Two-Year Post graduate Programme

Master of Pharmacy

Pharmaceutics

Faculty of Pharmacy

Parul University

Vadodara, Gujarat, India

Faculty of Pharmacy
Master of Pharmacy in Pharmaceutics

1. **Vision of the Department**

To nurture pharmacy aspirants to serve the society with comprehensive subject knowledge, high professional values, excellent skills and outstanding research aptitude.

2. **Mission of the Department**

M1 Foster humanitarian values, passion for learning and creativity.
M2 Move towards high quality, futuristic educational and research ecosystem.
M3 Develop socially responsible future pharmacists; committed to creating self-reliant India.

3. **Program Educational Objectives**

PEO 1	Cultivate pharmaceutics professionals with in-depth knowledge of Pharmaceutical science principles and production methods.
PEO 2	Inculcate research aptitude, practical skills and professional values in the students along with problem solving capabilities in the field of pharmaceutical science.

4. **Program Learning Outcomes**

Program Learning outcomes are statements conveying the intent of a program of study.

PLO 1	**In-depth Knowledge of Pharmaceutical Science**	Acquire in-depth knowledge of all the theories and principle involved in pharmaceutical science.
PLO 2	**Professional and Interpersonal Skill Development**	Demonstrate necessary skills in pharmaceutical science like working independently, communication, coordination, time management and organizational skills. The students will demonstrate an adaptable, flexible and effective approach towards organizational development.
PLO 3	**Competency Development**	Develop an ability to communicate scientific knowledge in in non-expert/lay term by adopting various modes of scientific
PLO 4	**Technical Expertise**	Enable student handle pharmaceutical instruments in experiments. The student will also learn to draft the protocols and results based on the various research experiments.
PLO 5	**Knowledge Enhancement and Project**	Gain the knowledge by continue updating of technologies involving management of Pharmaceutical Quality System for continual improvement of Process Performance and Product Quality.

	management abilities	
PLO 6	**Innovative Approach for research**	Develop critical thinking quality, which leads to development of the novel ideas in the field of pharmaceutical science
PLO 7	**Individual and Team work**	Function individually as a member or as a leader in diverse team with technical expertise.
PLO 8	**Instrument handling skills**	Understand theoretical and practical skills of the instruments. To apply suitable methods, resources and standard procedures to handle all types of equipment for demonstrating Pharmaceutical activities
PLO 9	**Regulatory Compliance**	Understand the fine regulatory requirements for Pharmacy profession starting from drug discovery to final product marketing.
PLO 10	**Knowledge about Current Affairs and lifelong learning**	Exhibit latest and updated knowledge in the field of pharmacy and will develop the attitude and aptitude for lifelong learning.
PLO 11	**Environment and sustainability**	Understand the impacts of any research in societal and environmental contexts and develop any innovation with a second eye on environment and sustainability.

5. Program Specific Learning Outcomes

PSO 1	**Knowledge of Pharmaceutical formulation and development**	Post graduate student must possess knowledge of all the theories and principle involved in pharmaceutical formulation development and evaluation
PSO 2	**Trouble shooting and technical problem analysis**	Post graduate student must be able to apply the concepts of Pharmaceutical Science to resolve the problems during formulation development and in production.

6. Credit Framework

Semester wise Credit distribution of the programme

Category wise Credit distribution of the programme	
Category	**Credit**

Semester-1	26
Semester-2	26
Semester-3	21
Semester-4	20
Total Credits:	**93**

Major Core	28
Multidisciplinary	08
Skill Development Courses	20
Research Project/Dissertation	37
Total Credits:	**93**

7. Program Curriculum

Semester 1						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lect**	**Lab**	**Tut**
1	MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	-	-
2	MPH102T	Drug Delivery System	4	4	-	-
3	MPH103T	Modern Pharmaceutics	4	4	-	-
4	MPH104T	Regulatory Affair	4	4	-	-
5	MPH105P	Pharmaceutics Practical I	6	-	12	-
6		Seminar/Assignment	4	7	-	-
		Total	**26**	**23**	**12**	**-**
Semester 2						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lect**	**Lab**	**Tut**
1	MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	-	-
2	MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	-	-
3	MPH203T	Computer Aided Drug Delivery System	4	4	-	-
4	MPH204T	Cosmetic and Cosmeceuticals	4	4	-	-
5	MPH205P	Pharmaceutics Practical II	6	-	12	-
6		Seminar/Assignment	4	7	-	-
		Total	**26**	**23**	**12**	**-**
Semester 3						

Sr. No.	Subject Code	Subject Name	Credit	Lect	Lab	Tut
1	MRM 301T	Research Methodology and Biostatistics	4	4	-	-
2	MPH302P	Pre Dissertation-I	1	-	1	-
3	MPH303P	Pre Dissertation-II	2	-	2	-
4	MPH304P	Pre Dissertation-III	14	-	28	-
		Total	21	**4**	31	**-**
Semester 4						
Sr. No.	**Subject Code**	**Subject Name**	**Credit**	**Lect**	**Lab**	**Tut**
1	MPH401P	Dissertation-I	1	-	1	-
2	MPH402P	Dissertation-II	16	-	31	-
3	MPH403P	Dissertation-III	3	-	3	-
		Total	**20**	**-**	**35**	

ANNEXURE-III
Semester I

a. **Course Name:** MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
b. **Course Code:** MPH 101T
c. **Prerequisite:** Having basic knowledge of pharmaceutical analysis
d. **Rationale:** This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc
e. **Course Learning Objective:**

CLOBJ 1	Infer locate Chemicals and Excipients
CLOBJ 2	Analyse various drugs in single and combination dosage form
CLOBJ 3	Theoretical and practical skills of the instruments

f. **Course Learning Outcomes:**

CLO 1	Apply various Spectroscopic techniques like UV, IR, AAS, Flame Emission and fluorescence spectroscopy for analysis.
CLO 2	Construct the concepts of NMR, FT NMR and 13C NMR.
CLO 3	Recognize & build the detail concepts of Mass spectroscopy.
CLO 4	Identify & build the detail concepts of Various Chromatographic Techniques.

CLO 5	Illustrate principles of separation of biomolecules and application of electrophoresis and analyse the crystal nature of compound by X-ray crystallography, Learning about Potentiometry and various thermal analytical methods.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**		**75**		**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	**Content**	**Weightage (%)**	**Teaching Hours**
1	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.	**18.33**	**11**
2	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	**18.33**	**11**

	FT-NMR and 13C NMR. Applications of NMR spectroscopy.		
3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	**18.33**	**11**
4	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	**18.33**	**11**
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.	**18.33**	**11**
6	Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence	**8.33**	**5**
		100	**60**

i. Text Book and Reference Book:

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

a. **Course Name:** DRUG DELIVERY SYSTEMS

b. Course Code: MPH 102T

c. Prerequisite: Having basic knowledge of drug delivery systems.

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

e. Course Learning Objective:

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

f. **Course Learning Outcomes:**

CLO 1	Infer the principles, fundamentals and use of polymers in development of controlled and sustained drug delivery systems, personalized medicines, bioelectronic medicines, 3D printing of pharmaceuticals and telemedicines.
CLO 2	Illustrate and interpret various approaches for development of rate controlled drug delivery systems.
CLO 3	Build the concept of gastro retentive drug delivery system and Buccal Drug Delivery Systems with advance methods and evaluation parameters
CLO 4	Extend recent advances in transdermal drug delivery system and ocular drug delivery systems
CLO 5	Develop the concept of protein and peptide delivery system and vaccine delivery systems.

i. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

g. Course Content:

Sr. No.	**Content**	**Weightage (%)**	**Teaching Hours**

1	Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Tele-pharmacy.	**16.66**	**10**
2	Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	**16.66**	**10**
3	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco-adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	**16.66**	**10**
4	Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barrier	**10**	**06**
5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	**16.66**	**10**
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	**13.33**	**08**
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	**10**	**06**
		100	**60**

h. Text Book and Reference Book:

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. Encyclopaedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim

4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, 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.

a. **Course Name:** MODERN PHARMACEUTICS
b. **Course Code:** MPH 103T
c. **Prerequisite:** Having basic knowledge of pharmaceutical product development
d. **Rationale:** Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries
e. **Course Learning Objective:**

CLOBJ 1	Utilize the elements of preformulation studies in product development
CLOBJ 2	Outline and interpret the Active Pharmaceutical Ingredients and Generic drug Product development
CLOBJ 3	Infer locate the Active Pharmaceutical Ingredients and Generic drug Product development
CLOBJ 4	Utilize Optimization Techniques & Pilot Plant Scale Up Techniques
CLOBJ 5	Extend Stability Testing, sterilization process & packaging of dosage forms

f. **Course Learning Outcomes:**

CLO 1	Utilize the elements of pre-formulation studies like drug interactions, stability testing, concept of pharmaceutical dispersions& parenterals.
CLO 2	Extend optimization techniques in pharmaceutical formulation and processing
CLO 3	Demonstrate pharmaceutical validation and policies of current good manufacturing practices, ICH, WHO guidelines and validation of dosage forms, types of validation, government regulations and manufacturing process models, validation of facilities.
CLO 4	Infer the concept of cGMP & industrial management along with Total Quality Management, statistical tests and concept of significance.
CLO 5	Make use of tablet compression & compaction, diffusion & dissolution parameters, pharmacokinetic parameters and build the concept of consolidation parameters.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**		**75**		**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	**16.66** **16.66**	**10** **10**
2	Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	**16.66**	**10**
3	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	**16.66**	**10**
4	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	**16.66**	**10**
5	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.	**16.66**	**10**
		100	**60**

i. Text Book and Reference Book:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann

2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.

3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.

4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.

5. Modern Pharmaceutics; By Gillbert and S. Banker.

6. Remington's Pharmaceutical Sciences.

7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.

8. Physical Pharmacy; By Alfred martin

9. Bentley's Textbook of Pharmaceutics – by Rawlins.

10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.

11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.

12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.

13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.

14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.

15. Pharmaceutical Preformulations; By J.J. Wells.

16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

17. Encyclopaedia of Pharmaceutical technology, Vol I

a. **Course Name:** REGULATORY AFFAIR
b. Course Code: MPH 104
c. Prerequisite: Having a basic know-how of pharmaceutical product development
d. **Rationale:** Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents.
e. Course Learning Objective:

CLOBJ 1	Recognize the concepts of innovator and generic drugs, drug development process
CLOBJ 2	Infer the regulatory guidance's and guidelines for filing and approval process
CLOBJ 3	Outline the preparation of Dossiers and their submission to regulatory agencies in different countries
CLOBJ 4	Construct post approval regulatory requirements for actives and drug products
CLOBJ 5	Submission of global documents in CTD/ eCTD format
CLOBJ 6	Sketch Clinical trials requirements for approvals for conducting clinical trials
CLOBJ 7	Describe pharmacovigilance and process of monitoring in clinical trials.

f. Course Learning Outcomes:

CLO 1	Make use of in-depth knowledge of documentation in Pharmaceutical Industry & Post marketing surveillance, BA- BE studies and drug assessment.
CLO 2	Interpret knowledge of Regulatory requirement for product approval process by filing NDA, ANDA, US registration for foreign drugs.
CLO 3	Identify CMC, post approval regulatory requirements, CTD/ eCTD formats. ICH guidelines- Q, S, E, M & Regulatory requirement of EU, MHRD, TGA and ROW Countries.
CLO 4	Outline the non clinical drug development, global submission of IND, NDA, ANDA, IMPD & its components, and Investigational Brochure.
CLO 5	Summarize the development of clinical trial protocol, Institutional review board, informed consent, HIPPA and pharmacovigilance safety monitoring in clinical trials.

i. Teaching & Examination Scheme:

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**		**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

g. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	**20** **20**	**12** **12**
2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW	**20**	**12**
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB)	**20**	**12**
4	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.	**20**	**12**
		100	**60**

h. Text Book and Reference Book:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, 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

Annexure IV

Semester I

a. **Course Name:** PHARMACEUTICS PRACTICALS - I
b. **Course Code:** MPH105P
c. **Prerequisite:** Having a basic pharmaceutical practical knowledge
d. **Rationale:** The subject deals with advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Alongside also deals with formulation, evaluation and characterization of various dosage forms
e. **Course Learning Objective:**

CLOBJ 1	Experiment with analytical instrumental techniques for identification, characterization and quantification of drugs
CLOBJ 2	Develop formulation, evaluation and characterization of various dosage forms

f. **Course Learning Outcomes:**

CLO 1	Experiment with analytical instrumental techniques for identification, characterization and quantification of drugs
CLO 2	Develop formulation, evaluation and characterization of various dosage forms

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
-	**-**	**12**	**6**			**50**		**100**	**150**

L- Lectures; **T-** Tutorial; **P-** Practical; **C-** Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. **Text Book and Reference Book:**
1. Indian Pharmacopoeia 2022.
2. US Pharmacopoeia2023

i. **Experiment List:**

Exp. No.	**Name of the Experiment**
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

Exp. No.	Name of the Experiment
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.

Annexure III
Semester II

a. **Course Name:** MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)
b. **Course Code:** MPH 201T
c. **Prerequisite:** Having a basic knowledge of dosage forms
d. **Rationale:** This course is designed to impart knowledge on the area of advances in novel drug delivery systems.
e. **Course Learning Objective:**

CLOBJ 1	Apply various approaches for development of novel drug delivery systems.
CLOBJ 2	Interpret the criteria for selection of drugs and polymers for the development of NTDS
CLOBJ 3	Develop formulation and conduct evaluation of novel drug delivery systems.

f. **Course Learning Outcomes:**

CLO 1	Recognize the basic concepts, events and biological process involved in targeted drug delivery systems.
CLO 2	Build the concept of targeting methods, nanoparticles & liposomes
CLO 3	Illustrate delivery systems like microcapsules / microspheres, monoclonal antibodies; niosomes, aquasomes, phytosomes, electrosomes.
CLO 4	Develop the concept of pulmonary & intra nasal drug delivery systems, its preparation and evaluation.
CLO 5	Identify and build concept of nucleic acid based therapeutic delivery systems & its bio-distribution and pharmacokinetics.

i. Teaching & Examination Scheme:

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

g. **Course Content:**

Sr. No.	Content	Weightage (%)	Teaching Hours
1	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	**20**	**12**
2	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	**20**	**12**
3	Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	**20**	**12**
4	Pulmonary Drug Delivery Systems: Aerosols, propellants, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	**20**	**12**
5	Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	**20**	**12**
		100	**60**

h. Text Book and Reference Book:

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, Vallabh Prakashan, New Delhi, First edition 2002.

3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

a. **Course Name:** ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
b. **Course Code:** MPH 202T
c. **Prerequisite:** Having a basic knowledge of biopharmaceutics and pharmacokinetics
d. **Rationale:** This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics and pharmacokinetic principles in practical problem solving.
e. **Course Learning Objective:**

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

f. **Course Learning Outcomes:**

CLO 1	Outline and relate drug Absorption from the gastrointestinal tract, various transport models.
CLO 2	Employ biopharmaceutical considerations in drug product design and in-vitro drug product performance.
CLO 3	Compute the concept of pharmacokinetic and compartment modelling; non-linear pharmacokinetics & drug interactions.
CLO 4	Make use of the concept of drug product performance In- vivo: Bioavailability, bioequivalence, methods of permeability estimation: generic biologics & substitutions.
CLO 5	Employ applications of pharmacokinetics related to modified-release drug products, targeted drug delivery systems & biotechnological products and drug interactions.

i. Teaching & Examination Scheme:

Teaching Scheme				**Evaluation Scheme**		
L	**T**	**P**	**C**	**Internal Evaluation**	**ESE**	**Total**

				MSE	CE	P	Theory	P	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

g. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	**20**	**12**
2	Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug	**20**	**12**
3	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modelling: 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,	**20**	**12**

	cytochrome p450-based drug interactions, drug interactions linked to transporters.		
4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	**20**	**12**
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	**20**	**12**
		100	**60**

h. Text Book and Reference Book:

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, 2 ndedition, 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 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.

a. **Course Name:** COMPUTER AIDED DRUG DEVELOPMENT
b. **Course Code:** MPH203T
c. **Prerequisite:** Having a basic knowledge of use of computer in pharmacy
d. **Rationale:** This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process.
e. **Course Learning Objective:**

CLOBJ 1	Summarize the history of computers in pharmaceutical research and development
CLOBJ 2	Infer computational modelling of drug disposition
CLOBJ 3	Illustrate the use of computers in preclinical development
CLOBJ 4	Apply optimization techniques in pharmaceutical formulation
CLOBJ 5	Use of computers in market analysis
CLOBJ 6	Use of computers in clinical development
CLOBJ 7	Illustrate the knowledge of Artificial Intelligence (AI) and Robotics
CLOBJ 8	Build the concept of Computational fluid dynamics(CFD)

f. Course Learning Outcomes:

CLO 1	Sketch the use of computers in pharmaceutical research and development; Statistical modelling, Quality-by-Design, ICH Q8 guideline, Regulatory and industry views on QbD.
CLO 2	Illustrate and interpret computational modelling of drug disposition; Modelling Techniques.
CLO 3	Demonstrate computer aided formulation development using various optimization techniques & screening design, legal protection & the ethics of computing in pharmaceutical research.
CLO 4	Infer computer-aided biopharmaceutical characterization & computer simulations in pharmacokinetics and pharmacodynamics.
CLO 5	Build concept of Artificial Intelligence (AI), Robotics & and Computational fluid dynamics in pharmaceutical automation and its applications.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**		
L	**T**	**P**	**C**	**Internal Evaluation**	**ESE**	**Total**

				MSE	CE	P	Theory	P	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
1	a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modelling in Pharmaceutical research and development: Descriptive versus Mechanistic Modelling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modelling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	**20**	**12**
2	Computational Modelling Of Drug Disposition: Introduction ,Modelling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	**20**	**12**
3	Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	**20**	**12**
4	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in vivo correlation, Bio waiver considerations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation:	**20**	**12**

	Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems		
5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	**20**	**12**
		100	**60**

i. Text Book and Reference Book:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.

2. Computer-Aided Applications in Pharmaceutical Technology, 1 st Edition, Jelena Djuris, Woodhead Publishing

3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

a. **Course Name:** COSMETICS AND COSMECEUTICALS
b. **Course Code:** MPH 204T
c. **Prerequisite:** Having a basic information of cosmetics
d. **Rationale:** This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.
e. **Course Learning Objective:**

CLOBJ 1	Recognize the key ingredients used in cosmetics and cosmeceuticals.
CLOBJ 2	Identify and illustrate the key building blocks for various formulations.
CLOBJ 3	Compute current technologies in the market
CLOBJ 4	Categorise various key ingredients and basic science to develop cosmetics and cosmeceuticals
CLOBJ 5	Employ scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy

f. **Course Learning Outcomes:**

CLO 1	Recognize the need and applications of cosmetics and cosmeceuticals regulatory guidelines.
CLO 2	Infer biological aspects of skin and hair to design the cosmetics.
CLO 3	Recognize the building blocks of various cosmetic formulations & perfumes.
CLO 4	Interpret various key ingredients and basic science to design & develop cosmetics and cosmeceuticals.
CLO 5	Identify and illustrate herbal ingredients used in cosmetics formulation, review guidelines, regulation and the challenges in formulating herbal cosmetics.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
4	**-**	**-**	**4**	**15**	**10**	**-**	**75**	**-**	**100**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. **Course Content:**

Sr. No.	Content	Weightage (%)	Teaching Hours
1	Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labelling 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	**20**	**12**
2	Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	**20**	**12**
3	Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane	**20**	**12**
4	Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	**20**	**12**
5	Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.	**20**	**12**
		100	**60**

i. Text Book and Reference Book:

1. Harry’s Cosmeticology. 8 th edition.

2. Poucher’s perfume cosmetics and Soaps,10 th edition.

3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4 th edition

4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition

5. Cosmetic and Toiletries recent suppliers catalogue.

6. CTFA directory.

Annexure IV
Semester II

a. **Course Name:** PHARMACEUTICS PRACTICALS - II
b. **Course Code:** MPH 205P
c. **Prerequisite:** Having a basic knowledge of formulation development
d. **Rationale:** The subject deals with formulation, evaluation and characterization of various dosage forms, formulation development for herbal products. Alongside includes the advanced learning of Design of experiment, Software, QbD, Computer simulation and modelling, clinical data collection manual.
e. **Course Learning Objective:**

CLOBJ 1	Experiment with formulation, evaluation and characterization of various dosage forms, formulation development for herbal products.
CLOBJ 2	Employ Design of experiment, Software, QbD, Computer simulation and modelling, clinical data collection manual.

f. **Course Learning Outcomes:**

CLO 1	Experiment with formulation, evaluation and characterization of various dosage forms, formulation development for herbal products.
CLO 2	Employ Design of experiment, Software, QbD, Computer simulation and modelling, clinical data collection manual.

g. **Teaching & Examination Scheme:**

Teaching Scheme				**Evaluation Scheme**					
L	**T**	**P**	**C**	**Internal Evaluation**			**ESE**		**Total**
				MSE	**CE**	**P**	**Theory**	**P**	
-	**-**	**12**	**6**	**-**	**-**	**50**	**-**	**100**	**150**

L- Lectures; **T**- Tutorial; **P-** Practical; **C**- Credit; **MSE-** Mid-Semester Evaluation, **CE**- Continuous Evaluation, **ESE-** End Semester Examination

h. **Text Book and Reference Book:**
1. Indian Pharmacopoeia 2022.
2. US Pharmacopoeia2023

i. **Experiment List**

Exp. No.	**Name of the Experiment**
1	To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation

Exp. No.	Name of the Experiment
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 Modelling Of Drug Disposition
17	Computational Modelling Of Drug Disposition
18	To carry out Sensitivity Analysis, and Population
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 incorporate herbal and chemical actives to develop products

Annexure III
Semester III

a. **Course Name: Research Methodology and Biostatistics**
b. **Course Code: MRM301T**
c. **Prerequisite:** Having a basic knowledge of pharmaceutical research and statistics
d. **Rationale:** The course is designed to study research methodology in terms of basic concepts of statistical analysis, principles of medical research, ethics and patents, maintenance of laboratory animals and design research work.
e. **Course Learning Objective:**

CLOBJ 1	Analyse the value, scope, objectives and requirements of research
CLOBJ 2	Discuss the basic concepts of statistical analysis
CLOBJ 3	Apply the basic principles of medical research and ethics.
CLOBJ 4	Outline the guidelines for the maintenance of laboratory animals.
CLOBJ 5	Create efficiency in solving practical difficulties and design research work.

f. **Course Learning Outcomes:**

CLO 1	Extend research methodology to select the appropriate study design and develop appropriate research hypothesis for a research project
CLO 2	Develop the basic concepts of biostatistics and different parametric and non-parametric tests
CLO 3	Recognize the functions of ethics committees in medical research
CLO 4	Outline CPCSEA guidelines for laboratory animal facility

CLO 5	Discuss the genesis of bioethics with special reference to Helsinki declaration

g. Teaching & Examination Scheme:

Teaching Scheme				Evaluation Scheme					
L	T	P	C	Internal Evaluation			ESE		Total
				MSE	CE	P	Theory	P	
4	-	-	4	15	10	-	75	-	100

L- Lectures; **T-** Tutorial; **P-** Practical; **C-** Credit; **MSE-** Mid-Semester Evaluation, **CE-** Continuous Evaluation, **ESE-** End Semester Examination

h. Course Content:

Sr. No.	Content	Weightage (%)	Teaching Hours
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, blinding techniques.	**20**	**12**
2	**UNIT – 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 (Wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	**20**	**12**
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, 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.	**20**	**12**

4	**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, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	**20**	**12**
5	**UNIT – V** Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**20**	**12**
		100	**60**

i. Text Book and Reference Book:

1. Research Methodology : Methods & Techniques, C.R. Kothari, Viswa Prakashan,
2. Research Methods- A Process of Inquiry, Graziano, A.M., Raulin, M.L, Pearson Publications.
3. Pharmaceutical Statistics: Practical and Clinical Applications, Sanford Bolton and CharlesBon.
4. Thesis projects in Science & Engineering – Richard M. Davis.
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. How to Write a Thesis: Murray, R. Tata McGraw Hill
8. Writing For Academic Journals, Murray, R., McGraw Hill International.
9. A Handbook of Academic Writing, Murray, R. and Moore, S., Tata McGraw Hill International
10. Writing for Publication, Henson, K.T., Allyn & Bacon.
11. Effective Business Report Writing –Leland Brown
12. Manual for evaluation of industrial projects-United Nations
13. Practical Introduction to copyright.- Gavin Mcfarlane
14. Operational research by Dr. S.D.Sharma, Kedarath, Ramnath & Co.
15. Various Guidelines like: ICH – GCP- International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6
16. ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects. Indian GCP – Central Drugs Standard Control Organization.
17. Good Clinical Practices – Guidelines for Clinical Trials on Pharmacuetical Products in India. New Delhi: Ministry of Health; 2001. Schedule Y