SARDAR PATEL UNIVERSITY
VallabhVidyanagar, Gujarat
(Reaccredited with 'A' Grade by NAAC (CGPA 3.25)
Syllabus with effect from the Academic Year 2022-2023

PROGRAMME STRUCTURE
Master of Pharmacy in Pharmaceutics
M. Pharm (Pharmaceutics) Semester: II

Programme Outcome (PO) - For M. Pharm (MPH) Programme	At the end of Master of Pharmacy (M. Pharm) program, the students will be able to: 1. Acquire knowledge and comprehension of the advancements in the core and specialization area of pharmacy. 2. Demonstrate a degree of expertise in laboratory practices, analytical techniques and scientific tools. 3. Independently carry out research/investigation and development work to solve problem. 4. Write and present a substantial scientific document and technical report. 5. Apply reasoning by contextual knowledge to assess societal impact, environmental impact, health, safety and legal issues and the consequent responsibilities relevant to the pharmacy profession.
Programme Specific Outcome (PSO) - For M. Pharm (MPH) Semester - II	After completion of the program students are able to: 1. Students will understand the concept of targeted drug delivery to various organs of body with its complexity and evaluation 2. How the drug can affect the body and how the body can affect the administered drug will be learnt by the students. 3. Current scenario of drug development through computer aided as well as through artificial intelligence will be also understood by students 4. Students will learn various regulatory guidelines and constrains in development of cosmetic products 5. Students will also learn the development of cosmetic products for allopathic as well as herbal ingredients

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PROGRAMME STRUCTURE
M. Pharm (Pharmaceutics) Semester: II

To Pass	At least 50% Marks in the University Examination in each paper and 50% Marks in the aggregate of University and Internal examination in each course of Theory, Practical & Research work.

Course Type	Course Code	Name of Course	Theory/ Practical	Credit	Exam Duration in hrs	Component of Marks		
						Internal	External	Total
Employability, Entrepreneurship	PP02CMPH01	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	T	4	3	25	75	100/50
Employability, Entrepreneurship	PP02CMPH02	Advanced Bio-pharmaceutics & Pharmacokinetics	T	4	3	25	75	100/50
Employability, Entrepreneurship	PP02CMPH03	Computer Aided Drug Delivery System	T	4	3	25	75	100/50
Employability, Entrepreneurship	PP02CMPH04	Cosmetics and Cosmeceuticals	T	4	3	25	75	100/50
Employability, Entrepreneurship, Skill development	PP02CMPH05	Pharmaceutics Practical II	P	6	6	50	100	150/75
Employability, Skill development	PP02SMPH01	Seminar/Assignment	S	4	-	100	-	100/50
		Total:	**-**	**26**	**-**	**250**	**400**	**650/325**

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - II

Course Code	PP02CMPH01	Title of the Course	Molecular Pharmaceutics (Nano Tech and Targeted DDS)
Total Credits of the Course	4	Hours per Week	4

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 systems related to gene delivery. 4. Formulation of various nano-micro delivery systems for targeting

Course Content		
Unit	**Description**	**Hrs.**
I	**Targeted Drug Delivery Systems: C**oncepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery	**12**
II	**Targeting Methods**: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation	**12**
III	**Micro Capsules / Micro Spheres:** Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. **Dispersion Systems** - Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability **Nano formulations for Parenteral use** - Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.	**12**
IV	**Pulmonary Drug Delivery Systems** : Aerosols, propellents, Containers, Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation	**12**
V	**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**

Teaching-Learning Methodology	1. Students will be oriented about the course content in the first session of the course 2. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 3. Virtual teaching and examination will also utilized for the learners of the course. 4. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 5. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 6. Internal theory test will be conducted as a part of regular curriculum. 7. Attendance will be marked for each session as a part of overall evaluation. 8. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern

Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes:

1.	Acquire skill of developing various targeted drug delivery systems and their evaluations
2.	Design various formulation approaches like nano technology, aerosols, nebulizers and dry powder inhalers for effective pulmonary delivery
3.	Strategic development for improving nasal absorption in the design of nasal drug delivery systems
4.	Application of gene therapy in the treatment of cancer and inherited diseases

Suggested References:

Sr. No	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)

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - II

Course Code	PP02CMPH02	Title of the Course	Advanced Bio-pharmaceutics & Pharmacokinetics
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	Upon completion of this course it is expected that students will be able understand, 1. The basic concepts in bio-pharmaceutics 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 bio-pharmaceutics studies involving drug product equivalency. 4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and bio-pharmaceutics parameters. 5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Course Content

Unit	Description	Hrs.
I	**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**
II	**Bio-pharmaceutics considerations in drug product design and In Vitro Drug Product Performance:** Introduction, bio-pharmaceutics 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**
III	**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-	**12**

	binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters	
IV	**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. Bio-pharmaceutics 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**
V	**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	**12**

Teaching-Learning Methodology	9. Students will be oriented about the course content in the first session of the course 10. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Power-point presentations, audio-visual presentations. 11. Virtual teaching and examination will also be utilized for the learners of the course. 12. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 13. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 14. Internal theory test will be conducted as a part of regular curriculum. 15. Attendance will be marked for each session as a part of overall evaluation. 16. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes:	
1.	Learn the mechanism of drug absorption, bioavailability and various factors affecting
2.	Comprehend the concept of various dissolution testing models
3.	Basic considerations of pharmacokinetic and dynamic models

4.	Various regulatory aspects of bio-availability and bioequivalence studies

Suggested References:	
Sr. No	**References**
1	Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2	Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
3	Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
4	Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
5	Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987
6	Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971
7	Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996
8	Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
9	Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003
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.

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - II

Course Code	PP02CMPH03	Title of the Course	Computer Aided Drug Delivery System
Total Credits of the Course	4	Hours per Week	4

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 Modelling of Drug Disposition 3. Computers in Preclinical Development 4. QbD 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 Content

Unit	Description	Hrs.
I	**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 **Quality-by-Design In Pharmaceutical Development** a. Introduction, objectives, elements, benefits and current status b. Aspects of QbD to product development – QTPP, CQA, CMA, CPP, Risk Assessment, Design Space, Control Strategy, Product Life Cycle Management and Continuous Improvement c. Implementation of QbD in product development (Case Studies)	**12**
II	**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**
III	**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,	**12**

	The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	
IV	**(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**
V	**Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions	**12**

Teaching-Learning Methodology	17. Students will be oriented about the course content in the first session of the course 18. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 19. Virtual teaching and examination will also utilized for the learners of the course. 20. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 21. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 22. Internal theory test will be conducted as a part of regular curriculum. 23. Attendance will be marked for each session as a part of overall evaluation. 24. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes:	
1.	Application of computers in pharmaceutical product development
2.	Implement various computational modeling and drug disposition studies
3.	Learn the use of computers in Clinical Data Collection and Management
4.	Acquire the prerequisite of industrial automation by application of artificial intelligence, robotics and computational fluid dynamics

Suggested References:	
Sr. No	**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

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - II

Course Code	PP02CMPH04	Title of the Course	Cosmetics and Cosmeceuticals
Total Credits of the Course	4	Hours per Week	4

Course Objectives:	Upon completion of the course, the students shall be able to understand 1. Key ingredients used in cosmetics and cosmeceuticals. 2. Key formulation building blocks for various cosmetics. 3. Current herbal cosmetic technologies in the market 4. Various key ingredients and basic science to develop skin care products 5. Scientific knowledge to controversial ingredients towards cosmetic products

Course Content		
Unit	**Description**	**Hrs.**
I	**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**
II	**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**
III	**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**
IV	**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**
V	**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**

Teaching-Learning Methodology	25. Students will be oriented about the course content in the first session of the course 26. Class-room teaching will be based on interactive sessions using chalk and board teaching method as well as teaching aids such as Powepoint presentations, audio-visual presentations. 27. Virtual teaching and examination will also utilized for the learners of the course. 28. Seminar/assignments on advanced, recent and useful topics related to the course will be an integral part of course teaching and learning methodology. 29. Quiz and Q & A sessions for the topics covered will be conducted at regular interval. 30. Internal theory test will be conducted as a part of regular curriculum. 31. Attendance will be marked for each session as a part of overall evaluation. 32. Teaching will be facilitated by reading material, discussion forum, task-based learning and case discussions.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes:	
1.	Apply various regulatory provisions related to the import, manufacture and labeling of cosmetics
2.	Theorize various Biological aspects and constraints in the development of cosmetics.
3.	Utilize various technologies for designing cosmetics and cosmeceuticals with desired safety, stability and efficacy
4.	Selection of synthetic and herbal ingredients in the cosmetic formulations for hair care, skin care and oral care

Suggested References:	
Sr. No	**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.

Master of Pharmacy

M. Pharm, Pharmaceutics, Semester - II

Course Code	PP02CMPH05	Title of the Course	Pharmaceutics Practical II
Total Credits of the Course	6	Hours per Week	12

Course Objectives:	1. Knowledge of various particulate and conventional Drug Delivery System 2. Dissolution Profiles and Improvisation. 3. Application of Design of Experiment & other Data Analysis Software 4. Knowledge of synthetic as well as Herbal chemicals/Expedients

Course Content	
Unit	**Description**
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* 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

Teaching-Learning Methodology	1. Practical training will be facilitated by demonstrations and check-list preparation. 2. Training of instrument or equipment will be imparted with demonstration of components of equipment and standard operating procedure. 3. Students will be instructed for performance of experiment followed by recording of observation, analysis and interpretation of data and discussion on the conclusion. 4. Quiz, viva-voce and performance test will be conducted for evaluation of practical understanding.

Evaluation Pattern		
Sr. No	Details of Evaluation	Marks
1.	Continuous Mode	10
2.	Sessional Examination	15
3.	End Semester Examination	75

Course Outcomes:	
1.	Able to formulate and evaluate various macro, micro and Nano Drug Delivery System
2.	Capable to improve solubility/ dissolution of drug with knowledge of Dissolution mechanism for Bioavailability testing
3.	Ability to Handle Statistical Tools for Data Analysis in formulation Development & Pharmacokinetic – Dynamic simulation
4	Selection of synthetic and Herbal Ingredients in Dosage Form Development