



FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: Master of Pharmacy (Pharmaceutics)

Semester: II

Course Code: 108320201

Course Title: Molecular Pharmaceutics (Nanotechnology and Targeted DDS) (NTDDS)

Course 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 systems.

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
Lecture	Tutorial	Practical		Theory		J/V/P*		Total
				Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* J: Jury; V: Viva; P: Practical

Detailed Syllabus:

Sr.	Contents	Hours
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, Phytosomes, Electrosomes.	12
4	Pulmonary Drug Delivery Systems: Aerosols, propellants, Containers, Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12
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. Bio-distribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12



Reference Books:

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).

Pedagogy:

1. Traditional teaching methodology (Blackboard)
2. ICT Tools (PowerPoint presentation, video sharing on Projector)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						R: Remembering; U: Understanding; A: Applying; N: Analyzing; E: Evaluating; C: Creating
R	U	A	N	E	C	
30	35	15	12	6	2	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Gain knowledge for selection and evaluation of drug and excipients for novel drug delivery system	40
CO-2	Learn targeted drug delivery systems for tumor and brain	20
CO-3	Understand the methods for development and evaluation of particulate and vesicular drug delivery systems	17
CO-4	Develop and evaluate nucleic acid (aptamer)-based drug delivery systems	23

Curriculum Revision:

Version:	1
Drafted on (Month-Year):	June 2020
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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: Master of Pharmacy (Pharmaceutics)
Semester: II
Course Code: 108320202
Course Title: Advanced Bio-Pharmaceutics and Pharmacokinetics

Course Objectives: Upon completion of this course it is expected that students will be able understand,

1. The basic concepts in biopharmaceutics and pharmacokinetics.
2. The use raw data and derive the pharmacokinetic models and parameters that 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 biopharmaceutical parameters.
5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
Lecture	Tutorial	Practical		Theory		J/V/P*		Total
				Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* J: Jury; V: Viva; P: Practical

Detailed Syllabus:

Sr.	Contents	Hours
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	Biopharmaceutical considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutical 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 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, and drug interactions linked to transporters.	12
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
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamics, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12

Reference Books:

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., Vallab Prakashan, Pitampura, Delhi
3	Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 2nd edition, 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 Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995
8	Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9	Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10	Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 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, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13	Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc., 2003.

Pedagogy:

1. Traditional teaching methodology (Blackboard)
2. ICT Tools (PowerPoint presentation, video sharing on Projector, Software's)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						R: Remembering; U: Understanding; A: Applying; N: Analyzing; E: Evaluating; C: Creating
R	U	A	N	E	C	
30	34	18	12	5	1	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Learn ADME, drug interaction and pharmacokinetic models	40
CO-2	Understand pharmacokinetic and bio-pharmaceutics parameters for pharmaceutical products	25
CO-3	Learn drug product performance with respect to BA BE studies	20
CO-4	Apply pharmacokinetics in modified release drug products	15

Curriculum Revision:

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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: Master of Pharmacy (Pharmaceutics)

Semester: II

Course Code: 108320203

Course Title: Computer Aided Drug Delivery Systems

Course Objectives: Upon completion of this course it is expected that students will 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 fluid dynamics(CFD)

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
Lecture	Tutorial	Practical		Theory		J/V/P*		Total
				Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* J: Jury; V: Viva; P: Practical

Detailed Syllabus:

Sr.	Contents	Hours
1	<p>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.</p> <p>b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application</p>	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-Choline Transporter.	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 vitro-in vivo correlation, Bio-waiver 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

Reference Books:

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.

Pedagogy:

1. Traditional teaching methodology (Blackboard)
2. ICT Tools (PowerPoint presentation, video sharing on Projector, software's)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						R: Remembering; U: Understanding; A: Applying; N: Analyzing; E: Evaluating; C: Creating
R	U	A	N	E	C	
28	37	14	16	5	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.



Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Understand the applications of computers in drug research and drug product development process	41
CO-2	Know optimization techniques, Artificial Intelligence (AI) and Robotics in Pharmaceuticals	19
CO-3	Understand computer applications in pre-clinical and clinical studies	18
CO-4	Learn the concept of Computer-aided formulation development and biopharmaceutical characterization	22

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CVM UNIVERSITY

Aegis: Charutar Vidya Mandal (Estd.1945)

FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: Master of Pharmacy (Pharmaceutics)

Semester: II

Course Code: 108320204

Course Title: Cosmetics and Cosmeceuticals

Course Objectives: Upon completion of the course the student shall be able to

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.

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
Lecture	Tutorial	Practical		Theory		J/V/P*		Total
				Internal	External	Internal	External	
4	-	-	4	25/10	75/30	-	-	100/40

* J: Jury; V: Viva; P: Practical

Detailed Syllabus:

Sr.	Contents	Hours
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 syndet bars. Perfumes: Classification of perfumes. Perfume ingredients listed as allergens 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, body odor, 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 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	12

Reference Books:

1	Harry's Cosmeticology, 8th edition.
2	Poucher'sperfumecosmeticsandSoaps,10 th edition
3	Cosmetics - Formulation, Manufacture and quality control, PP. Sharma, 4 th 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

Pedagogy:

1. ICT tools (LCD projector, Laptop)
2. Conventional method (Black board)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						R: Remembering; U: Understanding; A: Applying; N: Analyzing; E: Evaluating; C: Creating
R	U	A	N	E	C	
25	30	20	20	5	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.



Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Explain Indian regulatory requirements for manufacture and sale of cosmetics	20
CO-2	Describe cosmetic biological aspects	20
CO-3	Design, formulate and evaluate cosmetics and cosmeceuticals	25
CO-4	Know advances and challenges in formulating herbal cosmetics by using various delivery systems	20
CO-5	Explain Indian regulatory requirements for manufacture and sale of cosmetics	15

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FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: Master of Pharmacy (Pharmaceutics)

Semester: II

Course Code: 108320205

Course Title: Pharmaceutics Practical-II

Course Objective: Upon completion of the course student shall be able to understand

1. Design, develop and evaluate various pharmaceutical formulations.
2. The principles of biopharmaceutics and pharmacokinetics for development of efficacious dosage forms.
3. Implementation of the computer application in pharmacokinetics-pharmacodynamics modelling and simulation study.
4. Develop cosmetics and cosmeceuticals and novel drug delivery systems with desired safety and stability.

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
Lecture	Tutorial	Practical		Theory		J/V/P*		Total
				Internal	External	Internal	External	
-	-	12	6	-	-	50/20	100/40	150/60

* J: Jury; V: Viva; P: Practical

List of Practical's:

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 gelatine/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 Modeling of Drug Disposition
17	To develop Clinical Data Collection manual
18	To carry out Sensitivity Analysis, and Population Modelling
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

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Prepare and evaluate novel drug delivery systems such as microspheres, liposomes, niosomes	30
CO-2	Learn software for quality-by-design approach for product development, Pharmacokinetic study and analysis of data for bioequivalence study	26
CO-3	Perform BA/BE, IVIVC, Sensitivity Analysis and Population Modeling test	18
CO-4	Compare dissolution profile of various marketed pharmaceutical products	9
CO-5	Formulate and evaluate various cosmetic products	17

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CVM UNIVERSITY

Aegis: Charutar Vidya Mandal (Estd.1945)

FACULTY OF PHARMACEUTICAL SCIENCES

Effective from Academic Batch: 2020-21

Programme: Master of Pharmacy (Pharmaceutics)

Semester: II

Course Code: 108320206

Course Title: Seminar/Assignment

Course Objectives:

At completion of this course student shall be able to

1. Develop skills to collect and organize data
2. Acquire knowledge on the current topic in field Pharmaceutical science
3. Perform effective presentation and communication skill

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
Lecture	Tutorial	Practical		Theory		J/V/P*		Total
				Internal	External	Internal	External	
-	-	8	4	-	-	100/40	-	100/40

* J: Jury; V: Viva; P: Practical

Guidelines

Seminar will be given on the current topic in the field of Pharmaceutical science. Student will gather information, compile data in the form of report and give presentation on the topic given.

Course Outcomes (CO):

Sr.	Course Outcome Statements	%weightage
CO-1	Develop skills to collect and organize information for the given topic	25
CO-2	Compile data and develop write-up skill on the topic given for seminar presentation	25
CO-3	Develop communication and presentation skills	25
CO-4	Effectively respond to the queries and questions raised	25

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