SECOND SEMESTER

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

(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

12 Hrs

1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved 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 Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.

2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, 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).

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 to understand,

 The basic concepts in biopharmaceutics and pharmacokinetics.

 The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

 The critical evaluation of biopharmaceutic studies involving drug product equivalency.

 The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

 The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY 60 Hrs

12 Hrs

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting 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. Gastrointestinalabsorption: 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 Hrs

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 Hrs

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 proteinbinding interactions,the effect of tissue-binding interactions,cytochrome p450-based drug interactions,druginteractions linked to transporters.

12 Hrs

4 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.

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.

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.

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

12 Hrs

1. a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modelling in Pharmaceutical research and development: Descriptive versus Mechanistic 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.

12 Hrs

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-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.

12 Hrs

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 Hrs

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

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development,

Sean Ekins, 2006, John Wiley & Sons.

2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition,

Jelena Djuris, Woodhead Publishing

3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick,

James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS

(MPH 204T)

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.

THEORY 60 Hrs

12 Hrs

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 provisionsrelating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

12 Hrs

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 Hrs

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 as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

12 Hrs

4 Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

12 Hrs

5 Herbal Cosmetics : Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry’s Cosmeticology. 8th edition.

2. Poucher’sperfumecosmeticsandSoaps,10th edition.

3. Cosmetics - Formulation, Manufacture and quality control, 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. CTFA directory.

PHARMACEUTICS PRACTICALS - II

(MPH 205P)

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 WinnolineR 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 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