GANPAT UNIVERSITY

FACULTY OF PHARMACY

TEACHING AND EXAMINATION SCHEME

Program	Master of Pharmacy (M.Pharm)	Branch	Pharmaceutics	Semester	II	Version	2.0.0.0
Effective from	2018-19	Effective for batches admitted onwards	2018-19				

S. N	Subject Code	Subject Name	Theory / Practical/ Seminar	Teaching Scheme		Examination Scheme			
				Credit	Hours Per Week	Marks			Total Marks
						CE	SE	ES	
1	MPH201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	Theory	4	4	10	15	75	100
2	MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	Theory	4	4	10	15	75	100
3	MPH203T	Computer Aided Drug Delivery System	Theory	4	4	10	15	75	100
4	MPH204T	Cosmetic and Cosmeceuticals	Theory	4	4	10	15	75	100
5	MPH205P	Pharmaceutics Practical II	Practical	6	12	20	30	100	150
6	MEL206S	Seminar	Seminar	4	8	-	-	100	100
			Total	26	36	60	90	500	650

GANPAT UNIVERSITY										
FACULTY OF PHARMACY										
Program	Master of Pharmacy			Branch/Spec.	Pharmaceutics					
Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPH201T	Subject Name		Molecular Pharmaceutics(Nano Tech and Targeted DDS)						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

Upon completion of this course the student should be able to

- 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.

Learning Outcome:

- Know the concept of nanotechnology and targeted drug delivery system.
- Understand the various approaches for development targeted drug delivery systems.
- Recognize the application of nano/micro formulation in targeted drug delivery systems.
- Comprehend the rationale of drugs and excipients in the development of targeted drug delivery systems.
- Evaluate the novel formulations for various parameters indicative of successful formulation.
- Perform the design, formulate and evaluate targeted drug delivery system.

Syllabus- Theory

Unit	Content	Hrs
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, 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. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12

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, 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).

GANPAT UNIVERSITY										
FACULTY OF PHARMACY										
Program	Master of Pharmacy			Branch/Spec.	Pharmaceutics					
Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPH202T	Subject Name		Advanced Biopharmaceutics & Pharmacokinetics						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

Upon completion of this course the student should be able to

- 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

Learning Outcome:

Know the concept of biopharmaceutics and pharmacokinetics and their significance in the dosage form development.

Understand the absorption process and biopharmaceutical considerations in dosage form development.

Apply different pharmacokinetic equations used in calculating various parameters

Analyze and understand the pharamcokinetic models for developing optimum dosage regimen.

Evaluate the drug product performance on the basis of Bioavailability and Bioequivalence

Learn the applications of Pharmacokinetics in the development of different types of drug products.

Syllabus- Theory

Unit	Content	Hrs
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 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 and absolute bioavailability. 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-	12

	situ and In-vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	
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), Genetherapies.	12

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, Vallab Prakashan, Pitampura, Delhi.
3	Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC,2nd edition, Connecticut Appleton Century Crofts,1985.
4	Textbook of Biopharmaceutics andPharmacokinetics, 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, Lea and 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 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, 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.

GANPAT UNIVERSITY										
FACULTY OF PHARMACY										
Program	Master of Pharmacy			Branch/Spec.	Pharmaceutics					
Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPH203T	Subject Name		Computer Aided Drug Delivery System						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

Upon completion of this course the student should be able to

- 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 fluiddynamics (CFD)

Learning Outcome:

Know about various computational modeling of drug disposition.

Develop understading for necessary computer aided applications in preclinical development.

Apply various computer aided optimization techniques in pharmaceutical formulation

Analyze and learn artificial intelligence(AI) and robotics in various drug delivery systems.

Evaluate and learn about principles and applications of Computational fluid dynamics (CFD)

Creatre and perform population modeling, statistics and various models for handling data in product development.

Syllabus- Theory

Unit	Content	Hrs
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-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, 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, John Wiley & Sons.
2	Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing.
3	Encyclopedia of Pharmaceutical Technology, Vol 1, James Swarbrick, James.G.Boylan, Marcel Dekker Inc, New York, 1996.

GANPAT UNIVERSITY										
FACULTY OF PHARMACY										
Program	Master of Pharmacy			Branch/Spec.	Pharmaceutics					
Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPH204T	Subject Name		Cosmetic and Cosmeceuticals						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 hr.	3 hr.	

Pre-requisites

Nil

Scope and Objectives:

Upon completion of this course the student should be able to

- 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

Learning Outcome:

- Know regulations, manufacture, import and sale of cosmetics and cosmeceuticals.
- Understand basic science and key properties of ingredients used for formulation of cosmetics.
- Apply the knowledge gained from the subject for exploring various marketed cosmetic products.
- Analyze cosmetic products for conforming about the quality of the product and understanding the importance of ingredients employed.
- Evaluation of cosmetic products using physical, chemical and microbiological tests.
- Create formulations of cosmetic products, such as creams, shampoo, toothpaste, perfume, lipstick, etc.

Syllabus- Theory

Unit	Content	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 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, 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 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

REFERENCES:

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 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. 3rd edition.

5	Cosmetic and Toiletries recent suppliers catalogue.
6	CTFA directory.

GANPAT UNIVERSITY										
FACULTY OF PHARMACY										
Program	Master of Pharmacy			Branch/Spec.	Pharmaceutics					
Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MPH205P	Subject Name		Pharmaceutics Practical II						
Teaching scheme		Examination scheme								
Credit	6		CE	SE	ES	Total		SE	ES	
Hours	12	Marks	20	30	100	150	Duration	1 hr.	3 hr.	
Pre-requisites										
Nil										
Learning Outcome										
	Know the concept of nanotechnology and targeted drug delivery system.									
	Understand the various approaches for development targeted drug delivery systems.									
	Recognize the application of nano/micro formulation in targeted drug delivery systems.									
	Comprehend the rationale of drugs and excipients in the development of targeted drug delivery systems.									
	Evaluate the novel formulations for various parameters indicative of successful formulation.									
	Perform to design and formulate targeted drug delivery systems.									
List of Practicals:										
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 cells 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 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.									

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Program	Master of Pharmacy			Branch/Spec.	Pharmaceutics					
Semester	II			Version	2.0.0.0					
Effective from Academic Year		2018-19		Effective for the batches Admitted onwards				June 2018		
Subject code	MEL206S	Subject Name		Seminar						
Teaching scheme		Examination scheme								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	8	Marks	-	-	100	100	Duration	-	3 hr.	
Pre-requisites										
Nil										
Scope and Objectives:										
	• To develop know how of the latest development in the area of pharmaceutical science. • To develop the presentation skill for the information collected and compilated in the form of seminar.									
Learning Outcome:										
	Knowledge of the latest development in the area of pharmaceutical sciences									
	Understand the use of the library and internet resources for the referencing and literature purpose									
	Apply the knowledge of surfing and referencing to collect and compile relevant data in scientific way									
	Analyse the problems and strengthen ability for presentations and defending the viva voce									
	Evaluate the hypothesis, study design, method and results in a systemic manner									
	Develop presentation skill utilizing various tools and techniques for the data analysis and meaningful conclusion									