M. PHARM. PHARMACEUTICS

Total Contact Hours = 34 **Total Marks = 600** **Total Credits = 25**

SEMESTER 1st		Contact Hrs			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA1- 101	Pharmacokinetics and Biopharmaceutics	3	1	-	40	60	100	4
MPHA1- 102	Dosage form Design, Development and Process Validation	3	1	-	40	60	100	4
MPHA1- 103	Novel Drug Delivery Systems	3	1	-	40	60	100	4
MPHA1- 104	Basics of Pharmaceutical Research- I	3	1	-	40	60	100	4
MPHA1-105	Pharmaceutics Laboratory-I	-	-	14	60	40	100	7
MPHA1- 106	Seminar	-	-	4	100	-	100	2
Total	**Theory = 5 Lab = 1**	**12**	**4**	**18**	**320**	**280**	**600**	**25**

Total Contact Hours = 32 **Total Marks = 600** **Total Credits = 26**

SEMESTER 2nd		Contact Hrs			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA1-207	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	0	-	40	60	100	4
MPHA1-208	Regulatory Affairs	4	0	-	40	60	100	4
MPHA1-209	Computer Aided Drug Delivery System	4	0	-	40	60	100	4
MPHA1-210	Cosmetic and Cosmeceuticals	4	0	-	40	60	100	4
MPHA1-211	Pharmaceutics Practical- II	-	-	12	60	40	100	6
MPHA1-212	Seminar/Assignment	-	4	-	100	-	100	4
Total	**Theory = 4 Lab = 1**	**16**	**4**	**12**	**320**	**280**	**600**	**26**

SEMESTERS 3rd & 4th		Marks			Credits
Subject Code	**Subject Name**	**Int. (Seminar & Viva on Thesis)**	**Ext. (Evaluation of Thesis)**	**Total**	
MPHA1 - 413	Research Work	100	200	300	24

Note: Thesis shall be presented by the candidate at the end of record academic year.

Overall

Semester	Marks	Credits
1st	600	25
2nd	600	26
3rd & 4th	300	24
Total	**1500**	**75**

PHARMACOKINETICS AND BIOPHARMACEUTICS

Subject Code – MPHA1 -101 **L T P C** **Duration – 45 Hrs**
3 1 0 4

UNIT-I (12 Hrs)

Compartmental Pharmacokinetics: Review of fundamentals, Terminology, Basics of kinetics of single and multiple dose administration following instantaneous and non-instantaneous routes, one and two compartment body model kinetics, limitations of compartmental analysis.

UNIT-II (13 Hrs)

Non-Compartmental Pharmacokinetic Modelling Approach - Merits of Model-Independent Non-Compartmental Approaches, Definition and Significance, Statistical Moments, AUC, AUMC and Their Determination Using Trapezoidal and Log-Trapezoidal Techniques, MRT and Its Significance in Pharmacokinetics, Computation of Statistical Moments from Plasma and Urine Data, Cut-Off Error, MDT, MTT, MAT, Problem Solving.

Nonlinear Pharmacokinetics - Definition, Significance and Applications with Literature Examples, Recognition of Non-Linearity, Computation of Nonlinear Pharmacokinetic Parameters (V_m, K_m, AUC, Etc.) by Single Michaelis Menten Kinetics.

UNIT-III (8 Hrs)

Protein Binding – Theory of Plasma Protein Binding and Implications, Elements of Scatchard, Klotz and Rosenthal Analysis for Computation of Binding Parameters, Experimental Techniques to Determine Protein Binding with Their Merits and Limitations, Factors Influencing Protein Binding, Effect of Binding on Drug Pharmacokinetics.

Biopharmaceutics - Review of Physicochemical, Pharmaceutical and Physiological variables affecting Drug Absorption from Gastrointestinal tract.

UNIT – IV (8 Hrs)

Bioavailability and Bioequivalence Concepts - Assessment of Bioavailability from Plasma and Urine Level Data, Design and Analysis of Bioequivalence Trials, Crossover Designs, Bioavailability of Oral and Non-Oral Dosage Forms, Statistical Analysis of Bioavailability and Bioequivalence, Pharmacodynamic Models, Federal Perspectives.

***IN VITRO-IN VIVO* correlations (IVIVC) -** Concepts, Biopharmaceutical Classification Scheme (BCS), Varied IVIVC approaches with applications and limitations, dissolution as a surrogate to bioavailability for immediate release and extended release formulations, Federal perspectives

Recommended Books

1. J.G. Wagner, 'Fundamentals of Clinical Pharmacokinetics', Drug Intelligence Publications, Hamilton, III, **1975.**
2. J.G. Wagner, 'Pharmacokinetics for the Pharmaceutical Scientist', Technomic, Pa, **1993.**
3. L. Shargel, and A. Yu, 'Applied Biopharmaceutics and Pharmacokinetics, Appleton and Large', Norwalk, C.T., **1993.**
4. M. Gibaldi and D. Perrier, 'Pharmacokinetics', J. Swarbrick, ed., Marcel Dekker, N.Y..
5. M. Gibaldi, 'Biopharmaceutics and Clinical Pharmacokinetics', Lea & Febiger Philadelphia.
6. R.D. Purves, 'Optimum Numerical Integration Methods for the Estimation of Area under the Curve (AUC) and Area under the Moment Curve (AUMC)', J. Pharmac. Biopharma., 20 (3), **1992.**
7. P.G. Welling, F.L.S. Tse and S.V. Dighe (eds), 'Pharmaceutical Bioequivalence', Marcel Dekker Inc., New York, USA, **1991.**

DOSAGE FORM DESIGN, DEVELOPMENT AND PROCESS VALIDATION

Subject Code – MPHA1 -102 **L T P C** **Duration – 45 Hrs**
3 1 0 4

UNIT-I (12 Hrs)

Pre-Formulation:

The Scope of Pre-Formulation Studies: Introduction, Preformulation Testing Criteria, Regulatory Requirements, Testing Systems, Solid-State Characterization, Transport Across Biological Membranes

Dissociation, Partitioning and Solubility: Introduction, The Ionization Principle, Quantitative Structure– Activity Relationships, Partitioning, Measurement Strategies

Release, Dissolution, and Permeation: Introduction, Release, Assay Systems, The Biopharmaceutics Drug Classification Systems

Solid-State Properties: Introduction, Crystal Morphology, Polymorphism, High-Throughput Crystal Screening, Solvates, Hydrates, Amorphous Forms, Hygroscopicity, Solubility, Study Methods

Dosage Form Considerations in Pre-formulation: Introduction, Solid Dosage Form Considerations, Solution Formulations, Emulsion Formulations, Freeze- Dried Formulations, Suspensions, Topical, Pulmonary Delivery, General Compatibility

Chemical Drug Substance Characterization: Introduction, Scheme of Characterization, Impurities, Good Manufacturing Practice

Characterization of Biopharmaceutical Drugs: Introduction, Preformulation Studies, Packaging and Materials, Physio-Chemical Characterization Tests, Design of Preformulation Studies

UNIT - II (10 Hrs)

Excipients: General Considerations of Excipients Used in Formulations and Factors Governing Selection.

Compatibility Issues Regarding Excipients: Drug-Excipients and Excipient-Excipient, Excipients-Package Interactions, Safety and Regulatory Issues of Excipients

Study of Novel Excipients: Super Disintegrants, Directly Compressible and Spray Dried Diluents, Film Coating Materials, Solubilizing Agents like Surfactants, Cyclic Glucose Polymers, Polymeric Excipients for Controlled Release Applications, Improved Excipients Functionality by Co Processing, Standardization of Excipient

UNIT– III (13 Hrs)

Polymers: Polymer Classification, Physiochemical Properties and Polymer Solutions. Biodegradable and Non-Biodegradable Polymers. Application of Polymers in Controlled Release of Drugs, Transport of Small Molecules in Polymers, Ionic Polymers as Drug Carriers.

Advances in Industrial Process

Granulation: Roller Compaction Technology, High-Shear Granulation, Low-Shear Granulation, Batch Fluid Bed Granulation, Extrusion/Spheronization as a Granulation Technique, Effervescent Granulation, Melt Granulation and Palletisation, Rapid Release Granulation, Continuous Granulation Technologies

Lyophilisation: LYOGUARD (New Concept for Bulk Freeze-Drying) Coating: Film-Coating Materials and Their Properties

Sterilization - Air Handling: AHUs, Laminar Airflow Equipment, HEPA and VEPA Filters, HVAC, Clean Room Classification

UNIT – IV (10 Hrs)

Pharmaceutical Process Validation: Basic Concept, Definition and Regulatory Basis of Validation. Benefits of Validation, Phases of Equipment Validation Such as Pre-Purchase, Post-Purchase (IQ, OQ and PQ) and Qualification Of Established /In-Use Equipment. Types of Process Validation Related to Prospective, Retrospective and Concurrent Process Validation. Re-Validation of Validation Process and Scale-Up and Post Approval Changes (SUPAC), Validation of Tablets, Liquids and Sterile Products, Validation of Steam, Dry Heat, Gaseous, Radiation and Filtration Sterilization Processes.

Recommended Books

1. S.H. Yalkowsky (Ed), 'Techniques of Solubilisation of Drugs', Marcel Decker Inc., New York USA.
2. A. Martin, 'Physical Pharmacy', 3rd Edn., B.I. Waverly Pvt. Ltd., New Delhi, India, **1995.**
3. J.I. Wells, 'Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances', Ellis Horwood, Chiechester (UK), **1998.**
4. R. Berry and R.A. Nash, 'Pharmaceutical Process Validation', Marcel Dekker, N.Y., **1993.**
5. N.K. Jain (Editor), 'Pharmaceutical Product Development', 1st Edn., CBS Publishers and Distributer, New Delhi.
6. G.S Banker and C.T. Rhodes, 'Modern Pharmaceutics', 2nd Edn., Marcel Decker Inc., New York, USA.
7. S.P. Vyas and R.K. Khar, 'Controlled Drug Delivery, Concept and Advances', 1st Edn., Vallabh Prakashan, Delhi, **2002.**

NOVEL DRUG DELIVERY SYSTEM

Subject Code – MPHA1-103 **L T P C** **3 1 0 4** **Duration - 45 Hrs**

UNIT-I (14 Hrs)

Controlled Drug Delivery - Fundamentals of Controlled Release (CR) Drug Delivery: Rationale of Sustained/Controlled Drug Delivery; Physicochemical and Biological Factors Influencing Design and Performance of CR Products, Therapeutic Status of CDDS. Theory of Mass Transfer; Fick's First and Second Laws and Their Applications in Drug Release and Permeation. Pharmacokinetic/Pharmacodynamic Basis of Controlled Drug Delivery; Bioavailability Assessment of CR Systems.

Design and Fabrication of Technology Based CR Systems - Strategies and Design of Oral Controlled Release Delivery Systems, Oral Systems Based on Dissolution, Diffusion and Dissolution, Ion-Exchange Resins, Ph-Independent Formulations, Altered Density Formulations. Bucco/Mucoadhesive Systems, Osmotic Controlled Oral Drug Delivery

UNIT-II (11 Hrs)

Parenteral System - Parenteral Systems, Biopharmaceutic Considerations, Design and Development, Polymeric Microspheres, Dispersed Drug Delivery. Implantable Therapeutic Systems, Biocompatibility of Polymers and Carriers; Intrauterine Devices and Intravaginal Devices.

Transdermal Drug Delivery System - Transdermal Therapeutic Systems (TTS): Drug Absorption Through Skin, Permeation Enhancers, Basic Components of TTS, Approaches to Development and Kinetic Evaluation, Testing of Transdermal Patches, Pressure Sensitive Adhesives; Iontophoresis, Sonophoresis and Electroporation.

UNIT– III (12Hrs)

Design and Fabrication of Technology Based CR Systems:

Novel Ocular Drug Delivery Systems: Ocular Therapeutics and Constraints to Effective Delivery, Formulation Considerations to Improve the Ocular bioavailability, Ocular Inserts Including Insoluble and Soluble Inserts, Non-Corneal Routes and Their Use for Systemic Drug Delivery.

Colloidal and Supramolecular Delivery Systems-I

1. Closed Bi-Layered System: Historical Background, Structural Aspects, Preparation, Characterization, Evaluation and Applications, Specialized Liposomes and Niosomes.
2. Nanoparticles, Microspheres: Method of Preparation, Characterization, Evaluation and Pharmaceutical Applications.
3. Multiple W/O/W Emulsions as Drug Vehicles. Introduction, Composition of The Multiple Emulsion and Stability, Influence of The Nature of Oily Phase, Methods for Stabilizing W/O/W Multiple Emulsions, Mechanisms of Transport of Solutes, *IN VIVO* Studies.

UNIT– IV (15 Hrs)

Colloidal and Supramolecular Delivery Systems -II: Micro emulsions: Introduction, Structure of Micro emulsions, Solubilisation and Formulation of Micro emulsions, Self-emulsifying Drug Delivery Systems (SEDDS), Transport Properties and Pharmaceutical applications of Emulsions.

Targeted Drug Delivery - History, Concept, Types and Key Elements; Ideal Carrier System and Approach with Special Reference to Organ Targeting (e.g. Brain, Tumour, Lung, Liver and Lymphatics); Basics of Temperature, pH and Magnetically Induced Targeting Tactics

Recommended Books

1. J.R. Robinson & V.H.L. Lee (Eds), 'Controlled Drug Delivery, Fundamentals and Applications,' Vol 29 & Vol. 31**,** 2nd Edn., Marcel Dekker, N.Y., **1987.**
2. Y.W. Chien (Ed.), 'Transdermal Controlled Systemic Medications', Marcel Dekker, N.Y., **1987.**
3. S.D. Bruck, 'Controlled Drug Delivery, (Basic Concepts)' Vol. I, CRC Press. Florida, **1983.**
4. S.D. Bruck, 'Controlled Drug Delivery, (Clinical Applications)' Vol. II, CRC Press, Florida, **1983.**
5. L.F. Prescot and W.S. Nimmo, 'Novel Drug and its Therapeutic Applications', John Willy and Sons, Chichester, **1990.**
6. N.K. Jain, 'Controlled and Novel Drug Delivery', CBS, New Delhi, **1997.**
7. N.K. Jain, 'Advances in Controlled and Novel Drug Delivery', CBS, New Delhi, **2001.**

BASICS OF PHARMACEUTICAL RESEARCH - I

Subject Code – MPHA1-104 **L T P C** **Duration – 45 Hrs**

3 1 0 4

UNIT– I (8 Hrs)

Drug Design and Discovery: Stages of Drug Discovery, Discovery of Lead Compounds, Pharmacophore Identification and Structure Modification, Physicochemical Alterations, Quantitative Structure Activity Relationship, High Throuput Screening, Acute, Sub-Acute and Chronic Studies, In-Vivo and In –Vitro Studies, Introduction To Preclinical and Clinical Trials, Toxicological Studies, FDA Review Process and Approval.

UNIT-II (9 Hrs)

Good Laboratory Practice: Scope of GLP, Definitions, Current GLP in manufacturing, responsibilities. General provision, organization and Personnel, Building and Facilities, Equipment, Control of Components and Drug product, Laboratory and Control of Records and Reports, Non-clinical Testing, Controls on Animal House, Report Preparation and Documentation, Application of Computers in Quality Control Laboratory

Good Clinical Practices: Introduction, Regulatory perspectives, Provisions, Documentation.

UNIT-III (16 Hrs)

Principles of Experimental Pharmacology: Common Laboratory Animals in Pharmacological Research, Limitations of Animal Tests, Alternatives to Animal Use, Anaesthetics used in Laboratory Animals, Some Standard Techniques Used in Laboratory Animals, Euthanasia of Experimental Animals. Regulations for The Care and Use of Laboratory Animals, CPCSEA, OECD Guidelines.

Analytical Method Validation: General Principles, Validation of Analytical and Bio-analytical Method as Per ICH Guidelines.

Calibration and Qualification of Analytical Instruments: Electronic Balance, Ph Meter, UV-Visible Spectrophotometer, FTIR, GC, HPLC, HPTLC, Disintegration and Dissolution Test Apparatus. **Qualification of Glassware:** Volumetric Flask, Pipette, Beakers and Burette

UNIT-IV (12 Hrs)

Methods in Material Characterization - Particle Dimensions: Particle Size and Powder Surface Area, Particle Shape and Surface Morphology.

Characterization of Solid State Structure: Spectroscopy in Pharmaceutical Analysis, X-Ray Diffraction, Solid-State Nuclear Magnetic Resonance, Vibrational Spectroscopy, Calorimetry in Pharmaceutical Analysis, Water Vapour Sorption, Electron and Confocal Microscopy, Density Measurements.

Thermal Methods of Analysis: Theory, Instrumentation and Applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA)

X-Ray Diffraction Methods: Introduction, Generation of X-Rays, X-Ray Diffraction, Bragg's Law, X-Ray Powder Diffraction, Interpretation of Diffraction Patterns and Applications.

Recommended Books

1. M.E. Wolff Burger, 'Medicinal Chemistry and Drug Discovery, Principle and Practice', John Wiley and Sons, New York.
2. R. Franke, 'Theoretical Drug Design Methods', Vol. VII. Elsevier, New York.
3. R.B. Silverman, 'The Organic Chemistry of Drug Design and Action', Academic Press Inc., San Diego, USA.
4. P.I. Good, 'A Managers Guide to Design and Conduct of Clinical Trials', Wiley-Liss, Hobokem, U.S.A., **2002.**
5. A.C. Cartwright and B.R. Matthews (eds.), 'International Pharmaceutical Product Registration', Elis Horwood, New York, U.S.A., **1994.**
6. H.G. Vogel (ed), 'Drug Discovery and Evaluation-Pharmacological Assays', 2nd Edn., Springer Verlag, Berlin, Germany, **2002**.
7. M.N. Ghosh, 'Fundamentals of Experimental Pharmacology', 2nd Edn., Scientific Book Agency, Calcutta, India, **1984.**
8. Sandy Weinberg, 'Good Laboratory Practices', Vol. 129, 3rd Edn., Drugs and Pharm. Sci. Series, Marcel Dekker Inc.

9. Robert M. Silverstein, 'Spectrometric Identification of Organic Compounds', 6th Edn., Wiley & Sons Publication.
10. Donglass A. Skoog, Holler, Nieman, 'Principles of Instrumental Analysis', 5th Edn., Thomson & Brooks Cole Publication.
11. Hobert H. Willard, 'Instrumental Methods of Analysis', 7th Edn., CBS Publication.
12. Gary D. Christian, 'Analytical Chemistry', 6th Edn., Wiley & Sons Publication.
13. A.H. Beckett, J.B. Stenlake, 'Practical Pharmaceutical Chemistry', Volume I & II, 4th Edn., CBS Publications.

PHARMACEUTICAL LABORATORY - I

Subject Code – MPHA1-105 **L T P C**
0 0 14 7

1. Experiment based on Biopharmaceutics and Pharmacokinetics.
2. Experiment based on Dosage Form Design.
3. Experiment based on Novel Drug Delivery System.

SEMINAR

Subject Code – MPHA1-106 **L T P C**
0 0 4 2

1. Introduction, information and retrieval systems.
2. Writing assignments and term papers.
3. Reading research papers.
4. Organization and presentation of scientific material, research work, dissertations, patents, etc.
5. Skills in oral and technical presentations.

Each student has to present at least three seminars during the semester.

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

Subject Code – MPHA1-207 **L T P C** **Duration – 50 Hrs**
4 0 0 4

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.

UNIT-I (13 Hrs)

Targeted Drug Delivery Systems:

- Concepts, events and biological process involved in drug targeting.
- Tumour targeting and Brain specific delivery

Targeting Methods
- Introduction preparation and evaluation.

UNIT-II (12 Hrs)

Nano Particles & Liposomes
- Types, preparation and evaluation.

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

UNIT-III (12 Hrs)

Pulmonary Drug Delivery Systems:
- Aerosols, propellants,
- Container Types, preparation and evaluation.
- Intra Nasal Route Delivery systems; Types, preparation and evaluation.

UNIT-IV (13 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.

Recommended Books

1. Y.W. Chien, 'Novel Drug Delivery Systems', 2nd Edn., Marcel Dekker, Inc., New York, **1992.**
2. S.P. Vyas and R.K. Khar, 'Controlled Drug Delivery - Concepts and Advances', Vallabh Prakashan, New Delhi, **2002**.
3. N.K. Jain, 'Controlled and Novel Drug Delivery', 1st Edn., CBS Publishers & Distributors, New Delhi, **2001.**

REGULATORY AFFAIRS

Subject Code – MPHA1-208 **L T P C** **Duration – 50 Hrs**

4 0 0 4

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

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
- Pharmacovigilance and process of monitoring in clinical trials.

UNIT-1 (14 Hrs)

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 (13 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

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-III (11 Hrs)

Non Clinical Drug Development

Global submission of IND, NDA, ANDA, Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

UNIT-IV (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

Recommended Books

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker Series, Vol.143.
2. Edited by Ira R. Berry and Robert P. Martin, 'The Pharmaceutical Regulatory Process', 2nd Edn., Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. Richard A Guarino, MD, 'New Drug Approval Process: Accelerating Global Registrations', 5th Edn., Drugs and the Pharmaceutical Sciences, Vol. 190.
4. 'Guidebook for Drug Regulatory Submissions / Sandy Weinberg', John Wiley & Sons.Inc.
5. 'FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics', edited by Douglas J. Pisano, David Mantus.
6. Fay A. Rozovsky and Rodney K. Adams, 'Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance', www.ich.org/www.fda.gov/europa.eu/index_en.htm https://www.tga.gov.au/tga-basics

COMPUTER AIDED DRUG DEVELOPMENT

Subject Code – MPHA1-209 **L T P C** **Duration - 50 Hrs**
4 0 0 4

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)

UNIT-I(12 Hrs)

Computers in Pharmaceutical Research and Development: 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

Quality-by-Design in Pharmaceutical Development

- Introduction.
- ICH Q8 guideline.
- Regulatory and industry views on QbD., Scientifically based QbD - examples of application.

UNIT-II (11 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-III (14 Hrs)

Computer-Aided Formulation Development

- Concept of optimization,
- Optimization parameters,
- Factorial design, Optimization technology & Screening design.
- Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro emulsion drug carriers.
- Legal Protection of Innovative Uses of Computers in R&D.

- The Ethics of Computing in Pharmaceutical Research.
- Computers in Market analysis.

Computer-Aided Biopharmaceutical Characterization

- Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial.
- Fed vs. Fasted state.
- In vitro dissolution and in vitro-in vivo correlation.
- Biowaiver considerations.

UNIT-IV (13 Hrs)

Computer Simulations in Pharmacokinetics and Pharmacodynamics

- Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

Computers in Clinical Development:

- Clinical Data Collection and Management.
- Regulation of Computer Systems Artificial Intelligence (AI),
- Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages.
- Current Challenges and Future Directions.

Recommended Books

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

COSMETICS AND COSMECEUTICALS

Subject Code – MPHA1-210 **L T P C** **Duration – 50 Hrs**

4 0 0 4

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.

UNIT-I (14 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.

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 needs for face, eye lids, hands, feet, nail, scalp, neck, body and under arm.

UNIT-II (14 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-III (11 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-IV (11 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 formulation herbal cosmetics.

Recommended Books

1. 'Harry's Cosmeticology'. 8th Edn.
2. Poucher's perfumecosmetics and Soaps, 10th Edn.
3. PP.Sharma, 'Cosmetics - Formulation, Manufacture and Quality Control'.
4. A.O. Barel, M. Paye and H.I. Maibach. 'Handbook of Cosmetic Science and Technology', 3rd Edn.
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PHARMACEUTICAL PRACTICALS - II

Subject Code – MPHA1-211 **L T P C**
0 0 12 6

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation.
2. Preparation and evaluation of Alginate beads.
3. Formulation and evaluation of gelatin/albumin microspheres.
4. Formulation and evaluation of liposomes/niosomes.
5. Formulation and evaluation of spherules.
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands.
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug.
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software.
11. In vitro cell studies for permeability and metabolism.
12. DoE Using Design Expert® Software.
13. Formulation data analysis Using Design Expert® Software.
14. Quality-by-Design in Pharmaceutical Development.
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics.
16. Computational Modelling of Drug Disposition
    - To develop Clinical Data Collection manual
    - To carry out Sensitivity Analysis, and Population Modelling.
17. Development and evaluation of Creams
18. 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

SEMINAR

Subject Code – MPHA1-212 **L T P C**
0 0 7 4

1. Introduction, information and retrieval systems.
2. Writing assignments and term papers
3. Reading research papers
4. Organization and presentation of scientific material, research work, dissertations, patents etc.
5. Skills in oral and technical presentations
6. Tutorials related to subject taught

Each student has to present atleast three seminars during the semester.