SAURASHTRA UNIVERSITY

Accredited Grade 'A'
by NAAC

FACULTY OF PHARMACY

Master of Pharmacy (M. Pharm) in Pharmaceutics

Ordinances and Regulations
Effective from
June 2017
(Two-Year full-time PG Course)

Department of Pharmaceutical Sciences
Saurashtra University
Rajkot - 360 005
www.saurashtrauniversity.edu

PROGRAM OUTCOMES

POs of M. Pharm (Pharmaceutics)

Students of all post undergraduate pharmacy degree programs at the time of graduation will be able to learn:

PO 1: Research and development

The students will be able to generate ideas for research, analyse them, execute them and publish the findings.

PO 2: Domain knowledge:

Students will be able to acquire knowledge and comprehension of the core and specialization subjects of the respective pharmacy specialization.

PO 3: Communication skills:

Students will be able to learn communication by giving seminars, journal club and other organizational activities. They will be able to comprehend and write effective reports, make effective presentations and documentation.

PO 4: Planning skills:

Students will be able to demonstrate effective planning abilities including time management, resource management, and organizational skills. They will be able to develop and implement plans and organize work to meet deadlines.

PO 5: Problem analysis:

Students will be able to develop, critical thinking and analytical skills while solving problems and making decisions in dissertation research.

PO 6: Usage of contemporary research tools and techniques:

Students will be able to learn, select, and apply appropriate current methods and procedures in modern pharmaceutical research with an understanding of the limitations.

PO 7: Social responsibilities:

Students will be able to understand, analyze and communicate the value of their professional roles in society (e.g. as health care professionals, promoters of health, educators, managers, employers, employees).

PO 8: Continuous learning:

They will be able to recognize the need for continuous up gradation of their knowledge and skills

PROGRAM SPECIFIC OUTCOMES

PSOs of M. Pharm (Pharmaceutics)

After successful completion of the program the students will be able to

PSO1

Apply the principles of drug delivery system in the development of eco-friendly, efficacious dosage forms.

PSO2

Knowledge of basic principles and their applications in the field of pharmaceutical sciences and technology.

PSO3

Analyse, criticize, coordinate, improvise, and manage pharmaceutical production related records, data and information.

PSO4

Execute team-based research to implement innovative solutions in the area of formulation, quality assurance and technology transfer.

PSO5

Students will demonstrate research and development expertise in all pharmaceutical science disciplines.

PSO6

Students will show the understanding of impact of Pharmaceutical sciences on the society and also will be aware of modern issues

PSO7

Validate the knowledge and skills gained through education to gain recognition in Pharmaceutical society and related field.

PSO8

Set-up pharmaceutical production unit to design and formulate pharmaceutical dosage forms

PSO9

Students will be inculcated with professional values, effective research communication skills, prioritizing problems and solutions and an ability to view pharmaceutical issues in broader context.

Course Structure and Scheme of Examination

M. Pharm Pharmaceutics (MPH)

Semester I

Subject Code	Title of the Course	Course Credits	No. of Hrs. Per Week	Weightage for Internal Examination	Weightage for Semester End Examination	Total Marks	Duration of Semester End Exam in Hrs.
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	25	75	100	3 Hrs
MPH102T	Drug Delivery System	4	4	25	75	100	3 Hrs
MPH103T	Modern Pharmaceutics	4	4	25	75	100	3 Hrs
MPH104T	Regulatory Affair	4	4	25	75	100	3 Hrs
MPH105P	Pharmaceutics Practical I	6	12	50	100	150	6 Hrs
-	Seminar/Assignment	4	7	-	-	100	-
Total		**26**	**35**			**650**	

Semester II

Subject Code	Title of the Course	Course Credits	No. of Hrs. Per Week	Weightage for Internal Examination	Weightage for Semester End Examination	Total Marks	Duration of Semester End Exam in Hrs.
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	25	75	100	3 Hrs
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	25	75	100	3 Hrs
MPH203T	Computer Aided Drug Delivery System	4	4	25	75	100	3 Hrs
MPH204T	Cosmetic and cosmeceuticals	4	4	25	75	100	3 Hrs
MPH205P	Pharmaceutics Practical II	6	12	50	100	150	6 Hrs
-	Seminar/Assignment	4	7	-	-	100	-
Total		**26**	**35**			**650**	

Semester III

Subject Code	Title of the Course	Course Credits	No. of Hrs. Per Week	Weightage for Internal Examination	Weightage for Semester End Examination	Total Marks	Duration of Semester End Exam in Hrs.
MRM301T	Research Methodology and biostatistics*	4	4	25	75	100	3 Hrs
-	Journal club	1	1	25	-	25	-
-	Discussion/presentation (Proposal presentation)	2	2	50	-	50	-
-	Research work	14	28	-	350	350	1 Hrs
Total		**21**	**35**			**525**	

*Non-University exam

Semester IV

Subject Code	Title of the Course	Course Credits	No. of Hrs. Per Week	Weightage for Internal Examination	Weightage for Semester End Examination	Total Marks	Duration of Semester End Exam in Hrs.
-	Journal club	1	1	25	-	25	-
-	Discussion/Final Presentation	3	3	75	-	75	-
-	Research work	16	31	-	400	400	1 Hrs
Total		**20**	**35**			**500**	

M.PHARM SEMESTER I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Theory: 4 Hrs. /Week

Scope

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.

Objectives

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

Course Outcomes

CO1: At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques

CO2: This is important for qualitative as well as quantitative analysis of drug substances and drug product.

CO3: Moreover. Several aspects of the interpretations of the various spectroscopic data will be taught.

Course content

Unit 1 — 11 Hrs

1. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible spectroscopy.
2. **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
3. **Spectrofluorimetric:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
4. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

Unit 2 — 11 Hrs

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

Unit 3 **11 Hrs**

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

Unit 4 **11 Hrs**

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

Unit 5 **11 Hrs**

Electrophoresis:

1. 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
2. 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.

Unit 6 **5 Hrs**

Immunological assays:

RIA (Radio immunoassay), ELISA, 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

M.PHARM SEMESTER I

DRUG DELIVERY SYSTEMS (MPH 102T)

Theory: 4 Hrs. /Week

Scope

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

Objectives

After completion of course student is able to know,

- 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

Course Outcomes

CO1 At the end of the course, the student will get acquainted with approaches, formulations, technologies, and systems of New Drug Delivery Systems for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effect.

CO2 Moreover, students can select research-based project in subsequent semesters for specific type of delivery systems.

CO3 The knowledge gained by the students during the study of this course can also help them in handling of NDDS related research projects in Pharma industry

Course content

Unit 1 — 10 Hrs

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, Bioelectronics Medicines, 3D printing of pharmaceuticals, Telepharmacy.

Unit 2 **10 Hrs**

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

Unit 3 **10 Hrs**

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.

Unit 4 **6 Hrs**

Occular Drug Delivery Systems:

Barriers of drug permeation, Methods to overcome barriers.

Unit 5 **10 Hrs**

Transdermal Drug Delivery Systems:

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

Unit 6 **8Hrs**

Protein and Peptide Delivery:

Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

Unit 7 **6Hrs**

Vaccine delivery systems

Vaccines, uptake of antigens, single 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. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. Encyclopedia 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. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.

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

M.PHARM SEMESTER I

MODERN PHARMACEUTICS (MPH 103T)

Theory: 4 Hrs. /Week

Scope

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

Objectives

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

- 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.

Course Outcomes

CO1 At the end of the course, the student will be able to understand the various structural and documentary requirements in the pharmaceutical industry.

CO2 The students will also be able to get useful information regarding the management of pharmaceutical industry.

CO3 Moreover, they will understand the importance about the preformulation considerations as well as time saving optimization techniques like designs which are very useful in successful and efficient formulation

Course content

Unit 1 **20 Hrs**

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

Unit 2 **10 Hrs**

Validation:

Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipment, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

Unit 3 **10 Hrs**

cGMP & Industrial Management:

Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment 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.

Unit 4 **10 Hrs**

Compression and compaction:

Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.

Unit 5 **10 Hrs**

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.

REFERENCES

1. Theory and Practice of Industrial Pharmacy by Lachmann and Liebermann
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.

M.PHARM SEMESTER I

REGULATORY AFFAIRS (MPH 104T)

Theory: 4 Hrs. /Week

Scope

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
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements

Objectives

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.

Course Outcomes

CO1 At the end of the course, the student will be having a good understanding of the drug development process as a whole and the practical concepts, regulatory aspects related to Research & Development as well as manufacturing and marketing of Pharmaceutical Products.

CO2 The students will become familiar to various guidelines and regulatory requirements of various countries

CO3 The students will acquire knowledge regarding the protocols in developing clinical trials and various procedures regarding the same.

CO4 Information regarding the important pharmacokinetic parameters and various tests will be achieved

Course content

Unit 1 — 24 Hrs

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

Unit 2 **12 Hrs**

CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

Unit 3 **12 Hrs**

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

Unit 4 **12 Hrs**

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 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: 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

M.PHARM SEMESTER I
PHARMACEUTICS PRACTICALS-1 (MPH 105P)
Practical: 12 Hrs. /Week

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 Mucoadhesive 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.

M.PHARM SEMESTER II

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY& TARGETED DDS) (NTDS) (MPH201T)

Theory: 4 Hrs. /Week

Scope

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

Objectives

Upon completion of the course student shall be able to understand

- 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.

Course Outcomes

CO1 The students should be able to select the right kind of materials, able to develop nano formulations like Liposomes, Niosomes, Aquasomes, Phytosomes, Electrosomes with appropriate technologies

CO2 Design drug delivery systems for targeting drugs to tumours and to the brain

CO3 Design various formulation approaches like aerosols, nebulizers and dry powder inhalers for effective pulmonary delivery.

CO4 Develop strategies for improving nasal absorption in the design of nasal drug delivery systems

CO5 Apply knowledge of gene therapy in the treatment of cancer and inherited diseases

CO6 Design novel drug delivery systems by apply knowledge of antisense molecules and aptamers.

Course content

Unit 1 — 12 Hrs

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting.

Tumor targeting and Brain specific delivery.

Unit 2 — 12 Hrs

Targeting Methods: introduction preparation and evaluation.

Nano Particles & Liposomes: Types, preparation and evaluation.

Unit 3 — 12 Hrs

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

Unit 4 **12 Hrs**

Pulmonary Drug Delivery Systems: Aerosols, Propellants, Containers Types, preparation and evaluation,

Intra Nasal Route Delivery systems; Types, preparation and evaluation.

Unit 5 **12 Hrs**

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.

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, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

M.PHARM SEMESTER II

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

(MPH 202T)

Theory: 4 Hrs. /Week

Scope

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.

Objectives

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

Course Outcomes

CO1 Learn the mechanism of drug absorption &various factors affecting drug absorption

CO2 understand the concept of dissolution, In - vitro dissolution testing models and Invitro- *In–vivo* correlation

CO3 Learn various biopharmaceutic factors affecting drug bioavailability

CO4 Understand basic considerations of pharmacokinetic models and different compartment model and non-compartment model.

CO5 Explain the design and evaluation of dosage regimens of the drugs using pharmacokinetic and `biopharmaceutic parameters.

CO6 Understand the objectives of bioavailability, concept and measurements of bio-availability. Learn the regulatory aspects of bio-availability and bioequivalence studies

CO7 Design and evaluation of bioequivalence studies.

Course content

Unit 1 **12 Hrs**

- **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.

Unit 2 **12 Hrs**

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 product.

Unit 3 **12 Hrs**

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 k_{max} and v_{max}.

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

Unit 4 **12 Hrs**

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.

Unit 5 **12 Hrs**

Application of Pharmacokinetics:

Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamics, drug interactions.

Pharmacokinetics and pharmacodynamics of biotechnology drugs.

Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

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., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, 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 Malcolm Rowland and Thom N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, 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. Encyclopaedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.

13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003

M.PHARM SEMESTER II

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Theory: 4 Hrs. /Week

Scope

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.

Objectives

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

- History of Computers in Pharmaceutical Research and Development
- Computational Modelling 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)

Course Outcomes

CO1 learn the applications of computers in pharmaceutical product development

CO2 Learn various in silicon models of Drug Disposition

CO3 Understand the basics of Quality by design in formulation development

CO4 Learn computational model for biopharmaceutical characterization of drugs

CO5 Learn computer Simulations in Pharmacokinetics and Pharmacodynamics

CO6 Study the use of computers in Clinical Data Collection and Management

CO7 Understand the prerequisite of industrial automation by application of artificial intelligence, robotics and computational fluid dynamics

Course content

Unit 1 — 12Hrs

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.

Unit 2 **12 Hrs**

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.

Unit 3 **12 Hrs**

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

Unit 4 **12 Hrs**

a) **Computer-aided biopharmaceutical characterization**: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitroin vivo correlation, Biowaiver considerations

b) **Computer Simulations in Pharmacokinetics and Pharmacodynamics**: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c) **Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems

Unit 5 **12 Hrs**

Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, 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. Encyclopaedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.

M.PHARM SEMESTER II

COSMETICS AND COSMECEUTICALS (MPH 204T)

Theory: 4 Hrs. /Week

Scope

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives

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.

Course Outcomes

CO1 Learn various the regulatory provisions related to the import and manufacture of cosmetics

CO2 Apply the knowledge of various Biological aspects in the development of optimized cosmetic formulation.

CO3 Able to select key ingredients suitable in the formulation of various cosmetics

CO4 Utilize various technologies for designing cosmetics and cosmeceuticals with desired safety, stability and efficacy

CO5 Select herbal ingredients in the formulation of cosmetics for hair care, skin care and oral care

CO6 Learn various the regulatory provisions related to the herbal cosmetics

Course content

Unit 1 **12 Hrs**

- 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.

Unit 2 **12 Hrs**

Cosmetics Biological aspects:

- Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odour. Structure of hair and hair growth cycle.
- Common problems associated with oral cavity.
- Cleansing and care need for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

Unit 3 **12 Hrs**

- Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals.
- Surfactants – Classification and application. Emollients, rheological additives
- Classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy.
- Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.
- Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation
- Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

Unit 4 **12 Hrs**

Design of cosmeceutical products:

Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun- protection, pigmentation, prickly heat, wrinkles, body odour. Dandruff, dental cavities, bleeding gums, mouth odour and sensitive teeth through cosmeceutical formulations.

Unit 5 **12 Hrs**

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, P. P. Sharma,4th 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.

M.PHARM SEMESTER II
PHARMACEUTICS PRACTICALS - II (MPH 205P)
Practical: 12 Hrs. /Week

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 gelatine /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. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modelling.
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

M.PHARM SEMESTER III
RESEARCH METHODOLOGY & BIOSTATISTICS
(MRM 301T)
Theory: 4 Hrs. /Week

Scope

This subject deals with various established methods used in pharmaceutical research.

Objectives

Upon completion of the course student shall be able to understand

- Learn general research methodology and the basic concepts of biostatistics.
- Understand the functions of ethics committees in medical research.

Course Outcomes

CO1 Able to carry out different parametric and non-parametric tests

CO2 Lean about the ethics committee and its function in medical research

CO3 Learn the guidelines for the experimentation on animals

CO4 prepare protocol for Animal study

Course content

Unit 1 **12 Hrs**

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 2 **12 Hrs**

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 3 **12 Hrs**

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 4 **12 Hrs**

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.

Unit 5 **12 Hrs**

Declaration of Helsinki:

History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.