GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: Molecular Pharmaceutics(Nano Tech and Targeted DDS)
Subject Code: MPH201T

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

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 system

Sr.	Topic	Hr
1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	**12**
2.	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	**12**
3.	Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, Preparation and application of Niosomes, Aquasomes, Phyotosomes, Electrosomes	**12**
4.	Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation andevaluation, Intra Nasal Route Deliverysystems;Types,preparationandevaluation	**12**
5.	Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for genetherapy (inherited disorder andcancer). Gene expression systems (viral andnonviral genetransfer). Liposomal gene deliverysystems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisensemoleculesandaptamersasdrugs offuture	**12**

REFERENCES:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker,Inc.,NewYork,1992
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances,VallabhPrakashan,New Delhi,Firstedition 2002
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors,NewDelhi,Firstedition 1997 (reprint in2001).

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: Advanced Biopharmaceutics & Pharmacokinetics
Subject Code: MPH202T

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 the course student shall be able to understand

1. The basic concepts in biopharmaceutics and pharmacokinetics.
2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
3. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Sr.	Topic	Hr
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 physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	**12**
2.	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.	**12**
3.	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	**12**

4.	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative andabsolute 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	**12**
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 andpeptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Genetherapies	**12**

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia,LeaandFebiger,1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal.,Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC,2ndedition,ConnecticutAppletonCenturyCrofts,1985
4. Textbook of Biopharmaceutics andPharmacokinetics, Dr. Shobha Rani R. Hiremath,PrismBook
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel DekkerInc.,New York,1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick.J,LeaandFebiger,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,Pennsylvania1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised andexpande byRobert. E. Notari, Marcel Dekker Inc,New YorkandBasel,1987
10. BiopharmaceuticsandRelevantPharmacokineticsbyJohn.G Wagnerand M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James.G.Boylan,MarcelDekkerInc,New York,1996
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceuticalpress,RPS Publishing,2009
13. Absorption and Drug Development- Solubility, Permeability, and Charge State,AlexAvdeef,JohnWiley&Sons,Inc,2003

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: COMPUTER AIDED DRUG DEVELOPMENT
Subject Code: MPH203T

Scope: This course is designed to impart knowledge andskills 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 the course student shall be able to understand

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers in Preclinical Development
4. Optimization Techniques in Pharmaceutical Formulation
5. Computers in Market Analysis
6. Computers in Clinical Development
7. Artificial Intelligence(AI) and Robotics
8. Computational fluiddynamics (CFD)

Sr.	Topic	Hr
1.	a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8guideline, Regulatory and industry views on QbD, Scientifically based QbD-examples of application	**12**
2.	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-CholineTransporter	**12**
3.	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	**12**
4.	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in 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	**12**

5.	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions	**12**

REFERENCES:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins,2006,JohnWiley&Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, JelenaDjuris,Woodhead Publishing 3. Encyclopedia of Pharmaceutical Technology, Vol 1
3. James Swarbrick, James.G.Boylan,MarcelDekkerInc,New York,1996**.**

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: COSMETICS AND COSMECEUTICALS
Subject Code: MPH204T

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 student shall be able to understand

1. Key ingredients used in cosmetics and cosmeceuticals.
2. Key building blocks for various formulations.
3. Current technologies in the market
4. Various key ingredients and basic science to develop cosmetics and cosmeceuticals
5. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy

Sr.	Topic	Hr
1.	Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties	**12**
2.	Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm	**12**
3.	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 asallergens in EU regulation Controversial ingredients: Parabens, formaldehyde liberators, dioxane	**12**
4.	Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, bodyodor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations	**12**
5.	Herbal Cosmetics : Herbal ingredients used in Hair care, skin care andoral 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	**12**

REFERENCES:

1. Harry'sCosmeticology.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.3rdedition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: PHARMACEUTICS PRACTICALS - II
Subject Code: MPH205P

1. To study the effect of temperature change , non solvent addition, incompatible polymer additionin microcapsules preparation
2. Preparation and evaluation of Alginatebeads
3. Formulation and evaluation of gelatin /albuminmicrospheres
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 Paracetamolin animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline R software
11. In vitro cells tudies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-DesigninPharmaceuticalDevelopment
15. Computer Simulation sin Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff