VELS

INSTITUTE OF SCIENCE, TECHNOLOGY & ADVANCED STUDIES (VISTAS)
(Deemed to be University Estd. u/s 3 of the UGC Act, 1956)
PALLAVARAM - CHENNAI
NAAC ACCREDITED WITH 'A' GRADE
Marching Beyond 25 Years Successfully

M.PHARM

[MASTER OF PHARMACY]

PHARMACEUTICS

Curriculum and Syllabus

Effective from the Academic Year

2019-2020

School of Pharmaceutical Sciences

Syllabus

Master of Pharmacy

Pharmaceutics

Semester –I

17MPH101T

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

COURSE OUTCOME:

At the end of this course the students will be able to,

CO 1: Demonstrate the analytical instrumental techniques for identification, characterization and quantification of drugs by UV-Visible, IR, Fluorometer, Atomic absorption spectrum and Flame emission

CO2: Illustrate the Principle, theory and the analytical techniques for identifications and characterization of compounds by NMR

CO3: Explain the Principle, theory and the analytical techniques for identifications and characterization of compounds by mass spectroscopy

CO4: Explain the principle and types of chromatographic technique with detailed emphasis on instrumentation and applications

CO5: Explain the principle and applications of immunological assays

Course Objectives Employability

After completion of course student is able to know about chemicals and excipients

1. The analysis of various drugs in single and combination dosage forms
2. Theoretical and practical skills of the instruments

UNIT I **11 HRS**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscoIR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopypy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy.

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy.

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

UNIT II **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 III **11 HRS**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV **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 V **11 HRS**

Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing X ray Crystallography: Production of X rays, Different X ray methods, Bragg,,s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

UNIT VI **5 HRS**

Immunological assays: RIA (Radio immune assay), ELISA, Bioluminescence assay.

TOTAL: 60 HRS

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, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

17 MPH 102T

DRUG DELIVERY SYSTEMS

COURSE OUTCOME:

At the end of this course the students will be able to,

CO1 Define Sustained Release and Controlled Release formulations and introduction basic concept and mechanism of action of sustained release formulation

CO2 Explain the 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

CO3 Explain 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 and details about Ocular Drug Delivery Systems

CO4 Explain Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. 6 Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

CO5 Importance of Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules and Vaccine delivery systems

Course Objective: Employability

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

- 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.

UNIT I **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, Bioelectronic Medicines,3D printing of pharmaceuticals, Telepharmacy.

UNIT II **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 III **16 HRS**

GASTRO-RETENTIVE DRUG DELIVERY SYSTEMS AND OCCULAR 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. Barriers of drug permeation, Methods to overcome barriers

UNIT IV **10 HRS**

TRANSDERMAL DRUG DELIVERY SYSTEMS:

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

UNIT V **14 HRS**

PROTEIN AND PEPTIDE DELIVERY AND VACCINE DELIVERYSYSTEMS:

Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and othermacromolecules. Vaccines, uptake of antigens, single shotvaccines,mucosalandtransdermaldelivery ofvaccines.

TOTAL: 60 HRS

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, MarcelDekker,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, Firstedition 1997(reprint in2001).

5.S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan,New Delhi,Firstedition2002

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

17MPH103T

Modern Pharmaceutics

COURSE OUTCOME:
At the end of this course the students will be able to,
CO1: Justify the elements of preformulation studies.
CO2: Examine the Active Pharmaceutical Ingredients and Generic drug Product development CO3: Explain Industrial Management and GMP Considerations
CO4: Categorize Optimization Techniques & Pilot Plant Scale Up Techniques CO5: Illustrate Stability Testing, sterilization process & packaging of dosage forms)

Course Objective: Employability

To study and understand the impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

UNIT I **12 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 II **12 HRS**

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.

UNIT III **12 HRS**

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.

UNIT IV **12 HRS**

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography.

UNIT V **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.

TOTAL: 60 HRS

REFERENCES:

TEXT BOOKS

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

REFERENCES

1. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
2. Pharmaceutical Preformulations; By J.J. Wells.
3. Applied production and operations management; By Evans, Anderson, Sweeney and Williams. Encyclopaedia of Pharmaceutical technology, Vol I – III.S

17 MPH 104 T

REGULATORY AFFAIRS

COURSE OUTCOME:

At the end of this course the students will be able to,

CO 1 Define Master formula record, DMF (Drug Master File), distribution records. Explain the ANDA regulatory approval process, NDA approval process and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing Bioavailability and Bio equivalence to CRO

CO 2 Explain the Regulatory requirement for API, biologics, novel, therapy obtaining NDA, ANDA for generic drugs

CO 3 Explain Chemistry, Manufacturing & Control (CMC) , post approval regulatory affairs. Regulation for combination products and medical devices. ICH - Guidelines . Illustrate Regulatory requirements of EU, MHRA, TGA and ROW countries.

CO 4 Explain about Non clinical drug development and Investigation of medicinal products dossier, dossier (IMPD) .

CO 5 Illustrate the clinical trial protocols, ethics committee , Consent process and procedures. HIPAA- new, requirement to clinical study process and pharmacovigilance safety monitoring in clinical trials.

Course Objective: Employability

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 of conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials

UNIT I **12 HRS**

REGULATIONS AND DOCUMENTATIONS

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

UNIT II **12 HRS**

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 III **12 HRS**

ICH GUIDELINES AND FDA

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 countriesforecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

UNIT IV **12 HRS**

NON CLINICAL DRUG DEVELOPMENT

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

UNIT V **10 HRS**

CLINICAL TRIALS

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.

TOTAL: 60 HRS

REFERENCES

1. Generic drug product development, solid oral dosage forms, Leon Shargel and IsaderKaufer, Markel 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 Guariano, MD, 5th edition, Drugs and Pharmaceutical sciences, Vol.190
4. Guide book for drug regulatory submissionsandy Weinberg. By John Wiley &Sons.Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical services, and biologics edited by Dougloas J. piasno, David Mantus
6. Clinical trials and human research: A practical guide to regulatory compliance BY Fay A.Rozovsky and Rodney K. Adams

17MPH105P

PHARMACEUTICS I PRACTICAL

COURSE OUTCOME:

At the end of this course the students will be able to,

CO1 : Differentiate the In-vitro dissolution profile of CR/ SR marketed formulation.

CO2 : Develop Formulation and evaluation of sustained release matrix tablets

CO3: Explain the preformulation studies of tablets

CO4: Explain the Micromeritic properties of powders and granulation.

CO5: Develop the Heckal plot, Higuchi and peppas plot and determine similarity factors

Course Objective: Skill Development

To study and understand the impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

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. Formulation and evaluation of sustained release matrix tablets
8. Formulation and evaluation osmotically controlled DDS
9. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
10. Formulation and evaluation of Muco adhesive tablets.
11. Formulation and evaluation of trans dermal patches.
12. To carry out preformulation studies of tablets.
13. To study Micromeritic properties of powders and granulation.
14. To study the effect of particle size on dissolution of a tablet.
15. To study the effect of binders on dissolution of a tablet.
16. To study the effect of compressional force on tablets disintegration time.
17. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors

REFERENCES

TEXT BOOKS

1. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
2. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
3. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
4. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.

SEMESTER II

17MPH201T

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

COURSE OUTCOME:

At the end of this course the students will be able to,

CO1 Explain the concepts of drug targeting and brain targeting.

CO2 Develop the nanoparticles, liposomes, microspheres and monoclonal antibodies and evaluate them for specific targeting.

CO3 Illustrate the preparation and applications of Niosomes, Aquasomes, Phytosomes, Electrosomes

CO4 Classify and explain about the aerosols and intra nasal delivery routes, their preparation methods and evaluation methods.

CO5 Focus on the gene therapy, diseases treated using gene therapy, Gene expression systems, liposomal drug delivery systems and its Biodistribution and Pharmacokinetics.

Course Objective: Employability

Upon completion of the course student shall be able to understand

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of NTDS
3. The formulation and evaluation of novel drug delivery systems

UNIT I **12 HRS**

TARGETED DRUG DELIVERY SYSTEMS

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

UNIT II **12 HRS**

TARGETING METHODS

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

UNIT III **12 HRS**

MICROCAPSULES/ MICROSPHERES

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

UNIT IV **12 HRS**

PULMONARY DRUG DELIVERY SYSTEMS

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

UNIT V **12 HRS**

NUCLEIC ACID BASED THERAPEUTIC DELIVERY SYSTEM

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.

TOTAL: 60 HRS

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).

17MPH202T

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

COURSE OUTCOME:

At the end of this course the students will be able to,

CO1 Explain drug absorption from the Gastrointestinal tract, factors affecting absorption, mechanism of absorption,

CO2 Develop biopharmaceutic considerations in drug product design and in vitro Drug Product Performance, dissolution methods, invitro-invivo correlation.

CO3 Focus on Pharmacokinetics basic considerations, pharmacokinetic models, compartment modelling,drug interactions.

CO4 Apply drug product performance invivo -bioavailability and Bioequivalence, assessing bioavailability, bioequivalence studies,

CO5 Analyse modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products

Course Objective: Employability

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

- The basic concepts in bio pharmaceutics 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.

UNIT I **12 HRS**

.Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factorsaffecting drug absorption, pH–partition theory of drug absorption. Formuulation 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 invivo 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 II **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 III **12 HRS**

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model :two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions ,cytochrome p450-based drug interactions, drug interactions linked to transporters.

UNIT IV **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 V **12 HRS**

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.

TOTAL: 60 HRS

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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

17MPH 203T

COMPUTER AIDED DRUG DEVELOPMENT

COURSE OUTCOME:

At the end of this course the students will be able to,

CO1: Administer the history of Computers in Pharmaceutical Research and Development Analyze queueing in open and closed networks.

CO2: Build the computational Modeling of Drug Disposition and Computers in Preclinical Development Solve problems using linear programming.

CO3: Categorize the optimization Techniques in Pharmaceutical Formulation.

CO4: Examine the computers in Market Analysis and Clinical Development

CO5: Illustrate the artificial Intelligence (AI) and Robotics, Computational fluid dynamics (CFD)

Course Objective: Employability

To study and understand the 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)

UNIT I **12 HRS**

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.

UNIT II **12 HRS**

COMPUTATIONAL MODELING OF DRUG DISPOSITION

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

UNIT III **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 IV **12 HRS**

COMPUTER-AIDED BIOPHARMACEUTICAL CHARACTERIZATION

a. 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 V **12 HRS**

ARTIFICIAL INTELLIGENCE

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

TOTAL: 60 HRS

REFERENCES

TEXT BOOKS

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.

17MPH204T

COSMETICS AND COSMECEUTICALS

COURSE OUTCOME:

At the end of this course the students will be able to,

CO1 Describe regulatory provisions for manufacturing and labeling of Cosmetic products as per Indian regulation

CO2 Explain biological aspects of skin ,hair problems , Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

CO3 Develop building blocks for different product formulations of cosmetics/cosmeceuticals

CO4 Establish design of Cosmeceutical products like Sun protection, sunscreens dry skin, acne, pigmentation, prickly heat, wrinkles, body odor.,dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth

CO5 Analyze herbal Cosmetics for skin, Hair and oral care, Challenges in formulating herbal cosmetics.

Course Objective: Employability

- Upon completion of this course it is expected that students will 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 CosmeceuticaL
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

UNIT I **12 HRS**

Cosmetics – Regulatory : Definition of cosmetic products as perIndian 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.

UNIT II **12 HRS**

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.

UNIT III **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.

UNIT IV **12 HRS**

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT V **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.

TOTAL: 60 HRS

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.CTFAdirectory.

17MPH 205P

PHARMACEUTICS II- PRACTICALS

Course Outcomes

CO1 Estimate the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation

CO2 Formulate and evaluate Alginate beads, gelatin /albumin microspheres, liposomes/niosomes and spherules. Influence of dissolution characteristics of slightly soluble drug by solid dispersion technique.

CO3 Development and evaluation of Creams Development and evaluation of Shampoo and Toothpaste base To incorporate herbal and chemical actives to develop products To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

Skill Development

1. o study the effect of temperature change, non-solvent addition, incompatible Preparation and evaluation of Alginate beads
2. Formulation and evaluation of gelatin /albumin microspheres
3. Formulation and evaluation of liposomes/niosomes
4. Formulation and evaluation of spherules
5. polymer addition in microcapsules preparation
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. Development and evaluation of Creams
11. Development and evaluation of Shampoo and Toothpaste base
12. To incorporate herbal and chemical actives to develop products
13. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff
14. Pharmacokinetic and IVIVC data analysis by Winnoline R software
15. In vitro celltudies for permeability and metabolism
16. DoE Using Design Expert® Software
17. Formulation data analysis Using Design Expert® Software

18. Quality-by-Design in Pharmaceutical Development
19. Computer Simulations in Pharmacokinetics and Pharmacodynamics
20. Computational Modeling Of Drug Disposition
21. To develop Clinical Data Collection manual
22. To carry out Sensitivity Analysis, and Population Modeling.

CO4 Compare dissolution of two different marketed products /brands and importance Protein binding studies of a highly protein bound drug & poorly protein bound drug and determine Bioavailability studies of Paracetamol in animals

CO5 Develop the Pharmacokinetic and IVIVC data by Winnoline R software for permeability and Design Expert® Software . generalise the Computational Modeling Of Drug Disposition To develop Clinical Data Collection manual To carry out Sensitivity Analysis, and Population Modeling