acne, and pigmentation.	An
5	Evaluate herbal ingredients and guidelines for herbal cosmetics and address formulation challenges in the development of herbal cosmeceuticals.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO-CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	2	2	2	3	3	2	3	3	3	3	2	2	3
CO2	3	3	2	2	3	1	2	2	2	3	2	3	3	2	3	2
CO3	3	3	3	2	3	1	2	3	2	3	2	3	3	3	3	3
CO4	3	3	3	3	3	1	2	3	2	3	3	3	3	3	3	3
CO5	3	3	2	2	3	2	2	2	2	3	2	3	3	2	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

1.	Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	12 Hrs
2.	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 Hrs
3.	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.	12 Hrs
4.	Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	12 Hrs
5.	Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.	12 Hrs

REFERENCES

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

Semester-II

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutics	I	II
Course Code	Course Title		Course Type
MPH205P	**Pharmaceutics Practical II**		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	--	--

Maximum Marks	CIA	ESE
150	50	100

Learning Objective (LO):

This course is designed to provide practical skills on formulation of various novel drug delivery systems. The course also includes experiments related to biopharmaceutics and pharmacokinetics, Quality by design and design of experiments.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Apply formulation techniques to develop and evaluate novel drug delivery systems including microcapsules, microspheres, liposomes, and niosomes	Ap
2	Analyze dissolution characteristics, perform bioavailability and pharmacokinetic studies, and apply in vitro–in vivo correlation concepts using relevant software tools.	Ap
3	Utilize Quality-by-Design (QbD) and Design of Experiments (DoE) tools to optimize pharmaceutical formulations and analyze experimental data.	U
4	Develop and evaluate cosmeceutical products like creams, shampoos, and herbal-based formulations addressing specific dermatological and oral conditions.	An
5	Perform computational modeling of drug disposition, simulations in pharmacokinetics/pharmacodynamics, and handle clinical data using modern software platforms.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO-CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	3	3	1	2	2	2	2	2	3	3	3	3	2
CO2	3	3	3	3	3	2	2	3	2	2	3	3	3	3	3	3
CO3	3	3	3	3	3	3	2	2	2	2	2	3	3	3	3	3
CO4	3	3	2	2	2	2	3	2	2	2	3	3	3	2	3	3
CO5	3	3	3	3	3	3	3	3	2	2	2	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

LIST OF PRACTICALS

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 Soliddispersion technique.
7. Comparison of dissolution of two different marketed products /brands.
8. Protein binding studies of a highly protein bound drug & poorly proteinbound drug.
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR 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 anddandruff.

Semester-II

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutics	I	II
Course Code	Course Title		Course Type
PCE-MPH206S	SEMINAR IN PHARMACEUTICS		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
–	–	–	--

Maximum Marks	CIA	ESE
100	--	100

Learning Objective (LO):

The subject is designed to create an environment where teachers provide the students a critical eye and openness to fortify the presentation and academic writing skills of students in the field of Pharmaceutics and industrial pharmacy.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Develop skills to gather, organize, deliver information, and defend a given topic in Pharmaceutics and industrial pharmacy.	Ap
2	Learn to organize complex concepts using audio-visual aids.	Ap
3	Acquire communication and presentation skills.	U
4	Effectively respond to questions raised by peers and stand scientific scrutiny.	An
5	Develop a write-up on the subject of seminar presentation and cultivate continuous learning.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO-CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	2	2	2	3	3	2	2	2	3	2	2	2	2
CO2	3	3	3	2	2	2	2	3	2	2	2	2	2	2	2	2
CO3	3	3	3	3	2	2	2	3	3	3	3	3	2	2	2	2
CO4	3	3	3	3	2	3	3	3	3	3	3	3	3	2	2	2
CO5	3	3	3	2	3	3	2	2	2	2	3	3	3	3	3	2

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester-III

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutics**	2	III
Course Code	Course Title		Course Type
MRM301T	**Research Methodology and Biostatistics**		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	--	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

- Understand the fundamentals of research methodology including study designs, bias elimination, controls, and randomization techniques.
- Apply biostatistical methods for analyzing data, interpreting statistical tests, and understanding the role of sample size in research.
- Comprehend the ethical principles and dilemmas in medical research, including patient autonomy, informed consent, confidentiality, and conflicts of interest.
- Learn the CPCSEA guidelines for proper laboratory animal care and management in compliance with ethical and regulatory standards.
- Recognize the significance of the Declaration of Helsinki in framing ethical standards for medical research involving human subjects.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Explain general research methodology, including study designs, bias elimination, controls, randomization, and blinding techniques.	Ap
2	Apply biostatistical concepts including sample size determination, parametric and non-parametric tests, and interpretation of results.	Ap
3	Discuss medical ethics principles, including autonomy, beneficence, informed consent, confidentiality, and ethical dilemmas.	U
4	Understand and implement CPCSEA guidelines for ethical treatment and management of laboratory animals in research facilities.	An
5	Describe the history, principles, and applications of the Declaration of Helsinki for ethical medical research.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	4	4	3	3	2	1	3	1	1	2	1	2	2	2	1	2
CO2	4	4	4	5	2	1	4	1	1	2	1	3	4	2	1	3
CO3	3	4	4	2	4	3	3	2	4	3	3	2	2	3	1	2
CO4	3	3	3	2	2	2	2	2	4	2	1	4	2	3	5	3
CO5	3	3	3	2	2	2	3	2	5	2	2	3	3	3	2	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
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.	4	1
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.	4	2
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.	4	3
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.	4	4
V	**Declaration of Helsinki:** History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	4	5

Books Recommended:

1. Research Methodology: Methods and Techniques by C.R. Kothari
2. Biostatistics: A Foundation for Analysis in the Health Sciences by Wayne W. Daniel and Chad L. Cross
3. Statistical Methods for Practice and Research by Ajai S. Gaur and Sanjaya S. Gaur
4. Principles of Biomedical Ethics by Tom L. Beauchamp and James F. Childress
5. Medical Ethics: Accounts of Ground-Breaking Cases by Gregory Pence
6. Ethics and the Practice of Psychology by Gerald P. Koocher and Patricia Keith-Spiegel
7. Guide for the Care and Use of Laboratory Animals by Institute for Laboratory Animal Research (ILAR)
8. CPCSEA Guidelines on Laboratory Animal Facilities and Ethics
9. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects

Semester-III

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutics**	2	III
Course Code	Course Title		Course Type
	JOURNAL CLUB IN PHARMACEUTICS		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
1	1	–	--

Maximum Marks	CIA	ESE
75	25	-

Learning Objective (LO):

The subject is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students. This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with principles of statistics and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Organize and present complex research concepts effectively using audio-visual aids.	Ap
2	Develop strong communication and presentation skills in the context of scientific research.	Ap
3	Critically analyze published research papers and respond effectively to scientific queries and scrutiny	U
4	Understand and apply principles of research methodology, ethics, and biostatistics in research analysis.	An
5	Foster continuous self-learning and knowledge upgradation in advanced research techniques.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	2	2	2	3	3	2	2	2	3	2	2	2	2
CO2	3	3	3	2	2	2	2	3	2	2	2	3	2	2	2	2
CO3	3	3	3	3	2	3	3	3	3	3	3	3	3	2	2	2
CO4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
CO5	3	3	3	2	3	3	2	2	2	2	3	3	3	3	3	2

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester-III

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutics**	2	III
Course Code	Course Title		Course Type
	DISCUSSION / PRESENTATION (PROPOSAL PRESENTATION)		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
2	2	--	--

Maximum Marks	CIA	ESE
50	50	--

Learning Objective (LO):

The subject is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students. This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with principles of statistics and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the significance of clear vision and well-defined objectives in pharmaceutical research	Ap
2	Identify and analyze the key components of vision and objectives statements in research proposals.	Ap
3	Develop a comprehensive and coherent vision and objectives statement for pharmaceutical research projects.	U
4	Enhance scientific communication and presentation skills through proposal and final presentations.	An
5	Critically evaluate peer presentations and provide constructive feedback to improve research quality.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	2	2	1	2	1	1	1	1	1	3	2	1	2	2
CO2	3	3	2	2	1	2	2	2	1	1	1	3	2	1	2	2
CO3	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3
CO4	3	3	3	2	2	2	2	3	2	2	2	3	2	2	2	2
CO5	3	3	3	3	2	3	3	3	3	2	2	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester-III

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutics**	2	III
Course Code	Course Title		Course Type
	RESEARCH WORK		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
14	--	–	28

Maximum Marks	CIA	ESE
350	--	350

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Design, conduct, and analyze original pharmaceutical research to contribute to the advancement of knowledge in pharmacy	Ap
2	Apply theoretical and practical knowledge to solve real-world pharmaceutical problems, develop research hypotheses, and critically evaluate scientific literature	Ap
3	Develop research skills including study design, data collection, analysis, interpretation, and prepare scientific manuscripts and presentations	U
4	Demonstrate expertise in a specific pharmacy area and innovate new methodologies or technologies to improve pharmaceutical practice and patient care.	An
5	Effectively communicate and present research findings through scientific writing, posters, and oral presentations to prepare for research and academic careers.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3
CO2	3	3	3	2	2	3	2	2	2	2	2	3	3	2	3	2
CO3	3	3	3	3	3	3	3	2	2	2	2	3	3	3	3	3
CO4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
CO5	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester- IV

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutics**	2	III
Course Code	Course Title		Course Type
	DISCUSSION / PRESENTATION (PROPOSAL PRESENTATION)		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
2	2	--	--

Maximum Marks	CIA	ESE
75	75	--

Learning Objective (LO):

The subject is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students. This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with principles of statistics and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the significance of clear vision and well-defined objectives in pharmaceutical research	Ap
2	Identify and analyze the key components of vision and objectives statements in research proposals.	Ap
3	Develop a comprehensive and coherent vision and objectives statement for pharmaceutical research projects.	U
4	Enhance scientific communication and presentation skills through proposal and final presentations.	An
5	Critically evaluate peer presentations and provide constructive feedback to improve research quality.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	2	2	1	2	1	1	1	1	1	3	2	1	2	2
CO2	3	3	2	2	1	2	2	2	1	1	1	3	2	1	2	2
CO3	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3
CO4	3	3	3	2	2	2	2	3	2	2	2	3	2	2	2	2
CO5	3	3	3	3	2	3	3	3	3	2	2	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester-IV

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutics**	2	III
Course Code	Course Title		Course Type
	RESEARCH WORK		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
31	--	--	16

Maximum Marks	CIA	ESE
400	--	400

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Design, conduct, and analyze original pharmaceutical research to contribute to the advancement of knowledge in pharmacy	Ap
2	Apply theoretical and practical knowledge to solve real-world pharmaceutical problems, develop research hypotheses, and critically evaluate scientific literature	Ap
3	Develop research skills including study design, data collection, analysis, interpretation, and prepare scientific manuscripts and presentations	U
4	Demonstrate expertise in a specific pharmacy area and innovate new methodologies or technologies to improve pharmaceutical practice and patient care.	An
5	Effectively communicate and present research findings through scientific writing, posters, and oral presentations to prepare for research and academic careers.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3
CO2	3	3	3	2	2	3	2	2	2	2	2	3	3	2	3	2
CO3	3	3	3	3	3	3	3	2	2	2	2	3	3	3	3	3
CO4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
CO5	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations andOther Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/ Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
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

Note: International Conference: Held Outside India
International Journal: The Editorial Board Outside India

*The credit points assigned for extracurricular and or co-curricular activities shallbe given by the Principals of the colleges and the same shall be submitted to theUniversity. The criteria to acquire this credit point shall be defined by the colleges from time to time.