SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

DIT UNIVERSITY
Dehradun

COURSE STRUCTURE

OF

M.PHARM (PHARMACEUTICS)
(AS PER PCI)

Approved by the Academic Council at its 17h Meeting held on 24.03.2021

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

COURSE STRUCTURE

Year: 1st **Semester: I**

Course Code	Course Title	L	T	P	Credit
MPH101T	Modern Pharmaceutical Analytical Techniques	4	-	-	4
MPH102T	Drug Delivery System	4	-	-	4
MPH103T	Modern Pharmaceutics	4	-	-	4
MPH104T	Regulatory Affair	4	-	-	4
MPH105P	Pharmaceutics Practical I	-	-	12	6
MPH106P	Seminar/Assignment	-	-	7	4
	Total				**26**

Year: 1st **Semester: II**

Course Code	Course Title	L	T	P	Credit
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	-	-	4
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	-	-	4
MPH203T	Computer Aided Drug Delivery System	4	-	-	4
MPH204T	Cosmetic and Cosmeceuticals	4	-		4
MPH205P	Pharmaceutics Practical II	-	-	12	6
MPH206P	Seminar/Assignment	-	-	7	4
	Total				**26**

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Year: 2nd **Semester: III**

Course Code	Course Title	L	T	P	Credit
MRM301T	Research Methodology and Biostatistics*	4	-	-	4
MPH302P	Journal club	-	-	1	1
MPH303P	Discussion / Presentation (Proposal Presentation)	-	-	2	2
MPH304P	Research Work	-	-	28	14
	Total		-	-	**21**

Year: 2nd **Semester: IV**

Course Code	Course Title	L	T	P	Credit
MPH401P	Journal Club	-	-	1	1
MPH402P	Research Work	-	-	31	16
MPH403P	Discussion/Final Presentation	-	-	3	3
	ELECTIVES				
CCA 404P	Co- curricular Activities				
CCA 404P.1	Co- curricular Activities- Participation in national level seminar/ conference/ workshop/ symposium/ training programs (related to the specialization of the student)	-	-	1	1
CCA 404P.2	Co- curricular Activities- Participation in international level seminar/ conference/ workshop/ symposium/ training programs (related to the specialization of the student)	-	-	2	2
CCA 404P.3	Co- curricular Activities- Academic award/ research award from State level/ National agencies	-	-	1	1
CCA 404P.4	Co- curricular Activities- Academic award/ research award from International	-	-	2	2

	agencies				
CCA 404P.5	Co- curricular Activities- Research/ review publication in National journals (indexed in Scopus/ Web of Science)	-	-	1	1
CCA 404P.6	Co- curricular Activities- Submission of research/ review publication in International journal	-	-	2	2
CCA 404P.7	Co- curricular Activities- Filing of patent application	-	-	2	2
	Total Minimum 22 Maximum 27			**35**	**27**

Summary of the Credit

Year	Semester	Credit
1	1	26
	2	26
2	3	21
	4	27
Total	**Minimum 95**	**Maximum 100**

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Modern Pharmaceutical Analytical Techniques		**Course Code:** MPH 101T	
Credit: 4	**L**	**T**	**P**
	4	0	0
Year: 1st		**Semester:** I	

Course Objective:
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.

Content:
1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, 11 Instrumentation associated with UV-Visible spectroscopy, Hrs 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. Spectrofluorometric: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Hrs Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C
NMR. Applications of NMR spectroscopy.

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass 11 Spectroscopy, Different types of ionization like electron impact, Hrs 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

4 Chromatography: Principle, apparatus, instrumentation, 11 chromatographic parameters, factors affecting resolution and Hrs applications of the following:
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography

5 a. Electrophoresis: Principle, Instrumentation, working 11 conditions, factors affecting separation and applications of the Hrs 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 X-ray diffraction.

6 Immunological assays: RIA (Radio immuno assay), ELISA, 5 Hrs Bioluminescence assays.

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

Learning Outcome: After completion of course student is able to know, Chemicals and Excipients
The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments.

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Drug Delivery Systems		**Course Code:** MPH 102T	
Credit: 4	**L**	**T**	**P**
	4	0	0
Year: 1st			**Semester:** I

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

Course Content

1.Sustained Release(SR) and Controlled Release (CR) 10 formulations: Introduction & basic concepts, advantages/ Hrs 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.

2 Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Hrs Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic Activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

3 Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time Hrs approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

4 Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

5 Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Hrs Systems, Formulation and evaluation.

6 Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and Hrs other macromolecules.

7 Vaccine delivery systems: Vaccines, uptake of antigens, single 06 shot vaccines, mucosal and transdermal delivery of vaccines.

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

Journals

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

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

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

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Modern Pharmaceutics			**Course Code:** MPH 103T
Credit: 4	**L**	**T**	**P**
	4	0	0
Year: 1st			**Semester:** I

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

Course Content

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

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.

3 cGMP & Industrial Management: Objectives and policies of 10 current good manufacturing practices, layout of buildings, Hrs 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.

4 Compression and compaction: Physics of tablet compression, 10 compressions, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.
5 Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel Hrs plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

References

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin

9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

Learning Outcome: Upon completion of the course, student shall be able to understand The elements of preformulation studies.
The Active Pharmaceutical Ingredients and Generic drug Product development
Industrial Management and GMP Considerations. Optimization Techniques & Pilot Plant Scale Up Techniques
Stability Testing, sterilization process & packaging of dosage forms.

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Regulatory Affairs			**Course Code:** MPH 104T
Credit: 4	**L**	**T**	**P**
	4	0	0
Year: 1st			**Semester:** I

course objective: Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA
To know the approval process of
To know the chemistry, manufacturing controls and their regulatory importance
To learn the documentation requirements for to learn the importance and

Course Content

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

2CMC, 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.
3 Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).
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.

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

Learning Outcome*:* Upon completion of the course, it is expected that the students will be able to understand
The Concepts of innovator and generic drugs, drug development process
The Regulatory guidance's and guidelines for filing and approval process
Preparation of Dossiers and their submission to regulatory agencies in different countries
Post approval regulatory requirements for actives and drug products Submission of global documents in CTD/ eCTD formats Clinical trials requirements for approvals for conducting clinical trials Pharmacovigilence and process of monitoring in clinical trials.

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Pharmaceutics Practicals - I			**Course Code:** MPH 105P
Credit: 6	**L**	**T**	**P**
	0	0	12
Year: 1st			**Semester:** I

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.

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Molecular Pharmaceutics (Nano Technology & Targeted Dds) (Ntds)		**Course Code:** MPH 201T	
Credit: 4	**L**	**T**	**P**
	4	0	0
Year: 1st			**Semester:** II

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

Course Content

1.Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Hrs Brain specific delivery.

2 Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

3 Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, Hrs preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

4 Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

5 Nucleic acid based therapeutic delivery system: Gene therapy, introductions (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.

Bio distribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.

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).

Learning Outcome: Upon completion of the course student shall be able to understand

The various approaches for development of novel drug delivery systems.

The criteria for selection of drugs and polymers for the development of NTDS

The formulation and evaluation of novel drug delivery systems.

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Approved by the Academic Council at its 17^{h} Meeting held on 24.03.2021

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Advanced Biopharmaceutics & Pharmacokinetics		**Course Code:** MPH 202T	
Credit: 4	**L**	**T**	**P**
	4	0	0
Year: 1st			**Semester:** II

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

Course Content

1.Drug Absorption from the Gastrointestinal Tract: 12 Gastrointestinal tracts, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight- Junction Complex.

2 Biopharmaceutics considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

3 Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV olus, 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.

4 Drug Product Performance, In Vivo: Bioavailability and 12 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.

5 Application of Pharmacokinetics: Modified-Release Drug 12 Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamics, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

References

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

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

The basic concepts in biopharmaceutics and pharmacokinetics. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

The critical evaluation of biopharmaceutic studies involving drug product equivalency.

The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic.

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Computer Aided Drug Development		**Course Code:** MPH 203T	
Credit: 4	**L**	**T**	**P**
	4	0	0
Year: 1st			**Semester:** II

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

Course Content

1. a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

b. Quality-by-Design in Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

2 Computational Modeling of Drug Disposition: Introduction 12, Modeling Techniques: Drug Absorption, Solubility, Intestinal Hrs Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

3 Computer-aided formulation development: Concept of 12 optimizations, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

4 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

5 Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Hrs Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

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.

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

- History of Computers in Pharmaceutical Research and Development Computational Modeling of Drug Disposition
- Computers in Preclinical Development Optimization Techniques in Pharmaceutical Formulation Computers in Market Analysis
- Computers in Clinical Development Artificial Intelligence (AI) and Robotics Computational fluid dynamics(CFD)

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Cosmetics And Cosmeceuticals		**Course Code:** MPH 204T	
Credit: 4	**L**	**T**	**P**
	4	0	0
Year: 1st		**Semester:** II	

Course Objective: This course is designed to impart knowledge and skills necessary forth fundamental need for cosmetic and cosmeceutical products.

Course Content

1.Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

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.

3.Formulation Building blocks: Building blocks for different 12 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.

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.

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.

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.

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

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

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Pharmaceutics Practicals - II		**Course Code:** MPH 205P	
Credit: 6	**L**	**T**	**P**
	0	0	12
Year: 1st		**Semester:** II	

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

SCHOOL OF PHARMACEUTICAL & POPULATIONS HEALTH INFORMATICS
COURSE STRUCTURE FOR M. PHARM IN PHARMACEUTICS
2022 ONWARDS

Course Title: Research Methodology & Biostatistics		**Course Code:** MRM301T	
Credit: 4	**L**	**T**	**P**
	4	0	0
Year: 1st		**Semester:** II	

Course Objective:
This course is designed with an objective to impart knowledge, skills and professional approach required for statistical analysis of research data. It is also with an objective to provide important information related ethics in biological and clinical evaluation drugs, and drug preparations.

Course Content

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.

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 (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

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.

Unit – IV
CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

Unit – V
Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

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

- Evaluate and appraise the scientific literature
- Design and develop a study and analyse the data collected from the research
- Summarize principles and procedure of medical research
- Recommend CPCSEA guidelines on ethical use of animals for experimentation and research
- Describe Declaration of Helsinki for research involving human trial