Course Syllabus
Gyanmanjari Pharmacy College
Semester-1(M. Pharm.)

Subject: Modern Pharmaceutics (MPHPC11503)

Type of course: Major

Prerequisite: B.Pharmacy

Rationale: The Modern Pharmaceutics course is to equip students with advanced knowledge of drug development, delivery systems, and formulation strategies. It focuses on understanding the principles of preformulation, biopharmaceutics, and pharmacokinetics, essential for designing effective dosage forms. The course emphasizes innovations in controlled and targeted drug delivery technologies to meet current industry standards. It prepares students for research and practical applications in pharmaceutical development, ensuring alignment with regulatory frameworks and patient-centered care.

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks					Total Marks
				Theory Marks		Practical Marks		CA	
CI	T	P	C	ESE	MSE	V	P	ALA	
4	-	-	4	75	25	-	-	50	150

Legends: CI-Class Room Instructions; T – Tutorial; P - Practical; C – Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V – Viva; CA - Continuous Assessment; ALA- Active Learning Activities.

Course Content:

Chapter No.	Course content	Hrs	% Weightage
1.	A. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability. Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.	10	16.66
2.	B. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	10	16.66
3.	Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10	16.66
4.	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management	10	16.66
5.	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10	16.66
6.	Study of consolidation parameters: Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1. Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10	16.66

Continuous Assessment:

Sr. No	Active Learning Activities	Marks
1.	**Socratic Questioning Sessions:** Faculty will assign each student and engage students in discussions through thought-provoking questions. E.g. "What happens if we reduce the particle size in a modified-release system?" A student stimulates critical thinking and deep understanding and upload GMIU web portal.	25
2.	**Role-Playing and Scenario-Based Learning:** Faculty assign students assume roles (e.g., formulator, regulator, or QA officer) in a manufacturing scenario. (Provides insight into interdisciplinary pharmaceutical processes) Students present their strategies for managing quality issues or improving product efficacy and can upload GMIU web portal.	25
Total		50

Suggested Specification table with Marks (Theory):75

Distribution of Theory Marks (Revised Bloom's Taxonomy)						
Level	Remembrance (R)	Understanding (U)	Application (A)	Analyze (N)	Evaluate (E)	Create (C)
Weightage	20%	40 %	25%	10%	05 %	-

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 Outcome:

After learning the course the students should be able to:	
CO1	Understand physicochemical properties of drugs and excipients and their impact on formulation development.
CO2	Apply concepts of sustained, controlled, and targeted drug delivery systems in designing pharmaceutical products.
CO3	Utilize statistical tools such as Design of Experiments (DoE) for optimizing formulations and processes.
CO4	Understand challenges in scale-up processes and technology transfer from lab to industry.

Instructional Method:

The course delivery method will depend upon the requirement of content and need of students. The teacher in addition to conventional teaching method by black board, may also use any of tools such as demonstration, role play, Quiz, brainstorming, MOOCs etc.

From the content 10% topics are suggested for flipped mode instruction.

Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory

The internal evaluation will be done on the basis of Active Learning Assignment

Practical/Viva examination will be conducted at the end of semester for evaluation of performance of students in laboratory.

Reference Books:

[1] Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.
[2] Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
[3] Pharmaceutical Dosage forms: Disperse systems, Vol. 1-2; By Leon Lachmann.
[4] Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
[5] Modern Pharmaceutics; By Gillbert and S. Banker.
[6] Remington's Pharmaceutical Sciences.
[7] Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
[8] Physical Pharmacy; By Alfred martin
[9] Bentley's Textbook of Pharmaceutics – by Rawlins.
[10] Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
[11] Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
[12] Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
[13] How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
[14] Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
[15] Pharmaceutical Preformulations; By J.J. Wells.
[16] Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
[17] Encyclopaedia of Pharmaceutical technology, Vol I – III.

JOURNALS:

[6] Indian Journal of Pharmaceutical Sciences (IPA)
[7] Indian drugs (IDMA)
[8] Journal of controlled release (Elsevier Sciences) desirable
[9] Drug Development and Industrial Pharmacy (Marcel & Decker) desirable