NIRMALA COLLEGE OF PHARMACY
MUVATTUPUZHA

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FIRST CYCLE NAAC ACCREDITATION 2023

CRITERION 1

CURRICULAR ASPECTS

1.3.1. Institution integrates crosscutting issues relevant to Professional Ethics, Gender, Human Values, Environment and Sustainability in transacting the Curriculum.

Submitted to

THE NATIONAL ASSESSMENT AND ACCREDITATION COUNCIL

List of M Pharm (Pharmaceutics) courses relevant to Gender, Human Values, Environment and Sustainability and Professional Ethics

- Gender Issues
- Human Values
- Environment And Sustainability
- Professional Ethics

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Date: 2023.12.28 11:21:26 +05'30'

1.3.1. QLM INSTITUTION INTEGRATES CROSSCUTTING ISSUES RELEVANT TO PROFESSIONAL ETHICS, GENDER, HUMAN VALUES, ENVIRONMENT AND SUSTAINABILITY IN TRANSACTING THE CURRICULUM.

KERALA UNIVERSITY OF HEALTH SCIENCES
Thrissur - 680596

SYLLABUS

POST GRADUATE COURSE IN PHARMACY
Master of Pharmacy (M.Pharm.)

PHARMACEUTICS	MPH
KUHS Course Code	276

(2019-20 Academic year onwards)

2019

Course of study for M.Pharm. I & II Semester

MPH	PHARMACEUTICS				
Course Code	**Course**	**Credit Hours**	**Credit Points**	**Hrs./wk**	**Marks**
Semester I					
MPT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH 102T	Drug Delivery Systems	4	4	4	100
MPH 103T	Modern Pharmaceutics	4	4	4	100
MPH 104T	Regulatory Affairs	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
Semester II					
MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH 202T	Advanced Biopharmaceutics &Pharmacokinetics	4	4	4	100
MPH 203T	Computer Aided Drug Development	4	4	4	100
MPH 204T	Cosmetics and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar /Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Course of study for M. Pharm. III & IV Semester

Course Code	Course	Credit Hours	Credit Points	Marks
Semester III				
MRM 301T	Research Methodology and Biostatistics	4	4	100
-	Journal Club	1	1	25
-	Discussion / Presentation(proposal presentation)	2	2	25
-	Research Work	28	14	350
Total		**35**	**21**	**500**
Semester IV				
-	Journal Club	1	1	25
-	Presubmission Discussion / Presentation	3	3	75
-	Research Work	31	16	400
Total		**35**	**20**	**500**

NIRMALA COLLEGE OF PHARMACY Muvattupuzha Ernakulam Dist. Kerala

PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPT 101T)

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

Upon completion of the course, student shall be able to know about

- Chemicals and excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills for handling of the instruments

THEORY **60 Hrs**

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation 10 Hrs associated with UV-Visible spectroscopy, Choice of solvents and solvent effectand Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factorsaffecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers,Instrumentation and Applications of fluorescence spectrophotometer.

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

2. NMR spectroscopy: Principle, Instrumentation, 10 Hrs 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, Briefoutline of principles of FT-NMR and 13C NMR. Applications of NMRspectroscopy.

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, 9 Hrs Different types of ionization like electron impact, chemical, field, FAB andMALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Massfragmentation and its rules, Meta stable ions, Isotopic peaks and Applications ofMass spectroscopy.

4. Chromatography: Principle, apparatus, instrumentation, chromatographic 9 Hrs parameters, factors affecting resolution, isolation of drug from excipients, datainterpretation and applications of the following:

a) Thin Layer chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High Performance Liquid chromatography
h) Affinity chromatography
i) Gel Chromatography

5. a.Electrophoresis: Principle, Instrumentation, Working conditions, factors 9 Hrs affecting separation and applications of the following:

i) Paper electrophoresis ii) Gel electrophoresis iii) Capillary electrophoresis iv)Zone electrophoresis v) Moving boundary electrophoresis vi) Iso electric focusing

b.X ray Crystallography: Production of X rays, Different X ray methods, Bragg'slaw, Rotating crystal technique, X ray powder technique, Types of crystals andapplications of X-ray diffraction.

6. a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 9 Hrs

b. Thermal Techniques: i) Differential scanning calorimetry (DSC): Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

ii)Differential Thermal Analysis (DTA): Principle, instrumentation and advantageand disadvantages, pharmaceutical applications, derivative differential thermalanalysis (DDTA).

iii)Thermo Gravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

7. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays. 4 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th Edition, John Wiley& Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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 Edition, P.S. Kalsi, Wiley Eastern Ltd, Delhi.
9. Textbook of Pharmaceutical Analysis, K.A. Connors, 3rd Edition, John Wiley & Sons, 1982.

DRUG DELIVERY SYSTEMS (MPH 102T)

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 delivering system
- The formulation and evaluation of Novel drug delivery systems..

THEORY 60 Hrs

1. SustainedRelease(SR)and ControlledRelease(CR)formulations:Introduction&basic concepts, advantages/ disadvantages, factors influencing, Physicochemical&biologicalapproachesforSR/CRformulation,Mechanismof DrugDeliveryfromSR/CRformulation.Polymers:introduction,definition, classification, properties and application Dosage Forms for Personalized Medicine:Introduction,Definition,Pharmacogenetics,CategoriesofPatientsfor Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines,3Dprintingofpharmaceuticals,Telepharmacy. 10 Hrs
2. Rate Controlled Drug Delivery Systems: Principles &Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated,pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems FeedbackregulatedDrugDeliverySystems;Principles&Fundamentals. 10 Hrs
3. Gastro-Retentive Drug Delivery Systems: Principle, concepts advantagesand disadvantages,ModulationofGItransittimeapproachestoextendGItransit. Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages,Mechanismofdrugpermeation,Methodsofformulationandits evaluations. 10 Hrs
4. Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. 06 Hrs
5. TransdermalDrugDeliverySystems:Structureofskinandbarriers, Penetrationenhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. 10 Hrs
6. ProteinandPeptideDelivery:Barriersforproteindelivery.Formulationand Evaluationofdeliverysystemsofproteinsandothermacromolecules. 08 Hrs
7. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.06 Hrs

REFERENCES

- Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
- Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York!Chichester/Weinheim
- N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002

JOURNALS

- Indian Journal of Pharmaceutical Sciences (IPA)
- Indian drugs (IDMA)
- Journal of controlled release (Elsevier Sciences) desirable
- Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS (MPH 103T)

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.

THEORY 60 HRS

1. PreformationConcepts–DrugExcipientinteractions-differentmethods, Kineticsofstability,Stabilitytesting.Theoriesofdispersionandpharmaceutical Dispersion(EmulsionandSuspension,SMEDDS)preparationandstabilityLarge andsmallvolumeparental–physiologicalandformulationconsideration, Manufacturing andevaluation.

Optimization techniques in Pharmaceutical Formulation:Concept and parameters of optimization, Optimization techniques in pharmaceutical formulationandprocessing.Statisticaldesign,Responsesurfacemethod, Contourdesigns,Factorialdesignsandapplicationinformulation 10Hrs

2. Validation: Introduction to Pharmaceutical Validation, Scope &merits of Validation,ValidationandcalibrationofMasterplan,ICH&WHOguidelinesfor calibration and validation of equipments, Validation of specific dosage form, Typesofvalidation.Governmentregulation,ManufacturingProcessModel,URS, DQ,IQ,OQ&P.Q.offacilities. 10 Hrs

3. cGMP&Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenanceProductionmanagement:Production organization, materialsmanagement, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control,industrialandpersonalrelationship.ConceptofTotalQualityManagement. 10 Hrs

4. Compression and compaction: Physics of tablet compression, compression, consolidation,effectoffriction,distributionofforces,compactionprofiles. Solubility. 10 Hrs

5. Study of consolidation parameters; Diffusion parameters,Dissolution parametersandPharmacokineticparameters,Heckelplots,Similarityfactors– f2andf1,HiguchiandPeppasplot,LinearityConceptofsignificance,Standarddeviation , Chi square test, students T-test , ANOVA test. 10 Hrs

REFERENCES

- Theory and Practice of Industrial Pharmacy ByLachmann and Libermann
- Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
- Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
- Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.

- Modern Pharmaceutics; By Gillbert and S. Banker.
- Remington's Pharmaceutical Sciences.
- Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean &A.H.Beckett.
- Physical Pharmacy; By Alfred martin
- Bentley's Textbook of Pharmaceutics – by Rawlins.
- Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
- Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
- Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
- How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
- Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
- Pharmaceutical Preformulations; By J.J. Wells.
- Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
- Encyclopaedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS (MPH 104T)

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

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.

THEORY 60 Hrs

1. DocumentationinPharmaceuticalindustry:Masterformularecord,DMF(Drug Master File), distribution records. Generic drugs product development Introduction,Hatch-Waxmanactandamendments,CFR(Code of Federal Regulation),drug product performance, in-vitro, ANDA regulatoryapproval

process,NDAapprovalprocess,BEanddrugproductassessment,in–vivo,scale upprocessapprovalchanges,postmarketingsurveillance,outsourcingBAand BE toCRO. Regulatoryrequirementforproductapproval:API,biologics,novel,therapies obtainingNDA,ANDAforgenericdrugswaysandmeansofUSregistrationfor foreigndrugs 12Hrs

2. CMC,postapprovalregulatoryaffairs.Regulationforcombinationproductsand Medicaldevices.CTDandECTDformat,industryandFDAliaison.ICH-Guidelines of ICH-Q, S, E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. 12 Hrs

3. Non clinical drug development: Global submission of IND, NDA, ANDA. Investigational medicinal products dossier (IMPD) and investigator brochure (IB). 12 Hrs

4. Clinical trials: Developing clinical trial protocols. Institutional review board/ independentethicscommitteeFormulationandworkingproceduresinformed Consentprocessandprocedures.HIPAA-new,requirementtoclinicalstudyprocess, pharmacovigilance safety monitoring in clinical trials 12 Hrs

REFERENCES

- Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
- 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.
- New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
- Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley &Sons.Inc.
- FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
- Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
- www.ich.org/
- www.fda.gov/
- europa.eu/index_en.htm
- https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS - I (MPH 105P)

- Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
- Simultaneous estimation of multi component containing formulations by UV spectrophotometry.
- Experiments based on HPLC
- Experiments based on Gas Chromatography
- Estimation of riboflavin/quinine sulphate by fluorimetry
- Estimation of sodium/potassium by flame photometry
- To perform In-vitro dissolution profile of CR/ SR marketed formulation
- Formulation and evaluation of sustained release matrix tablets

- Formulation and evaluation osmotically controlled DDS
- Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
- Formulation and evaluation of Muco adhesive tablets.
- Formulation and evaluation of transdermal patches.
- To carry out preformulation studies of tablets.
- To study the effect of compressional force on tablets disintegration time.
- To study Micromeritic properties of powders and granulation.
- To study the effect of particle size on dissolution of a tablet.
- To study the effect of binders on dissolution of a tablet.
- To plot Heckal plot, Higuchi and Peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS (NANOTECHNOLOGY & TARGETED DRUG DELIVERY SYSTEMS) (MPH 201T)

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.

THEORY 60 Hrs

1. TargetedDrugDeliverySystems:Concepts,Eventsandbiologicalprocessinvolved in drug targeting. Tumor targeting and Brain specific delivery. 12 Hrs
2. Targeting Methods: introduction preparation and evaluation. Nano Particles &Liposomes: Types, preparation and evaluation. 12 Hrs
3. Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. 12 Hrs
4. Pulmonary Drug Delivery Systems: Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. 12 Hrs
5. Nucleicacidbasedtherapeuticdeliverysystem:Genetherapy,introduction(ex- vivo &in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviralgenetransfer).Liposomalgenedeliverysystems. Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future. 12 Hrs

REFERENCES

- Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
- S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances VallabhPrakashan New Delhi First edition 2002.

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

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 biopharmaceutical studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutical parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics

THEORY 60 Hrs

1. Drug Absorption from the Gastrointestinal Tract:

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemicalfactors:Dissolutionrate,Dissolutionprocess,Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinalabsorption:roleofthedosageform:Solution(elixir,syrupand solution)asadosageform,Suspensionasadosageform,Capsuleasadosage form,Tabletasadosageform,Dissolutionmethods,Formulationandprocessing factors,Correlationofinvivodatawithinvitrodissolutiondata.Transport model:Permeability-Solubility-Charge State and the pH Partition Hypothesis, PropertiesoftheGastrointestinalTract(GIT),pHMicroclimateIntracellularpH Environment, Tight-JunctionComplex. 12 Hrs

2. Biopharmaceutical considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutical factors affecting drugbioavailability,rate-limitingstepsindrugabsorption,physicochemicalnatureofthe drug formulation factors affecting drug product performance,in vitro:dissolutionanddrugreleasetesting, compendia methodsofdissolution, alternative methods of dissolution testing,meeting dissolution requirements,problemsofvariablecontrolindissolutiontestingperformanceof drugproducts.Invitro–

invivocorrelation,dissolutionprofilecomparisons,drug productstability,considerationsinthedesignofadrugproduct.

3. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling:onecompartmentmodel-IVbolus,IVinfusion,extra-vascular.Multi compartment model:two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimationofkmaxandvmax.Druginteractions:introduction,theeffectof protein- binding interactions,the effect of tissue-binding interactions,cytochrome p450-based drug interactions,drug interactions linked totransporters. 12 Hrs

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug productperformance,purposeofbioavailabilitystudies,relativeandabsolute availability. Methods for assessing bioavailability, bioequivalence studies, design andevaluationofbioequivalencestudies,studydesigns,crossoverstudy designs,evaluationofthedata,bioequivalenceexample,studysubmissionand drug review process. biopharmaceutics classification system, methods. Permeability:In-vitro,in-situandIn-vivomethods. Genericbiologics(biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailabilityandbioequivalencestudies,genericsubstitution. 12 Hrs

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

REFERENCES

- Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi,4th edition, Philadelphia, Lea and Febiger, 1991
- Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
- Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
- Textbook of Biopharmaceutics and Pharmacokinetics, Dr.ShobhaRani R. Hiremath, Prism Books
- Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
- Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, LeaandFebiger, Philadelphia, 1970
- Dissolution, Bioavailabilityand Bioequivalence, Abdou.H.M, Mack PublishingCompany, Pennsylvania 1989
- Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
- Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
- Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
- Basic Pharmacokinetics, 1st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.

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

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

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 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)

THEORY 60 Hrs

1. ComputersinPharmaceuticalResearchandDevelopment:AGeneral Overview:HistoryofComputersinPharmaceuticalResearchandDevelopment. StatisticalmodelinginPharmaceuticalresearchanddevelopment:Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, OptimalDesign,Population Modeling

- Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples ofapplication. 12 Hrs

2. ComputationalModeling Of Drug Disposition: Introduction,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution,Drug Excretion, Active Transport;P-gp, BCRP, Nucleoside Transporters,hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter. 12 Hrs
3. Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology &Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis 12Hrs

4. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction,Parametersensitivityanalysis,Virtualtrial,Fedvs.fastedstate,In vitrodissolutionandinvitro-invivocorrelation,Biowaiverconsiderations

- Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction,ComputerSimulation:WholeOrganism,IsolatedTissues,Organs, Cell, Proteins andGenes.
- Computers in Clinical Development: Clinical Data Collection and Management, Regulation of ComputerSystems 12 Hrs

5. ArtificialIntelligence(AI),RoboticsandComputationalfluiddynamics:Generaloverview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions. 12 Hrs

REFERENCES

- Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
- Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, JelenaDjuris, Woodhead Publishing
- Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS (MPH 204T)

SCOPE

This course is designed to impart knowledge and skills necessary forthefundamental 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.

THEORY 60 Hrs

1. Cosmetics– Regulatory:Definitionofcosmeticproductsasper Indianregulation.Indianregulatoryrequirementsforlabelingof cosmeticsRegulatory provisionsrelatingtoimportofcosmetics,Misbrandedandspuriouscosmetics. Regulatory provisions

relating to manufacture of cosmetics – Conditions for obtaininglicense,prohibitionofmanufactureandsaleofcertaincosmetics,loan license,offencesandpenalties. 12 Hrs

2. Cosmetics-Biologicalaspects:Structureofskinrelatingtoproblemslikedry skin,acne,pigmentation,pricklyheat,wrinklesandbodyodor.Structureofhair andhairgrowthcycle.Commonproblemsassociatedwithoralcavity.Cleansing andcareneedsforface,eyelids,lips,hands,feet,nail,scalp,neck,bodyand under-arm. 12 Hrs

3. FormulationBuildingblocks:Buildingblocksfordifferentproductformulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives:classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservativeefficacy.Buildingblocksforformulationofamoisturizingcream,vanishingcream,coldcream,shampooandtoothpaste.Soapsandsyndetbars. 12 Hrs

Perfumes;Classificationofperfumes.PerfumeingredientslistedasallergensinEU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4. Designofcosmeceuticalproducts:Sunprotection,sunscreensclassificationand regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouthodorandsensitiveteeththroughcosmeceuticalformulations. 12 Hrs

5. HerbalCosmetics:HerbalingredientsusedinHaircare,skincareandoralcare. Review of guidelines for herbal cosmetics by private bodies like cosmos with respecttopreservatives,emollients,foamingagents,emulsifiersandrheologymodifiers. Challenges in formulating herbal cosmetics. 12 Hrs

REFERENCES

- Harry's Cosmeticology. 8th edition.
- Poucher'sperfumecosmeticsandSoaps,10th edition.
- Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
- Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition
- Cosmetic and Toiletries recent suppliers' catalogue.
- CTFA directory.

PHARMACEUTICS PRACTICALS - II (MPH 205P)

- To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
- Preparation and evaluation of Alginate beads
- Formulation and evaluation of gelatin /albumin microspheres
- Formulation and evaluation of liposomes/niosomes
- Formulation and evaluation of spherules

- Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
- Comparison of dissolution of two different marketed products /brands
- Protein binding studies of a highly protein bound drug & poorly protein bound drug
- Bioavailability studies of Paracetamol in animals.
- Pharmacokinetic and IVIVC data analysis by WinnolineR software
- In vitro cell studies for permeability and metabolism
- DoE Using Design Expert® Software
- Formulation data analysis Using Design Expert® Software
- Quality-by-Design in Pharmaceutical Development
- Computer Simulations in Pharmacokinetics and Pharmacodynamics
- Computational Modeling of Drug Disposition
- To develop Clinical Data Collection manual
- To carry out Sensitivity Analysis, and Population Modeling.
- 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

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, types of research, scientific methods of research, types of studies, study design.

Review of literature - Sources of information. Searching of library documents and databases online and offline (Pubmed, Biological abstracts, other databases in pharmaceutical sciences). Introduction to internet searching using advanced search tools.

UNIT – II

Collection and analysis of data: Types of data and data collection techniques, processing of data, coding, tabulation and analysis of data.

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (Student's 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, different software for statistical analysis.

UNIT – III

Medical Research: History, values in medical ethics, strategies to eliminate errors/bias, controls, randomisation, cross over design, placebo, blinding techniques 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, vendor relationships, treatment of family members.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Technical writing, thesis/research report writing, structure of thesis, editing and formatting, reference citations, abstracting, plagiarism and paraphrasing, tools for writing good research report.

UNIT – VI

Research reporting - poster presentation, seminar and conference presentation, publishing in journals, copyright.

REFERENCE BOOKS

AtiyaKhanum Irfan Ali Khan , Biostatistics for Pharmacy, 2nd Edition , 2007, Ukaaz Publications, Hyderabad

C. George Thomas . Research Methodology and Scientific Writing First edition, 2016, Ane Books Pvt. Ltd.;New Delhi,

C. R Kothari. Research Methodology: Methods and Techniques. New Age International (P) Ltd, Publishers. New Delhi

Mahajan, B.K. Methods in Biostatistics. For Medical Students and Research workers, 7th edition 2008 Jaypee Brothers

PutulMahanta , Medical Writing: A Guide for Medicos, Educators and Researchers Jaypee Brothers Medical Publishers; First edition (2018)

RanjanDas . Biomedical Research Methodology :IincludingBiostatistical Applications. 1st Edn .Jaypee Brothers

Ranjit Kumar, Research Methodology: A Step-by-Step Guide for Beginners, 3rd Edition 2011, Sage Publications India Pvt. Ltd. , New Delhi

Sharma Suresh.Research Methodology and Biostatistics. A Comprehensive Guide for Health Care Professionals. 1st Edn . Elsevier India

Sunder Rao. P.S.S and Richard, J. An introduction to Biostatistics: A manual for students in health sciences. Prentice-Hall of India Pvt.Ltd Publishers

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