Faculty of Pharmacy
Master of Pharmacy (M. Pharm.)
(W. E. F.: 2023-24)
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Name of Faculty	:	Faculty of Pharmacy
Name of Program	:	Master in Pharmacy
Course Code	:	1MPH03
Course Title	:	Modern Pharmaceutics
Type of Course	:	Pharmaceutics
Year of Introduction	:	2023-24

Prerequisite	:	To have sufficient knowledge about basics of pharmaceutical dosage forms
Course Objective	:	Upon completion of the course, student shall be able to understand, The elements of preformulation studies. The Active Pharmaceutical Ingredients and Generic drug Product development Industrial Management and GMP Considerations. Optimization Techniques & Pilot Plant Scale Up Techniques Stability Testing, sterilization process & packaging of dosage forms.
Course Outcomes	CO1	To understand the concept and importance of preformulation parameters, the fundamental concepts and principles related to consolidation, diffusion, dissolution, pharmacokinetics, and statistical analysis in pharmaceutical sciences.
	CO2	To apply the statistical design in the development of different formulations.
	CO3	To learn (Remember) the scope and merits of validation and different types of validation
	CO4	To Understand the cGMP & Industrial Management
	CO5	To evaluate the compression and consolidation process and the parameters for powders and granules in tablet development

Teaching and Examination Scheme

Teaching Scheme (Contact Hours)			Credits	Examination Marks				
				Theory Marks		Practical Marks		Total Marks
L	T	P	C	SEE	CIA	SEE	CIA	
04	00	00	04	75	25	00	00	100

Legends: ***L****-Lecture;* ***T****–Tutorial/Teacher Guided Theory Practice;* ***P****– Practical,****C*** *– Credit,* ***SEE*** *– Semester End Examination,* ***CIA*** *- Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.))*

Course Content

Unit No.	Topics	Teaching Hours	Weightage	Course outcome
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. **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	20	33.33%	CO1
2	**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%	CO2
3	**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%	CO3
4	**Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10	16.66%	CO4
5	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%	CO5

Suggested Distribution of Theory Marks Using Bloom's Taxonomy						
Level	Remembrance	Understanding	Application	Analyse	Evaluate	Create
Weightage	**20**	**40**	**20**	**0**	**20**	**0**

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

Suggested Learning Websites

Sr. No.	Name of Website
1	https://www.ich.org/
2	https://www.pharmaguideline.net/regulatory-affairs/
3	https://www.pharmaguideline.com/2021/07/investigational-medicinal-product-dossier.html
4	https://www.ich.org/
5	https://www.pharmaguideline.net/regulatory-affairs/
6	https://www.ema.europa.eu/en/documents/leaflet/european-regulatory-system-medicines_en.pdf
7	https://pci.nic.in/pdf/Syllabus_B_Pharm.pdf
8	https://www.aicte-india.org/downloads/bpharma.pdf.
9	https://www.ipc.gov.in/
10	https://www.ayush.gov.in/
11	https://ayudmla.gujarat.gov.in/home.php
12	https://www.fda.gov/
13	https://www.pharmacopoeia.com/
14	https://ipapharma.org/
15	https://gpat.nta.nic.in/
16	https://drnaitiktrivedi.com/
17	https://gdc4gpat.com/course/gpat/
18	https://niscpr.res.in/
19	https://delnet.in/
20	https://ihubgujarat.in/
21	https://www.ssipgujarat.in/

References

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 LeonLachmann.
4.	Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By LeonLachmann.
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 ofIndia.
12.	Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Easternpublishers, 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.