SARDAR PATEL UNIVERSITY
Vallabh Vidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.25)
Syllabus with effect from the Academic Year 2021-2022

PROGRAMME STRUCTURE

Master of Pharmacy in Pharmaceutics

M. Pharm (Pharmaceutics) Semester: I

Programme Outcome (PO) - For M. Pharm (PT) Programme	At the end of Master of Pharmacy (M. Pharm) program, the students will be able to: 1. Acquire knowledge and comprehension of the advancements in the core and specialization area of pharmacy. 2. Demonstrate a degree of expertise in laboratory practices, analytical techniques and scientific tools. 3. Independently carry out research/investigation and development work to solve problem. 4. Write and present a substantial scientific document and technical report. 5. Apply reasoning by contextual knowledge to assess societal impact, environmental impact, health, safety and legal issues and the consequent responsibilities relevant to the pharmacy profession.
Programme Specific Outcome (PSO) - For M. Pharm (PT) Semester -I	After successful completion of the program the students will be able to 1. To learn and implement basic as well as advanced techniques in developing various dosage forms. 2. To become skilful in documentation, data management, paper/book writing and communication. 3. To develop capabilities for acquiring new knowledge and updating in the pharmaceutical sciences. 4. To serve the society with knowledge and create awareness towards healthcare as a part of social responsibility.

To Pass	At least 50% Marks in the University Examination in each paper and 50% Marks in the aggregate of University and Internal examination in each course of Theory, Practical & Research work.

	Course Code	Name of Course	Theory/ Practical	Credit	Exam Duration in hrs	Component of Marks		
						Internal	External	Total
Employability	MPH101T	Modern Pharmaceutical Analytical Techniques	T	4	3	25	75	100/50
Employability	MPH102T	Drug Delivery System	T	4	3	25	75	100/50
Employability	MPH103T	Modern Pharmaceutics	T	4	3	25	75	100/50
Employability	MPH104T	Regulatory Affair	T	4	3	25	75	100/50
Employability, Entrepreneurship Skill Development	MPH105P	Pharmaceutics Practical I	P	6	6	50	100	150/75
Skill Development	MPH106S	Seminar/Assignment	-	4	-	-	-	100/50
				26		150	400	650/325

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - I

Course Code	MPH101T	Title of the Course	Modern Pharmaceutical Analytical Techniques.
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	
1	To clarify the concept in between chemical (API) and excipients
2	To carry out the analysis of various drugs in single and combination dosage forms
3	To review the basic concepts of theoretical and practical skills of the sophisticated analytical instruments.
4	To study the various detection test methods for the biological matrices

Course Content

Unit	Description	Hrs.
I	**UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	**11**
II	**NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	**11**
III	**Mass Spectroscopy**: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta	**11**

	stable ions, Isotopic peaks and Applications of Mass spectroscopy	
IV	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e)Gas chromatography f)High Performance Liquid chromatography g) Affinity chromatography	**11**
V	**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 **X ray Crystallography**: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction.	**11**
VI	**Immunological assays :** RIA (Radio immuno assay), ELISA, Bioluminescence assays	**5**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	**Details of Evaluation**	**Marks**
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Out comes: Upon completion of this course, students will be able to	
1.	Theorize the fundamentals of modern analytical techniques for the analysis of pharmaceuticals
2.	Optimize the experimental conditions of modern pharmaceutical analytical instruments
3.	Analyze or infer the results based on analytical data or observations recorded
4.	Apply modern pharmaceutical analytical techniques for the analysis of pharmaceuticals

Suggested References:	
Sr. No	**References**
1	Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004
2	Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998
3	Instrumental methods of analysis – Willards, 7th edition, CBS publishers
4	Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997
5	Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991
6	Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997
7	Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - I

Course Code	MPH102T	Title of the Course	Drug Delivery System
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	
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.
4.	The important of bio similar formulation in the drug delivery systems

Course Content

Unit	Description	Hrs.
I	**Sustained Release(SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized	**10**
II	**Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals	**10**
III	**Gastro-Retentive Drug Delivery Systems**: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	**10**
IV	**Occular Drug Delivery Systems**: Barriers of drug permeation, Methods to overcome barriers	**6**
V	**Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration	**10**

	enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation	
VI	**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	**8**
VII	**Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines	**6**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	**Details of Evaluation**	**Marks**
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes: Upon completion of this course, students will be able to	
1.	Acquire the basic aspect of sustained and rate controlled drug delivery system in the field of pharmaceutical sciences.
2.	Interpret the formulation susceptibility, strategy and justification of available various marketed formulation of Ocular and Gastro-retentive formulations.
3.	Evaluate the element of compatibility and stability in the selection of active pharmaceutical ingredients and excipients for the development of transdermal drug delivery system.
4.	Theorize the concept, usefulness and mechanism of biological matrices like proteins, peptides and vaccines in drug delivery system.

Suggested References:	
Sr. No	**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 WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4	N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001)
5	S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - I

Course Code	MPH103T	Title of the Course	Modern Pharmaceutics
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	1. The elements of pre-formulation studies. 2. The Active Pharmaceutical Ingredients and Generic drug Product development. 3. Industrial Management and GMP Considerations. 4. Optimization Techniques & Pilot Plant Scale Up Techniques 5. Stability Testing, sterilization process & packaging of dosage forms various approaches for development of novel drug deliverysystems.

Course Content		
Unit	**Description**	**Hrs.**
I	**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. **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** **10**
II	**Validation :** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities	**10**
III	**cGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management	**10**
IV	**Compression and compaction**: Physics of tablet compression, compression,	**10**

	consolidation, effect of friction, distribution of forces, compaction profiles. Solubility	
V	**Study of consolidation parameters**; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test	**10**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes: Upon completion of this course, students will be able to	
1.	Evaluate the basic aspect of pre-formulation and kinetic stability of pharmaceutical formulations.
2.	Determine the term of formulation optimization using statistical design and factorial design to implement into the pilot plant scale-up.
3.	Comprehend the concept of validation techniques by revising ICH, WHO, cGMP and other required guidelines for the pharmaceutical preparations.
4.	Gain significant knowledge about material procurement, safety and inventory management for the smooth in-line production in pharmaceutical industries.

5.	Theorize the basic principle of tablet compression, punching techniques and also its characteristics like dissolution parameters, diffusion parameters and pharmacokinetics study.

Suggested References:

Sr. No	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: Parenteral medications Vol. 1-2; By Leon Lachmann
4	Modern Pharmaceutics; By Gillbert and S. Banker
5	Remington's Pharmaceutical Sciences
6	Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
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

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - I

Course Code	MPH104T	Title of the Course	Regulatory Affairs
Total Credits of the Course	4	Hours per Week	4

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

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

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern

Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes: Upon completion of this course, students will be able to

1.	Elucidate the concept of innovator and generic drugs, drug development process and comprehend the regulatory guidance and guidelines for filing and approval process.
2.	Categorize the preparation of dossiers and their submission to regulatory agencies in different countries in CTD/ eCTD format.
3.	Assess the post approval regulatory requirements for drug substances and drug products.
4.	Describe the concept of non-clinical drug development, regulatory requirements for conducting clinical trials and pharmacovigilance monitoring.

Suggested References:

Sr. No	**References**
1	Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol.143

2	The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers
3	New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190
4	Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons Inc.
5	FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6	Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7	www.ich.org/
8	www.fda.gov/
9	europa.eu/index_en.htm
10	https://www.tga.gov.au/tga-basics

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - I

Course Code	MPH105P	Title of the Course	Pharmaceutics Practicals- I
Total Credits of the Course	6	Hours per Week	12

Course Content	
Unit	**Description**
1	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2	Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3	Experiments based on HPLC
4	Experiments based on Gas Chromatography
5	Estimation of riboflavin/quinine sulphate by fluorimetry
6	Estimation of sodium/potassium by flame photometry
7	To perform *In-vitro* dissolution profile of CR/ SR marketed formulation
8	Formulation and evaluation of sustained release matrix tablets
9	Formulation and evaluation osmotically controlled DDS
10	Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11	Formulation and evaluation of Muco adhesive tablets
12	Formulation and evaluation of trans dermal patches
13	To carry out preformulation studies of tablets
14	To study the effect of compressional force on tablets disintegration time
15	To study Micromeritic properties of powders and granulation
16	To study the effect of particle size on dissolution of a tablet.
17	To study the effect of binders on dissolution of a tablet
18	To plot Heckal plot, Higuchi and peppas plot and determine similarity factors

Teaching-Learning Methodology	1. Practical training will be facilitated by demonstrations and check-list preparation. 2. Training of instrument or equipment will be imparted with demonstration of components of equipment and standard operating procedure. 3. Students will be instructed for performance of experiment followed by recording of observation, analysis and interpretation of data and discussion on the conclusion. 4. Quiz, viva-voce and performance test will be conducted for evaluation of practical understanding.

Evaluation Pattern

Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	20
2.	Sessional Examination	30
3.	End Semester Examination	100

Course Outcomes: Upon completion of this course, students will be able to

1.	Accomplish the assessment of the drug/s applying various spectroscopic and chromatographic techniques.
2.	Comprehend the functional aspects of various analytical instruments/equipment.
3.	Accomplish the pre-formulation, formulation and characterization of various types of the modified release drug delivery systems.
4.	Exhibit the potential effects of excipients and processing parameters on various dosage forms.
5.	Comprehend and implement the various model dependent and model independent approaches for the assessment of dosage forms.

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PROGRAMME STRUCTURE

Master of Pharmacy in Pharmaceutics

M. Pharm (Pharmaceutics) Semester: II

Programme Outcome (PO) - For M. Pharm (PT) Programme	At the end of Master of Pharmacy (M. Pharm) program, the students will be able to: 1. Acquire knowledge and comprehension of the advancements in the core and specialization area of pharmacy. 2. Demonstrate a degree of expertise in laboratory practices, analytical techniques and scientific tools. 3. Independently carry out research/investigation and development work to solve problem. 4. Write and present a substantial scientific document and technical report. 5. Apply reasoning by contextual knowledge to assess societal impact, environmental impact, health, safety and legal issues and the consequent responsibilities relevant to the pharmacy profession.
Programme Specific Outcome (PSO) - For M. Pharm (PT) Semester - II	After successful completion of the program the students will be able to 1. To learn and implement basic as well as advanced techniques in developing various dosage forms. 2. To become skilful in documentation, data management, paper/book writing and communication. 3. To develop capabilities for acquiring new knowledge and updating in the pharmaceutical sciences. 4. To serve the society with knowledge and create awareness towards healthcare as a part of social responsibility.

To Pass	At least 50% Marks in the University Examination in each paper and 50% Marks in the aggregate of University and Internal examination in each course of Theory, Practical & Research work.

	Course Code	Name of Course	Theory/ Practical	Credit	Exam Duration in hrs	Component of Marks		
						Internal	External	Total
Employability	MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	T	4	3	25	75	100/50
Employability	MPH202T	Advanced Biopharmaceutics &Pharmacokinetics	T	4	3	25	75	100/50
Employability Skill Development	MPH203T	Computer Aided Drug Delivery System	T	4	3	25	75	100/50
Employability, Entrepreneurship	MPH204T	Cosmetic and Cosmeceuticals	T	4	3	25	75	100/50
Employability, Entrepreneurship Skill Development	MPH205P	Pharmaceutics Practical II	P	6	6	50	100	150/75
Skill Development	MPH206S	Seminar/Assignment	-	4	-	-	-	100/50
				26		150	400	650/325

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - II

Course Code	MPH201T	Title of the Course	Molecular Pharmaceutics (Nano Tech and Targeted DDS)
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	Upon completion of the course student shall be able to understand 1. The various approaches for development of novel drug delivery systems. 2. The criteria for selection of drugs and polymers for the development of NTDS 3. The formulation and evaluation of novel drug delivery systems.

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

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations.

	3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes:	
1.	Acquire skill of developing various targeted drug delivery systems and their evaluations
2.	Design various formulation approaches like nano technology, aerosols, nebulizers and dry powder inhalers for effective pulmonary delivery
3.	Strategic development for improving nasal absorption in the design of nasal drug delivery systems
4.	Application of gene therapy in the treatment of cancer and inherited diseases

Suggested References:	
Sr. No	**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 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)

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - II

Course Code	MPH202T	Title of the Course	Advanced Bio-pharmaceutics & Pharmacokinetics
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	Upon completion of this course it is expected that students will be able understand, 1. The basic concepts in bio-pharmaceutics and pharmacokinetics. 2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination. 3. The critical evaluation of bio-pharmaceutics studies involving drug product equivalency. 4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and bio-pharmaceutics parameters. 5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Course Content		
Unit	**Description**	**Hrs.**
I	**Drug Absorption from the Gastrointestinal Tract**: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	**12**
II	**Bio-pharmaceutics considerations in drug product design and In Vitro Drug Product Performance:** Introduction, bio-pharmaceutics 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.	**12**

III	**Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of 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	**12**
IV	**Drug Product Performance, In Vivo: Bioavailability and Bioequivalence**: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Bio-pharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	**12**
V	**Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies	**12**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Power-point presentations, audio-visual presentations. 3. Virtual teaching and examination will also be utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15

3.	End Semester Examination	75

Course Outcomes:	
1.	Learn the mechanism of drug absorption, bioavailability and various factors affecting
2.	Comprehend the concept of various dissolution testing models
3.	Basic considerations of pharmacokinetic and dynamic models
4.	Various regulatory aspects of bio-availability and bioequivalence studies

Suggested References:	
Sr. No	**References**
1	Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2	Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
3	Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
4	Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
5	Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987
6	Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971
7	Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996
8	Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
9	Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003
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,1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009
13	Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - II

Course Code	MPH203T	Title of the Course	Computer Aided Drug Delivery System
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	Upon completion of this course it is expected that students will be able to understand, 1. History of Computers in Pharmaceutical Research and Development 2. Computational Modelling of Drug Disposition 3. Computers in Preclinical Development 4. Optimization Techniques in Pharmaceutical Formulation 5. Computers in Market Analysis 6. Computers in Clinical Development 7. Artificial Intelligence (AI) and Robotics 8. Computational fluid dynamics(CFD)

Course Content		
Unit	**Description**	**Hrs.**
I	**Computers in Pharmaceutical Research and Development**: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling **Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application	**12**
II	**Computational Modeling Of Drug Disposition**: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter	**12**
III	**Computer-aided formulation development::** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	**12**

IV	**(a) Computer-aided biopharmaceutical characterization**: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro- in vivo* correlation, 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**
V	**Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions	**12**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes:	
1.	Application of computers in pharmaceutical product development
2.	Implement various computational modeling and drug disposition studies
3.	Learn the use of computers in Clinical Data Collection and Management
4.	Acquire the prerequisite of industrial automation by application of artificial intelligence, robotics and computational fluid dynamics

Suggested References:	
Sr. No	**References**
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 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - II

Course Code	MPH204T	Title of the Course	Cosmetics and Cosmeceuticals
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	Upon completion of the course, the students shall be able to understand 1. Key ingredients used in cosmetics and cosmeceuticals. 2. Key building blocks for various formulations. 3. Current technologies in the market 4. Various key ingredients and basic science to develop cosmetics and cosmeceuticals 5. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy

Course Content		
Unit	**Description**	**Hrs.**
I	**Cosmetics – Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties	**12**
II	**Cosmetics - Biological aspects:** Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	**12**
III	**Formulation Building blocks:** Building blocks for different product formulations of cosmetics/ cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. **Perfumes**; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation **Controversial ingredients:** Parabens, formaldehyde liberators, dioxane.	**12**

IV	**Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations	**12**
V	**Herbal Cosmetics:** Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics	**12**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes:	
1.	Apply various regulatory provisions related to the import, manufacture and labeling of cosmetics
2.	Theorize various Biological aspects and constraints in the development of cosmetics.
3.	Utilize various technologies for designing cosmetics and cosmeceuticals with desired safety, stability and efficacy
4.	Selection of synthetic and herbal ingredients in the cosmetic formulations for hair care, skin care and oral care

Suggested References:	
Sr. No	**References**
1	Harry's Cosmeticology. 8th edition.
2	Poucher'sperfumecosmeticsandSoaps,10th edition
3	Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4	Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5	Cosmetic and Toiletries recent suppliers catalogue
6	CTFA directory.

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - II

Course Code	MPH205P	Title of the Course	Pharmaceutics Practical II
Total Credits of the Course	6	Hours per Week	12

Course Objectives:	1. Knowledge of various particulate and conventional Drug Delivery System 2. Dissolution Profiles and Improvisation. 3. Application of Design of Experiment & other Data Analysis Software 4. Knowledge of synthetic as well as Herbal chemicals/Expedients

Course Content	
Unit	**Description**
1	To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2	Preparation and evaluation of Alginate beads
3	Formulation and evaluation of gelatin /albumin microspheres
4	Formulation and evaluation of liposomes/niosomes
5	Formulation and evaluation of spherules
6	Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique
7	Comparison of dissolution of two different marketed products / brands
8	Protein binding studies of a highly protein bound drug & poorly protein bound drug
9	Bioavailability studies of Paracetamol in animals
10	Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software
11	*In vitro* cell studies for permeability and metabolism
12	DoE Using Design Expert® Software
13	Formulation data analysis Using Design Expert® Software
14	Quality-by-Design in Pharmaceutical Development

15	Computer Simulations in Pharmacokinetics and Pharmacodynamics
16	Computational Modeling Of Drug Disposition
17	To develop Clinical Data Collection manual
18	To carry out Sensitivity Analysis, and Population Modeling.
19	Development and evaluation of Creams
20	Development and evaluation of Shampoo and Toothpaste base
21	To incorporate herbal and chemical actives to develop products
22	To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

Teaching-Learning Methodology	1. Practical training will be facilitated by demonstrations and check-list preparation. 2. Training of instrument or equipment will be imparted with demonstration of components of equipment and standard operating procedure. 3. Students will be instructed for performance of experiment followed by recording of observation, analysis and interpretation of data and discussion on the conclusion. 4. Quiz, viva-voce and performance test will be conducted for evaluation of practical understanding.

Evaluation Pattern

Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes:

1.	Able to formulate and evaluate various macro, micro and Nano Drug Delivery System
2.	Capable to improve solubility/ dissolution of drug with knowledge of Dissolution mechanism for Bioavailability testing
3.	Ability to Handle Statistical Tools for Data Analysis in formulation Development & Pharmacokinetic – Dynamic simulation
4	Selection of synthetic and Herbal Ingredients in Dosage Form Development

SARDAR PATEL UNIVERSITY
Vallabh Vidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.25)
Syllabus with effect from the Academic Year 2021-2022

PROGRAMME STRUCTURE
Master of Pharmacy in Pharmaceutics
M. Pharm (Pharmaceutics) Semester: III

Programme Outcome (PO) - For M. Pharm (PT) Programme	At the end of Master of Pharmacy (M. Pharm) program, the students will be able to: Acquire knowledge and comprehension of the advancements in the core and specialization area of pharmacy. Demonstrate a degree of expertise in laboratory practices, analytical techniques and scientific tools. Independently carry out research/investigation and development work to solve problem. Write and present a substantial scientific document and technical report. Apply reasoning by contextual knowledge to assess societal impact, environmental impact, health, safety and legal issues and the consequent responsibilities relevant to the pharmacy profession.
Programme Specific Outcome (PSO) - For M. Pharm (PT) Semester - III	After successful completion of the program the students will be able to 1. To learn and implement basic as well as advanced techniques in developing various dosage forms. 2. To become skilful in documentation, data management, paper/book writing and communication. 3. To develop capabilities for acquiring new knowledge and updating in the pharmaceutical sciences. 4. To serve the society with knowledge and create awareness towards healthcare as a part of social responsibility.

To Pass	At least 50% Marks in the University Examination in each paper and 50% Marks in the aggregate of University and Internal examination in each course of Theory, Practical & Research work.

	Course Code	Name of Course	Theory/ Practical	Credit	Exam Duration in hrs	Component of Marks		
						Internal	External	Total
Employability	MRM301T	Research Methodology and biostatistics	T	4	3	25	75	100/50
Employability	MPH302J	Journal club		1	-	25	-	25/13
Employability	MPH303D	Discussion/presentation		2	-	50	-	50/25
Employability, Entrepreneurship Skill Development	MPH304R	Research work		14	-	-	350	350/175
				21		100	425	525/263

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - III

Course Code	MRM301T	Title of the Course	Research Methodology & Biostatistics
Total Credits of the Course	4	Hours per Week	4

Course Objective: Upon completion of the course student shall be able to understand	
1.	Learn general research methodology and the basic concepts of biostatistics
2.	Understand the functions of ethics committees in medical research

Course Content

Unit	Description	Hrs.
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	**15**
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	**15**
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	**15**
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	**12**
V	**Declaration of Helsinki:** History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**03**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern

Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes: Students will be able to

1.	Theorize the elements of research methodology
2.	Apply statistical methodology for data analysis
3.	Practice ethical principles and regulatory considerations in medical research
4.	Acquire requirements for laboratory animal facility

Suggested References:

Sr. No	**References**
1	Research in Education- John V. Best, John V. Kahn 7th edition
2	Thesis & Assignment – Jonathan Anderson
3	Writing a technical paper- Donald Menzel
4	Pharmaceutical Statistics , Practical and Clinical Applications, Fifth Edition, Sanford

	Bolton, Charles Bon
5	ICMR guidelines for medical research
6	Principle and Practice of Clinical Trial Medicine, Richard Chin, Bruce Y. Lee, Academic Press
7	CPCSEA guideline for laboratory animal care and handling

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Syllabus with effect from the Academic Year 2021-2022

PROGRAMME STRUCTURE
Master of Pharmacy in Pharmaceutics
M. Pharm (Pharmaceutics) Semester: IV

Programme Outcome (PO) - For M. Pharm (PT) Programme	At the end of Master of Pharmacy (M. Pharm) program, the students will be able to: 1. Acquire knowledge and comprehension of the advancements in the core and specialization area of pharmacy. 2. Demonstrate a degree of expertise in laboratory practices, analytical techniques and scientific tools. 3. Independently carry out research/investigation and development work to solve problem. 4. Write and present a substantial scientific document and technical report. 5. Apply reasoning by contextual knowledge to assess societal impact, environmental impact, health, safety and legal issues and the consequent responsibilities relevant to the pharmacy profession.
Programme Specific Outcome (PSO) - For M. Pharm (PT) Semester -IV	After successful completion of the program the students will be able to 1. To learn and implement basic as well as advanced techniques in developing various dosage forms. 2. To become skilful in documentation, data management, paper/book writing and communication. 3. To develop capabilities for acquiring new knowledge and updating in the pharmaceutical sciences. 4. To serve the society with knowledge and create awareness towards healthcare as a part of social responsibility.

To Pass	At least 40% Marks in the University Examination in each paper and 40% Marks in the aggregate of University and Internal examination in each course of Theory, Practical & 40% Marks in Viva-voce.

	Course Code	Name of Course	Theory/ Practical	Credit	Exam Duration in hrs	Component of Marks		
						Internal	External	Total
Employability, Skill development	MPH401J	Journal club		1	-	25	-	25/13
Employability, Skill development	MPH402D	Discussion/ Presentation		3	-	75	-	75/38
Employability, Entrepreneurship, Skill development	MPH403R	Research work		16	1	-	400	400/200
				20		100	400	500/250