OBE DOCUMENT

School of Pharmacy
M.Pharm

Program Code:
SOP0103

2024-2026

Programme Structure with semester wise credit distribution

Proposed Batch: 2024-2026

Sr. No	Course Code*	Course Name		L	T	P	Credits
Semester I							
1	MPH101T	Modern Pharmaceutical Analytical Techniques		4	0	0	4
2	MPH102T	Drug Delivery System		4	0	0	4
3	MPH103T	Modern Pharmaceutics		4	0	0	4
4	MPH104T	Regulatory Affair		4	0	0	4
5	MPH105P	Pharmaceutics Practical I		0	0	12	6
6	MPS100S	Seminar/Assignment		7	0	0	4
		Total					**26**
			Semester I Total Minimum Credits: 26				
Semester II							
1	MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)		4	0	0	4
2	MPH202T	Advanced Biopharmaceutics & Pharmacokinetics		4	0	0	4
3	MPH203T	Computer Aided Drug Delivery System		4	0	0	4
4	MPH204T	Cosmetic and Cosmeceuticals		4	0	0	4
5	MPH205P	Pharmaceutics Practical II			0	12	6
6	-	Seminar/Assignment		7	0	0	4
		Total					**26**
			Semester II Total Minimum Credits: 26				

Semester III							
1	MRM 301T	Research Methodology and Biostatistics*		4			4
2	-	**J**ournal club		1			1
3	-	Discussion / Presentation (Proposal Presentation)		2			2
4	-	Research Work		28			14
5		Total					**21**
			Semester III Total Minimum Credits 21				
Semester IV							
1	-	**J**ournal Club		1			1
2	-	Research Work		31			16
3	-	Discussion/Final Presentation		3			3
							20
		Co-curricular activities (Attending conferences, Scientific presentations and other scholarly activities)					Min – 2 Max - 7
		Grand Total Minimum Credits for Programme:					**95**
		Grand Total Maximum Credits for Programme:					**100**

School:		**SOP**
Program:		**M. Pharm**
Branch:		**Pharmaceutics**
1	Course Code	MPH101T
2	Course Title	Modern Pharmaceutical Analytical Techniques
3	Credits	4
4	Contact Hours (L-T-P-C)	4-0-0-4
	Course Type	Compulsory
5	Course Objective	1. After completion of course student is able to know Various spectral techniques of analysis 2. The analysis of various drugs in single and combination dosage forms 3. Theoretical and practical skills of the instruments
6	Course Outcomes	CO1: To understand about the Instrumentation and applications of UV-Visible spectroscopy, IR spectroscopy and Spectroflourimetry CO2: To apply the basic Principle of NMR spectroscopy. CO3: To understand the basic principle, instrumentation, chromatographic parameters, factors affecting resolution and application of Chromatography. CO4: To analyze methods of preparation, tests for purity, assay, medicinal uses of important Drug Molecules. CO5: To evaluate the basic Principle, Instrumentation, Working, conditions, factors affecting separation and applications of Electrophoresis, Immunological assays and X ray Crystallography. CO6: To create and evaluate the basic Principle of Immunological assays.
7	Course Description	This course deals with the
8	Outline syllabus	
	1	**UNIT-I** **UV-Visible, IR, Spectroflourimetry:**

		a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy 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.
	2	**UNIT –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.
	3	**UNIT-III** Mass Spectroscopy : Principle, Theory, Instrumentation of Mass Spectroscopy, ifferent types of ionization like electron impact, chemical, field, FAB and MALDI, PCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation nd its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.
	4	**UNIT-IV** **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography
	5	**UNIT-V** **Electrophoresis:** A: 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) Isoelectric focusing B: X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray

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<tr><td></td><td></td><td colspan="3"></td></tr>
<tr><td></td><td>6</td><td colspan="3">UNIT-VI
Immunological assays:
RIA (Radio-Immuno-assay), ELISA, Bioluminescence assays.
Chemiluminescence for reactive oxygen species sensing
and imaging analysis, high-throughput ADME
screening in drug discovery, characterization and
quantification of antibody-drug conjugates, nucleic acid detection for coronavirus</td></tr>
<tr><td></td><td>Mode of examination</td><td colspan="3">Theory</td></tr>
<tr><td rowspan="2"></td><td rowspan="2">Weightage Distribution</td><td>Continuous Mode Assessment</td><td>Sessional Exam</td><td>ESE</td></tr>
<tr><td>10</td><td>15</td><td>75</td></tr>
<tr><td></td><td>Text book/s*</td><td colspan="3">1. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997 2. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

2. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.</td></tr>
<tr><td></td><td>Reference Book</td><td colspan="3">1.Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

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

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

4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume11, Marcel Dekker Series

5. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.</td></tr>
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School:		**SOP**
Program:		**M. Pharm**
Branch:		**Pharmaceutics**
1	Course Code	MPH102T
2	Course Title	**Drug Delivery System**
3	Credits	4
4	Contact Hours (L-T-P-C)	4-0-0-4
	Course Type	Compulsory
5	Course Objective	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.
6	Course Outcomes	CO1: To define Pre-formation and concepts and sustained release and controlled release formulations CO2: To Understand and optimize Pharmaceutical formulation. CO3: To apply different formulation for sustained drug delivery systems. CO4: To analyze the skills to solve different types of problems in solving the drug delivery. CO5: To Evaluate the Ocular Drug Delivery Systems & Transdermal Drug Delivery Systems. CO6: To apply various principles of Gastro retentive drug delivery systems.
7	Course Description	This course deals with the fundamentals of product development and their evaluation Process.
8	Outline syllabus	
	1	**UNIT-I** **Sustained Release (SR) and Controlled Release (CR) formulations:** Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/disadvantages, factors influencing, Physicochemical &

<table>
<tr><td></td><td></td><td colspan="3">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, Tele-pharmacy.</td></tr>
<tr><td></td><td>2</td><td colspan="3">UNIT –II
Rate Controlled Drug Delivery Systems
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.</td></tr>
<tr><td></td><td>3</td><td colspan="3">UNIT-III
Gastro-Retentive Drug Delivery Systems:
Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.</td></tr>
<tr><td></td><td>4</td><td colspan="3">UNIT-IV
Ocular Drug Delivery Systems & Transdermal Drug Delivery Systems:
Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and Evaluation.</td></tr>
<tr><td></td><td>5</td><td colspan="3">UNIT-V
Protein and Peptide Delivery & Vaccine delivery systems:
Protein and Peptide Delivery: Barriers for protein delivery. Formulation and evaluation of delivery systems of proteins and other macromolecules. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines</td></tr>
<tr><td></td><td>Mode of examination</td><td colspan="3">Theory</td></tr>
<tr><td rowspan="2"></td><td rowspan="2">Weightage Distribution</td><td>Continuous Mode Assessment</td><td>Sessional Exam</td><td>ESE</td></tr>
<tr><td>10</td><td>15</td><td>75</td></tr>
<tr><td></td><td>Text book/s*</td><td colspan="3">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.</td></tr>
</table>

		3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001). 4. S.P. Vyas and R. K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
	Reference Book	1. Encyclopaedia of Pharmaceutical technology, Vol I – III. 2. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim 3. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

School:		**SOP**
Program:		**M. Pharm**
Branch:		**Pharmaceutics**
1	Course Code	MPH103T
2	Course Title	Modern Pharmaceutics -Theory
3	Credits	4
4	Contact Hours (L-T-P-C)	4-0-0-4
	Course Type	Compulsory
5	Course Objective	Upon completion of the course, student shall be able to understand: 1. The cGMP aspects in a pharmaceutical industry 2. To appreciate the importance of documentation 3. To understand the scope of quality certifications applicable to Pharmaceutical industries. 4. To understand the responsibilities of QA & QC departments
6	Course Outcomes	CO1: To understand Pre-formation concepts and sustained release formulations. CO2: To Understand the types of validation and calibration, ICH & WHO Guidelines. CO3: To apply the principles of cGMP & Total Quality Management. CO4: To analyze the compaction & Compression principles of tablet. CO5: To evaluate Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, CO6: To apply the principles of Optimisation in Pharmaceutical formulation
7	Course Description	This course deals with Optimize Pharmaceutical Formulation and product development in industrial Management in the field of Pharmacy.
8	Outline syllabus	
	1	**UNIT-I** **Pre-formulation Concepts**- Drug Excipients 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 parenteral– 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.		
	2	**UNIT –II** **Validation:** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipment's, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.		
	3	**UNIT-III** **c-GMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment's 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**.**		
	4	**UNIT-IV** **Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.		
	5	**UNIT-V** **Study of consolidation parameters:** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test , ANOVA test.		
	Mode of examination	Theory		
	Weightage Distribution	Continuous Mode Assessment	Sessional Exam	ESE
		10	15	75
	Text book/s*	1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann 2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann. 3. Banker G.S., & Rhodes C.T., Modern Pharmaceutics, Marcel Dekker, New York. 4. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H.Beckett.		
	Reference Book	1. Encyclopedia of Pharmaceutical technology, Vol I – III. 2. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig. 3. Applied production and operations management; By Evans, Anderson, Sweeney and Williams 4. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.		

School:		**SOP**
Program:		**M. Pharm**
Branch:		**Pharmaceutics**
1	Course Code	MPH104T
2	Course Title	Regulatory Affairs
3	Credits	4
4	Contact Hours (L-T-P-C)	4-0-0-4
	Course Type	Compulsory
5	Course Objective	Upon completion of the course, it is expected that the students will be able to understand • The Concepts of innovator and generic drugs, drug development process • The Regulatory guidance's and guidelines for filing and approval process • Preparation of Dossiers and their submission to regulatory agencies in different countries • Post approval regulatory requirements for actives and drug products • Submission of global documents in CTD/ eCTD formats • Clinical trials requirements for approvals for conducting clinical trials • Pharmacovigilence and process of monitoring in clinical trials.
6	Course Outcomes	Student will be able C01: to understand the Concepts of innovator, generic drugs and drug development process. C02: to apply the Regulatory guidance's and guidelines for filing and approval process. C03: to understand Clinical trials requirements for approvals for conducting clinical trials C04 : to analyze Post approval regulatory requirements for actives and drug products C05 : to evaluate Submission of global documents in CTD/ eCTD formats C06: to create Dossiers and their submission to regulatory agencies in different countries.
7	Course Description	This course deals with 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.

8	Outline syllabus			
	1	**UNIT-I** a) Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development b) Introduction to 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 â€“vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. c) Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs		
	2	**UNIT –II** a) CMC, post approval regulatory affairs. Regulation for combination products and medical devices. b) CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M c) Regulatory requirements of EU, MHRA, TGA and ROW countries.		
	3	**UNIT-III** Non clinical drug development**,** Global submission of IND, NDA, ANDA.		
	4	**UNIT-IV** Medicinal products dossier a) Investigation of medicinal products dossier b) Investigator brochure (IB). c) Clinical trials: Developing clinical trial protocols		
	5	**UNIT-V** Pharmacovigilance safety monitoring in clinical trials a) Institutional review board/ independent ethics committee b) Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process c) Pharmacovigilance safety monitoring in clinical trials		
	Mode of examination	Theory		
	Weightage Distribution	Continuous	Sessional Exam	ESE

		Mode Assessment		
		10	15	75
	Text book/s*			
	Reference Book	Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143 The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers. 3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190. 4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc. 5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus. Clinical Trials and Human Research: A Practical Guide to RegulatoryCompliance By Fay A.Rozovsky and Rodney K. Adams		

School:		**SOP**
Program:		**M. Pharm**
Branch:		**Pharmaceutics**
1	Course Code	MPH105P
2	Course Title	Pharmaceutics Practical I
3	Credits	6
4	Contact Hours (L-T-P)	0-0-12
	Course Type	Compulsory
5	Course Objective	This course aims to provide students with comprehensive knowledge and practical skills in various analytical techniques commonly used in the development of pharmaceutical formulations, preparing them for roles in research, development, and quality control within the pharmaceutical industry.
6	Course Outcomes	CO1: Students will be able to examine the UV spectrophotometry CO2: Students will be able to understand the different analytical techniques. CO3: Students will able to analyze compounds by fluorimetry and photometry. CO4: Students will able to analyze and explain the different types drug delivery systems CO5: Students will be able to evaluate drug delivery systems. CO6: Students will be able to develop different drug delivery systems
7	Course Description	This course will provide students with comprehensive knowledge and practical skills in various analytical techniques commonly used in the development of pharmaceutical formulations, preparing them for roles in research, development, and quality control within the pharmaceutical industry.
8	Outline syllabus	
	1	**UNIT-I** **A.** Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer **B.** Simultaneous estimation of multi component containing formulations by UV spectrophotometry
	2	**UNIT-II**

<table>
<tr><td></td><td></td><td colspan="3">A. Experiments based on HPLC
B. Experiments based on Gas Chromatography</td></tr>
<tr><td rowspan="3"></td><td>3</td><td colspan="3">UNIT-III
A. Estimation of riboflavin/quinine sulphate by fluorimetry
B. Estimation of sodium/potassium by flame photometry</td></tr>
<tr><td>4</td><td colspan="3">UNIT-IV
A. To perform In-vitro dissolution profile of CR/ SR marketed formulation 8.
B. Formulation and evaluation of sustained release matrix tablets
C. Formulation and evaluation osmotically controlled DDS
D. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
E. Formulation and evaluation of Muco adhesive tablets.
F. Formulation and evaluation of trans dermal patches.</td></tr>
<tr><td>5</td><td colspan="3">UNIT-V
A. To carry out Preformulation studies of tablets.
B. To study the effect of compressional force on tablets disintegration time.
C. To study Micromeritic properties of powders and granulation.
D. To study the effect of particle size on dissolution of a tablet.
E. To study the effect of binders on dissolution of a tablet.
F. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.</td></tr>
<tr><td></td><td>Mode of examination</td><td colspan="3">Practical</td></tr>
<tr><td rowspan="2"></td><td rowspan="2">Weightage Distribution</td><td>Continuous Mode Assessment</td><td>Sessional Exam</td><td>ESE</td></tr>
<tr><td>20 Marks</td><td>30</td><td>100</td></tr>
<tr><td></td><td>Text book/s*</td><td colspan="3">1. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
2. Instrumental methods of analysis – Willards, 7th edition, CBS publishers
3. 3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Physical Pharmacy; By Alfred martin</td></tr>
</table>

School:		**SOP**
Program:		**M. Pharm**
Branch:		**Pharmaceutics**
1	Course Code	MPH 201T
2	Course Title	MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)
3	Credits	4
4	Contact Hours (L-T-P)	4-0-0
	Course Type	Compulsory
5	Course Objective	After the successful completion of this course, the student shall be able to: 1. The course aims to provide an understanding of basic knowledge on the area of Nano Technology. 2. To understand various approaches for development of Drug delivery systems. 3. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation
6	Course Outcomes	CO1: The students will understand the concepts and applications of Nano Technologies and formulate industrially feasible, cost effective strategy for development of new dosage forms. CO2: The student will be able to apply knowledge in developing various novel formulations as per requirements and to learn Targeting Methods of preparation and evaluation of Nano Particles & Liposomes. CO3: The student will be able to analyze various formulations & evaluation parameters of Niosomes, Aquasomes, Phytosomes, Electrosomes. CO4: The students will be able to formulate and development of Pulmonary Drug Delivery Systems and Nasal Drug Delivery System its issues and challenges, drug selection. CO5: The students will be able to plan about specific Nucleic acid based therapeutic delivery system. CO6: The Students will be able to develop therapeutic antisense molecules and aptamers as drugs of future.

7	Course Description	This subject is designed to impart basic knowledge on the area of Nano technology & targeted Drug Delivery System: 1. To understand various approaches for development of Nano technology & targeted Drug Delivery System. 2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation 3. To understand the therapeutic antisense molecules and aptamers as drugs of future.		
8	Outline syllabus			
	1	**A. Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. **B.** Tumor targeting and Brain specific delivery.		
	2	**A. Targeting Methods:** Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.		
	3	**A. Micro Capsules / Micro Spheres:** Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application **B. Preparation and application:** Niosomes, Aquasomes, Phytosomes, Electrosomes		
	4	**A. Pulmonary Drug Delivery Systems:**Aerosols, propellents, ContainersTypes, preparation and evaluation **B. Intra Nasal Route Delivery systems:** Types, preparation and evaluation.		
	5	**A. Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). **B. Potential target diseases for gene therapy (inherited disorder and cancer).** Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. **C. Bio distribution and Pharmacokinetics.** Knowledge of therapeutic antisense molecules and aptamers as drugs of future.		
	Mode of examination	Theory		
	Weightage Distribution	**Continuous Mode Assessment**	Sessional Exam	ESE
		10 Marks	15	75
	Text book/s*			

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

School:		**SOP**
Program:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	MPH202T
2	Course Title	Advanced Biopharmaceutics & Pharmacokinetics
3	Credits	4
4	Contact Hours (L-T-P)	4-0-0
	Course Type	Compulsory
5	Course Objective	Upon completion of this course it is expected that students will be able understand, □ The basic concepts in biopharmaceutics and pharmacokinetics. □ The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination. □ The critical evaluation of biopharmaceutics studies involving drug product equivalency. □ The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters. □ The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

6	Course Outcomes	CO1: Students will be able to define and differentiate the meaning of Biopharmaceutics and Pharmacokinetics CO2: Students will be able to plan about basic concepts and importance of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination. CO3: Students will be able to categorize, sketch and relate various compartment models and their orientation while learning the parameters involved in the biopharmaceutical expression and infer the findings from such studies. CO4: Students will be able to correlate a study and interpret basic concepts, measurement and calculation of zero order and first order absorption rate constant involved in various biopharmaceutical and pharmacokinetics measurements. CO5: Students will be able to interpret various constraints in developing data-base for individuals in diseased conditions and compare with the functioning of normal person while incorporating the concept of pharmacokinetic study. CO6: Students will be able to analyze Nonlinear Pharmacokinetics.
7	Course Description	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.
8	Outline syllabus	

	1	**UNIT-I** Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.
	2	**UNIT-II** Biopharmaceutics considerations in drug product design and in Vitro Drug Product Performance: Introduction, biopharmaceutics 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.
	3	**UNIT-III** Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modelling: one compartment model- IV bolus, IV infusion, Extravascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

<table>
<tr><td></td><td>4</td><td colspan="3">UNIT-IV
Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.</td></tr>
<tr><td></td><td>5</td><td colspan="3">UNIT-V
Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamics, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.</td></tr>
<tr><td></td><td>Mode of examination</td><td colspan="3">Theory</td></tr>
<tr><td rowspan="2"></td><td rowspan="2">Weightage Distribution</td><td>Continuous Mode Assessment</td><td>Sessional Exam</td><td>ESE</td></tr>
<tr><td>10 Marks</td><td>25</td><td>75</td></tr>
</table>

	Text book/s*	1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991. 2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi. 3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 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, Marcel Dekker Inc.,New York, 1982 6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970 7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995 8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989 9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987. 10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971. 11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996. 12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009. 13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

School:		**SOP**
Programme:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	**MPH203T**
2	Course Title	Computer Aided Drug Delivery system
3	Credits	**4**
4	Contact Hours (L-T-P)	**4-0-0**
	Course Type	Compulsory
5	Course Objective	Upon completion of this course, the student should be able to 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 and Clinical Development 6. Artificial Intelligence (AI), Robotics, and Computational fluid dynamics (CFD)
6	Course Outcomes	CO1: Upon successful completion of these courses, students will be equipped to contribute significantly to computer-aided drug discovery and development, while adhering to QbD principles for quality optimization. CO2: Students will gain a comprehensive understanding of computational modeling techniques used in predicting drug disposition, encompassing absorption, distribution, metabolism, and excretion (ADME) processes. CO3: Students will possess the knowledge and skills necessary to leverage computational techniques effectively in formulation development, navigate legal and ethical considerations, and utilize computers for market analysis in the pharmaceutical sector. CO4: Students will be equipped with the knowledge and skills necessary to utilize computational tools effectively in biopharmaceutical characterization, pharmacokinetics/pharmacodynamics modeling, and clinical development, contributing to the advancement of drug discovery and development processes. CO5: Students will be equipped with the knowledge and skills necessary to leverage AI, robotics, and computational fluid dynamics technologies effectively in pharmaceutical settings, addressing current challenges and driving innovation in drug research, development, and manufacturing. CO6: Students will be well-prepared to excel in roles related to computer-aided formulation development, making valuable contributions to the pharmaceutical industry, and advancing the field of drug delivery and formulation science.

7	Course Description	This course provides an in-depth exploration of the interdisciplinary field of Computer-Aided Drug Delivery Systems (CADD). It focuses on the integration of computational techniques, pharmaceutical sciences, and biotechnology to design, optimize, and deliver therapeutic agents efficiently and effectively. Through a combination of theoretical instruction, practical exercises, and case studies, students will develop a comprehensive understanding of the principles, methods, and applications of CADD in drug delivery.
8	**Outline syllabus (60 Hrs.)**	
	1	**UNIT-I** **a**. **Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, 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.
	2	**UNIT-II** **Computational Modeling of Drug Disposition**: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter**.**
	3	**UNIT-III** **Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis
	4	**UNIT IV** **a. Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitroin 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.
	5	**UNIT-V** **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.
	Mode of examination	Theory

	Weightage Distribution	**Continuous Mode Assessment**	**Sessional Exam**	**ESE**
		10 Marks	15 Marks	75 Marks
	Text book/s*	1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins,2006, John Wiley & Sons. 2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing 3. Encyclopedia of Pharmaceutical Technology, Vol 1 3. James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York,1996.		
	Other References	High reputed journals		

School:		**SOP**
Program:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	MPH204T
2	Course Title	Cosmetics and Cosmeceuticals
3	Credits	4
4	Contact Hours (L-T-P)	3-1-4
	Course Type	Compulsory
5	Course Objective	Upon completion of the subject student shall be able to; • Key ingredients used in cosmetics and cosmeceuticals. • Key building blocks for various formulations. • Current technologies in the market • Various key ingredients and basic science to develop cosmetics and cosmeceuticals • Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.
6	Course Outcomes	CO.1Students would be able to understand the basic concept about cosmetics like its manufacturing, import export and regulatory guidelines. CO.2 Students would be able to understand about the anatomy and physiology of the skin. CO.3 Students would be able to apply the concept of manufacturing for the formulation of different types of cosmetics. CO.4 Students would be able to analyze the design of cosmeceutical products: like sun screen, anti-ageing products etc. CO.5 Students would be able to plan about the regulatory aspect of herbal cosmetics and its preparation and manufacturing. CO.6 Student will be able to evaluate the scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.
7	Course Description	This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

8	Outline syllabus			
	1	**Unit I** Cosmetics–Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics–Conditionsfor obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license ,offences and penalties.		
	2	**Unit II** Cosmetics-Biological aspects : Structure of skin relating to problems like dry skin, acne ,pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck ,body and under-arm.		
	3	**Unit III** Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. 12 Hrs 12 Hrs 12 Hrs 52Controversial ingredients: Parabens, formaldehyde liberators, dioxane.		
	4	**Unit IV** Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects .Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, bodyodor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations		
	5	**Unit V** Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.		
	Mode of examination	Theory		
	Weightage Distribution	**Continuous Mode Assessment**	Sessional Exam	ESE
		10 Marks	15	75

	Text book/s*	1. Harry'sCosmeticology.8thedition. 2. Poucher'sperfumecosmeticsandSoaps,10th edition. 3. Cosmetics Formulation, Manufacture and quality control, PP. Sharma,4th edition 4. Handbook of cosmetic science and Technology A.O. Barel,M.Payeand H.I.Maibach.3rdedition 5. Cosmetic and Toiletries recent suppliers catalogue. 6. CTFA directory.

School:		**SOP**
Program:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	MPH205P
2	Course Title	Pharmaceutics Practical II
3	Credits	6
4	Contact Hours (L-T-P)	0-0-12
	Course Type	Compulsory
5	Course Objective	This course is designed to offer students a thorough grasp of a wide range of pharmaceutical formulation techniques, evaluation methods, bioavailability studies, quality by design attributes, and essential computational modeling pertinent to the dynamic field of pharmaceutical development.
6	Course Outcomes	CO1: Students will be able to define the novel drug delivery systems CO2: Students will be able to understand dissolution and protein binding of drugs CO3: Students will able to execute the bioavailability studies CO4: Students will able to illustrate the different types Quality-by-Design software CO5: Students will be able to evaluate various cosmetics formulations CO6: Students will be able to develop different cosmetics formulations
7	Course Description	This course is designed to offer students a thorough grasp of a wide range of pharmaceutical formulation techniques, evaluation methods, bioavailability studies, quality by design attributes, and essential computational modeling pertinent to the dynamic field of pharmaceutical development.
8	Outline syllabus	

	1	**UNIT-I** **A.** To study the effect of temperature change , non-solvent addition, incompatible polymer addition in microcapsules preparation **B.** Preparation and evaluation of Alginate beads **C.** Formulation and evaluation of gelatin /albumin microspheres **D**. Formulation and evaluation of liposomes/niosomes **E.** Formulation and evaluation of spherules		
	2	**UNIT-II** **A.** Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique. **B.** Comparison of dissolution of two different marketed products /brands **C.** Protein binding studies of a highly protein bound drug & poorly protein bound drug		
	3	**UNIT-III** **A.** Bioavailability studies of Paracetamol in animals. **B.** Bioavailability studies of Paracetamol in animals. **C.** Pharmacokinetic and IVIVC data analysis by Winnoline R software **D.** In vitro cell studies for permeability and metabolism		
	4	**UNIT-IV** **A.** DoE Using Design Expert® Software **B.** Formulation data analysis Using Design Expert® Software **C.** Quality-by-Design in Pharmaceutical Development **D**. Computer Simulations in Pharmacokinetics and Pharmacodynamics **E.** Computational Modeling of Drug Disposition **F**. To develop Clinical Data Collection manual **J**. To carry out Sensitivity Analysis, and Population		
	5	**UNIT-V** **A.** Development and evaluation of Creams **B.** Development and evaluation of Shampoo and Toothpaste base **C.** To incorporate herbal and chemical actives to develop products **D.** To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff		
	Mode of examination	Practical		
	Weightage Distribution	Continuous Mode Assessment	Sessional Exam	ESE
		20 Marks	30	100

	Text book/s*	1. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition 2. Instrumental methods of analysis – Willards, 7th edition, CBS publishers 3. 3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann. 4. Computer-Aided Applications in Pharmaceutical Technology, 1 st Edition, Jelena Djuris, Woodhead Publishing

School:		**SOP**
Programme:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	**MRM 301T**
2	Course Title	**Research Methodology and Biostatistics**
3	Credits	**4**
4	Contact Hours (L-T-P)	**4-0-0**
	Course Type	Compulsory
5	Course Objective	Upon completion of this course, the student should be able to 1. Students will develop a comprehensive understanding of research methodology fundamentals and acquire the skills necessary to design, conduct, and evaluate research studies effectively in various fields of inquiry. 2. Students will be equipped with the necessary knowledge and skills to apply biostatistical methods effectively in analyzing and interpreting data in the fields of biology, medicine, public health, and related disciplines. 3. Students will gain a comprehensive understanding of the ethical principles, challenges, and responsibilities inherent in medical research and clinical practice, enabling them to navigate complex ethical dilemmas with integrity and professionalism. 4. Students will gain a thorough understanding of CPCSEA guidelines for laboratory animal facilities and develop the knowledge and skills necessary to ensure ethical and humane treatment of laboratory animals, compliance with regulatory standards, and the conduct of scientifically valid research. 5. Students will develop a comprehensive understanding of the Declaration of Helsinki and its ethical principles, enabling them to navigate ethical challenges and dilemmas in medical research involving human subjects with integrity, professionalism, and respect for participant rights and welfare. 6. Students will develop a comprehensive understanding of the ethical principles, challenges, and responsibilities inherent in medical research and clinical practice, preparing them to navigate complex ethical dilemmas with integrity and professionalism.

6	Course Outcomes	CO1: Students will be equipped with the knowledge, skills, and competencies necessary to design, conduct, and evaluate research studies effectively across various disciplines. CO2: Students will be well-prepared to utilize biostatistical methods confidently in their research endeavors and contribute meaningfully to advancements in biological and health sciences. CO3: Students will develop a comprehensive understanding of the ethical principles, challenges, and responsibilities inherent in medical research and clinical practice, preparing them to navigate complex ethical dilemmas with integrity and professionalism. CO4: Students will be equipped with the knowledge, skills, and competencies necessary to uphold ethical standards, ensure animal welfare, and promote scientific integrity in laboratory animal facilities adhering to CPCSEA guidelines. CO5: Students will be equipped with the knowledge, skills, and ethical framework necessary to navigate complex ethical issues in medical research, uphold the rights and welfare of research participants, and contribute to the advancement of medical knowledge in an ethically responsible manner. CO6: Students will be prepared to engage ethically and responsibly in medical research and practice, promoting the well-being of patients, advancing scientific knowledge, and upholding the highest standards of ethical conduct in their professional endeavors.
7	Course Description	This course provides a comprehensive introduction to the principles and techniques of research methodology and biostatistics in the field of pharmaceutical sciences. Students will learn essential concepts and methods necessary for conducting scientific research, analyzing data, and drawing valid conclusions. The course emphasizes the application of statistical tools and research methodologies specifically tailored to pharmaceutical research and development.
8	**Outline syllabus (60 Hrs.)**	
	1	**UNIT-I** **General Research Methodology:** Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, and blinding techniques.
	2	**UNIT-II** **Biostatistics:** Definition, application, sample size, the 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.

<table>
<tr><td></td><td>3</td><td colspan="3">UNIT-III
Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, the 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.</td></tr>
<tr><td></td><td>4</td><td colspan="3">UNIT IV
CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.</td></tr>
<tr><td></td><td>5</td><td colspan="3">UNIT-V
Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.</td></tr>
<tr><td></td><td>Mode of examination</td><td colspan="3">Theory</td></tr>
<tr><td rowspan="2"></td><td rowspan="2">Weightage Distribution</td><td>Continuous Mode Assessment</td><td>Sessional Exam</td><td>ESE</td></tr>
<tr><td>10 Marks</td><td>15 Marks</td><td>75 Marks</td></tr>
<tr><td></td><td>Text book/s*</td><td colspan="3">1. Basic & Clinical Biostatistics, Beth Dawson and Robert G. Trapp. Lange Medical Books/McGraw-Hill Medical Publishing Division.
2. Research Methodology, 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.</td></tr>
<tr><td></td><td>Other References</td><td colspan="3">High reputed journals</td></tr>
</table>

School:		**SOP**
Program:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	-
2	Course Title	Journal Club
3	Credits	1
4	Contact Hours (L-T-P)	1-0-0
	Course Type	Compulsory
5	Course Objective	The objective of a journal club is to critically evaluate and discuss current literature in a specific field to enhance understanding, promote critical thinking, and foster academic discourse among students.
6	Course Outcomes	CO1: Students will be able to define current trends and advancements in pharmaceutics through critical analysis and discussion of scholarly articles. CO2: Students will be able to understand the skills involved in evaluating scientific literature CO3: Students will able to execute collaborative learning to broaden perspectives and deepen insights into pharmaceutical formulation and delivery systems CO4: Students will able to illustrate critical thinking and communication skills essential for effectively disseminating research findings and contributing to advancements in the field. CO5: Students will be able to develop knowledge and analytical skills to address challenges in drug development and optimize therapeutic outcomes. CO6: Students will be able to build interdisciplinary dialogue to synthesize diverse perspectives from pharmaceutics, pharmacology, chemistry, and biotechnology to innovate drug delivery systems
7	Course Description	The objective of a journal club is to critically evaluate and discuss current literature in a specific field to enhance understanding, promote critical thinking, and foster academic discourse among students.

School:		**SOP**
Program:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	-
2	Course Title	Discussion/Presentation (Proposal Presentation)
3	Credits	2
4	Contact Hours (L-T-P)	2-0-0
	Course Type	Compulsory
5	Course Objective	The objective of a discussion/presentation is to effectively communicate ideas, research findings, or proposals to an audience, facilitating engagement, feedback, and potential collaboration. This aims to refine concepts, solicit input, and advance projects or initiatives towards their intended goals.
6	Course Outcomes	CO1: Students will be able to Develop proficiency in articulating ideas, research findings, or proposals clearly and persuasively to diverse audiences. CO2: Students will be able to enhance critical thinking skills through active engagement in discussions, analysis of feedback, and refinement of presentations. CO3: Students will able to foster collaborative skills by facilitating constructive dialogue, incorporating diverse perspectives, and soliciting input from peers. CO4: Students will able to demonstrate mastery in structuring presentations effectively, including organization, visual aids, and delivery techniques, to maximize audience comprehension and engagement. CO5: Students will be able to cultivate professional communication skills, such as active listening, clarity of expression, and responsiveness to questions or challenges. CO6: Students will be able to Apply knowledge gained from discussions and presentations to refine and improve future projects, proposals, or communication endeavors.
7	Course Description	The objective of a journal club is to critically evaluate and discuss current literature in a specific field to enhance understanding, promote critical thinking, and foster academic discourse among students.

School:		**SOP**
Program:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	-
2	Course Title	Research Work
3	Credits	14
4	Contact Hours (L-T-P)	28-0-0
	Course Type	Compulsory
5	Course Objective	To equip students with the necessary skills, knowledge, and methodologies required to conduct independent and rigorous research in their chosen field of study, fostering critical thinking, problem-solving abilities, and a deeper understanding of the research process.
6	Course Outcomes	CO1Students will be able to demonstrate comprehension of research methodologies, theories, and relevant literature, applying foundational knowledge to their research projects. CO2: Students will be able to interpret and summarize complex research findings, demonstrating understanding through written reports, presentations, or discussions. CO3: Students will able to apply research methodologies and techniques to collect, analyze, and interpret data, demonstrating proficiency in research design and execution. CO4: Students will be able to critically evaluate research findings, identifying patterns, trends, and relationships within data sets, and synthesizing information to draw meaningful conclusions. CO5: Students will be able to integrate findings from their research with existing knowledge, proposing new hypotheses, theories, or applications, and generating innovative insights or solutions. CO6: Students will be able to assess the strengths and limitations of their research methods and outcomes, utilizing evidence-based reasoning to make informed judgments and recommendations for future research directions.

7	Course Description	To equip students with the necessary skills, knowledge, and methodologies required to conduct independent and rigorous research in their chosen field of study, fostering critical thinking, problem-solving abilities, and a deeper understanding of the research process.

School:		**SOP**
Program:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	-
2	Course Title	Journal Club
3	Credits	1
4	Contact Hours (L-T-P)	1-0-0
	Course Type	Compulsory
5	Course Objective	The objective of a journal club is to critically evaluate and discuss current literature in a specific field to enhance understanding, promote critical thinking, and foster academic discourse among students.
6	Course Outcomes	CO1: Students will be able to define current trends and advancements in pharmaceutics through critical analysis and discussion of scholarly articles. CO2: Students will be able to understand the skills involved in evaluating scientific literature CO3: Students will able to execute collaborative learning to broaden perspectives and deepen insights into pharmaceutical formulation and delivery systems CO4: Students will able to illustrate critical thinking and communication skills essential for effectively disseminating research findings and contributing to advancements in the field. CO5: Students will be able to develop knowledge and analytical skills to address challenges in drug development and optimize therapeutic outcomes. CO6: Students will be able to build interdisciplinary dialogue to synthesize diverse perspectives from pharmaceutics, pharmacology, chemistry, and biotechnology to innovate drug delivery systems
7	Course Description	The objective of a journal club is to critically evaluate and discuss current literature in a specific field to enhance understanding, promote critical thinking, and foster academic discourse among students.

School:		**SOP**
Program:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	-
2	Course Title	Research Work
3	Credits	16
4	Contact Hours (L-T-P)	31-0-0
	Course Type	Compulsory
5	Course Objective	To equip students with the necessary skills, knowledge, and methodologies required to conduct independent and rigorous research in their chosen field of study, fostering critical thinking, problem-solving abilities, and a deeper understanding of the research process.
6	Course Outcomes	CO1Students will be able to demonstrate comprehension of research methodologies, theories, and relevant literature, applying foundational knowledge to their research projects. CO2: Students will be able to interpret and summarize complex research findings, demonstrating understanding through written reports, presentations, or discussions. CO3: Students will able to apply research methodologies and techniques to collect, analyze, and interpret data, demonstrating proficiency in research design and execution. CO4: Students will be able to critically evaluate research findings, identifying patterns, trends, and relationships within data sets, and synthesizing information to draw meaningful conclusions. CO5: Students will be able to integrate findings from their research with existing knowledge, proposing new hypotheses, theories, or applications, and generating innovative insights or solutions. CO6: Students will be able to assess the strengths and limitations of their research methods and outcomes, utilizing evidence-based reasoning to make informed judgments and recommendations for future research directions.

7	Course Description	To equip students with the necessary skills, knowledge, and methodologies required to conduct independent and rigorous research in their chosen field of study, fostering critical thinking, problem-solving abilities, and a deeper understanding of the research process.

School:		**SOP**
Program:		**M.Pharm**
Branch:		**Pharmaceutics**
1	Course Code	-
2	Course Title	Discussion/Presentation (final Presentation)
3	Credits	3
4	Contact Hours (L-T-P)	3-0-0
	Course Type	Compulsory
5	Course Objective	The objective of a discussion/presentation is to effectively communicate ideas, research findings, or proposals to an audience, facilitating engagement, feedback, and potential collaboration. This aims to refine concepts, solicit input, and advance projects or initiatives towards their intended goals.
6	Course Outcomes	CO1: Students will be able to Develop proficiency in articulating ideas, research findings, or proposals clearly and persuasively to diverse audiences. CO2: Students will be able to enhance critical thinking skills through active engagement in discussions, analysis of feedback, and refinement of presentations. CO3: Students will able to foster collaborative skills by facilitating constructive dialogue, incorporating diverse perspectives, and soliciting input from peers. CO4: Students will able to demonstrate mastery in structuring presentations effectively, including organization, visual aids, and delivery techniques, to maximize audience comprehension and engagement. CO5: Students will be able to cultivate professional communication skills, such as active listening, clarity of expression, and responsiveness to questions or challenges. CO6: Students will be able to Apply knowledge gained from discussions and presentations to refine and improve future projects, proposals, or communication endeavors.
7	Course Description	The objective of a journal club is to critically evaluate and discuss current literature in a specific field to enhance understanding, promote critical thinking, and foster academic discourse among students.