Nirma University

Institute of Pharmacy

Teaching & Examination Scheme of (M. Pharm. - Pharmaceutics)

Semester II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/ PW	T	C	Duration		Component Weightage		
							SEE	LPW /PW	CE	LPW/ PW	SEE
1	MPH201T	Molecular Pharmaceutics (NanoTech and Targeted DDS)	4	-	-	4	3.0	-	0.60	-	0.40
2	MPH202T	Advanced Biopharmaceutics and Pharmacokinetics	4	-	-	4	3.0	-	0.60	-	0.40
3	MPH203T	Computer Aided Drug Delivery System	4	-	-	4	3.0	-	0.60	-	0.40
4	MPH204T	Cosmetic and Cosmeceuticals	4	-	-	4	3.0	-	0.60	-	0.40
5	MPH205P	Pharmaceutics Practical II	-	12	-	6	-	6.0	-	1.00	-
6	MPH206P	Seminar / Assignment-II	-	7	-	4	-	-	-	1.00	-
7	-	Elective	2	-	-	2	3.0	-	0.6	-	0.40
		Total	16	19	-	26					
			35								

L: Lectures, P/T: Practicals/Tutorial, C: Credits

LPW/PW: Laboratory / Project WorK

SEE: Semester End Examination

CE: Continuous Evaluation

NIRMA UNIVERSITY

Institute of Pharmacy

(M. Pharm. : Pharmaceutics)

(Semester - II)

L	T	P	C
4	-	-	4

Course Code	MPH201T
Course Title	Molecular Pharmaceutics (Nano Tech & Targeted DDS)

Scope:

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives:

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

Course Learning Outcomes (CLO):

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

1. Understand the concepts of targeted and gene based drug delivery systems.
2. Compare various approaches for development of targeted drug delivery systems.

3. Explain types, manufacturing techniques and applications of microparticulate, nanoparticulate and vesicular drug delivery systems.
4. Discuss various approaches for pulmonary drug delivery systems.
5. Analyze various nano and targeted drug delivery systems.

Syllabus: Teaching Hours: 60 Hours

UNIT I 12 Hours

- Targeted Drug Delivery Systems:

  Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

UNIT II 12 Hours

- Targeting Methods:

  Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

UNIT III 12 Hours

- Micro Capsules / Micro Spheres:

  Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

UNIT IV 12 Hours

- Pulmonary Drug Delivery Systems :

  Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

UNIT V 12 Hours

- 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.

Suggested Readings^: (Latest edition)

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, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(M. Pharm. : Pharmaceutics)

(Semester - II)

L	T	P	C
4	-	-	4

Course Code	MPH202T
Course Title	Advanced Biopharmaceutics & Pharmacokinetics

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:

After completion of course student is able to know,

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

Course Learning Outcomes (CLO):

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

1. Understand concept of drug absorption in human.
2. Correlate drug dissolution with pharmacokinetics.
3. Derive the pharmacokinetic parameters alongwith its interpretation.
4. Estimate pharmacokinetics parameters with its application.
5. Explain development of BA-BE protocol as per various regulations.
6. Apply concepts of pharmacokinetics in clinical situations.

Syllabus: Teaching Hours: 60 Hours

UNIT I 12 Hours

- Drug Absorption From The Gastrointestinal Tract:

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH– partition theory of drug absorption. Factors affecting drug absorption: 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.

UNIT II 12 Hours

- Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance:

Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products. In Vitro–In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.

UNIT III 12 Hours

- Pharmacokinetics:

Basic considerations, Pharmacokinetic models, Compartment modeling: One

compartment model- IV bolus, IV infusion, Extravascular. Multi Compartment model: Two compartment - model in brief, Non Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation K_{max} and V_{max}. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

UNIT IV 12 Hours

- 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, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

UNIT V 12 Hours

- Application of Pharmacokinetics:

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

Suggested Readings^: (Latest edition)

1. Gibaldi Milo. Biopharmaceutics and Clinical Pharmacokinetics, Philadelphia, Lea and Febiger.

2. Brahmankar D. M., Jaiswal S. B. Biopharmaceutics and Pharmacokinetics: A Treatise, Delhi, Vallabh Prakashan.

3. Shargel, Applied Biopharmaceutics and Pharmacokinetics, Connecticut Appleton Century Crofts.

4. Rani S., Hiremath, R. Textbook of Biopharmaceutics and Pharmacokinetics, Prism Book

5. Gibaldi M., Perrier D. Pharmacokinetics, New York, Marcel Dekker Inc.

6. Swarbrick. J, Current Concepts in Pharmaceutical Sciences: Biopharmaceutics. Philadelphia,

Leaand Febiger.

7. Rowland M., Tozer T. Clinical Pharmacokinetics, Concepts and Applications Philadelphia, Leaand Febiger.

8. Abdou H. M Dissolution, Bioavailability and Bioequivalence, Pennsylvania, Mack Publishing Company.

9. Notari R. E. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, New York, Marcel Dekker Inc,

10. Wagner J. G., Pemarowski M. Biopharmaceutics and Relevant Pharmacokinetics, Hamilton, Illinois, Drug Intelligence Publications.

11. Swarbrick J., Boylan J. G. Encyclopedia of Pharmaceutical Technology, New York, Marcel Dekker Inc,

12. Jambhekar S. S., Breen P J. Basic Pharmacokinetics, pharmaceutical press, RPS Publishing.

13. Avdeef A. Absorption and Drug Development- Solubility, Permeability, and Charge State. John Wiley & Sons, Inc

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(Semester - II)

L	T	P	C
4	-	-	4

Course Code	**MPH203T**
Course Title	**Computer Aided Drug Delivery System**

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:

After completion of course student is able to know,

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 fluid dynamics(CFD)

Course Learning Outcomes (CLO):

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

1. Recall applications of computers in pharmaceutical research and development
2. Understand QbD guidelines with its implications.
3. Relate with Artificial intelligence (AI), Robotics and Computational fluid dynamics
4. Discuss significance of computational modeling of drug disposition
5. Apply optimization techniques in pharmaceutical formulation
6. Interpret computer generated market analysis and clinical development data.

Syllabus: **Teaching Hours**: **60 Hours**

UNIT I **12 Hours**

- **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 Parameter ,Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

- **Quality-by-Design In Pharmaceutical Development:**

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

UNIT II **12 Hours**

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

UNIT III **12 Hours**

- **Computer-aided formulation development:**
  Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

UNIT IV **12 Hours**

- **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
- **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

UNIT V **12 Hours**

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

REFERENCES: (Latest edition)

1. Ekins, S. Computer Applications in Pharmaceutical Research and Development. John Wiley & Sons. (2006)

2. Djuris, J. Computer-Aided Applications in Pharmaceutical Technology. First Edition. Woodhead Publishing.
3. Swarbrick, J. Boylan, J.G. Encyclopedia of Pharmaceutical Technology. (Volume 20) New York, Marcel Dekker Inc.

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(M. Pharm. : Pharmaceutics)

(Semester – II)

L	T	P	C
4	-	-	4

Course Code	**MPH204T**
Course Title	**Cosmetics and Cosmeceuticals**

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

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.

Course Learning Outcomes (CLO):

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

1. Understand regulatory requirements of cosmeceuticals.
2. Discuss safety, stability, and efficacy aspects of cosmetic products
3. Identify key ingredients used in cosmetics and cosmeceuticals.
4. Explain current technologies in the market for cosmetic manufacturing
5. Design, develop and evaluate cosmetic products including herbals

Syllabus: **Teaching Hours**: **60 Hours**

UNIT I **12 Hours**

- **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.

UNIT II **12 Hours**

- **Cosmetics - Biological aspects:**
  Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

UNIT III **12 Hours**

- **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 syndet bars.
  Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

  Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV **12 Hours**

- **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.

UNIT V **12 Hours**

- **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.

Suggested Readings^: (Latest Edition)

1. Rieger, M. (2009). *Harry's Cosmeticology: 8th edition 2 volume Set.*
2. Saraf, S., & Saraf, S. (2008). Cosmetics a practical manual. Hyderabad: PharmaMed Press.
3. Butler, H. (2000). *Poucher's perfumes, cosmetics, and soaps* (10th ed.). Dordrecht: Kluwer Academic .
4. Williams, D. F., & Schmitt, W. H. (1992). *Chemistry and Technology of the Cosmetics and Toiletries Industry*. Dordrecht: Springer Netherlands.
5. Barel, A. O., Paye, M., & Maibach, H. I. (2001). *Handbook of cosmetic science and technology*. New York: Marcel Dekker.
6. *1997 CTFA membership directory*. (1997). Washington: CTFA.
7. *Khar, R.* K. (2006). *Cosmetic Technology.* Delhi Birla Publications.
8. *Sharma, P.P.* (2005). *Cosmetic Formulations Manufacturing and Quality Control.* Delhi Vandana Publication

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(M. Pharm. : Pharmaceutics)

(Semester – II)

L	T	P	C
-	-	12	6

Course Code	**MPH 205P**
Course Title	**Pharmaceutics Practical II**

PRACTICALS **180 Hours**

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

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