



Program	Master of Pharmacy (M.Pharm)	Semester - 1
Type of Course	-	
Prerequisite		
Course Objective	-	
Effective From A.Y.	2023-24	

Teaching Scheme (Contact Hours)				Examination Scheme				
Lecture	Tutorial	Lab	Credit	Theory Marks		Practical Marks		Total Marks
				External Marks (T)	Internal Marks (T)	External Marks (P)	Internal Marks (P)	
4	-	-	4	75	25	-	-	100

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Course Content		T - Teaching Hours W - Weightage	
Sr.	Topics	T	W
1	Unit 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
2	Unit 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	20
3	Unit 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	18
4	Unit 4 Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10	10
5	Unit 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	19
Total		60	100



Suggested Distribution Of Theory Marks Using Bloom's Taxonomy

Level	Remembrance	Understanding	Application
Weightage	35	35	30

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.

Course Outcomes

At the end of this course, students will be able to:

CO1	Student should be able to understand various preformulation studies and experimental designs.
CO2	Students should understand various GMP aspects of pharmaceutical industry.
CO3	Students should have knowledge of tablet compression physics and various drug release kinetic models.

Reference Books

1.	Pharmaceutical Process Validation By Robert A. Nash, Alfred H. Wachter CRC Press 3, Pub. Year 2014
2.	Physical Pharmacy-PHYSICAL CHEMICAL PRINCIPLES I~ THE PHARMACEUTICAL SCIENCES By Alfred Martin, PILAR BUSTAMANTE, A. H. C. CHUN B. I. Waverly. Pvt Ltd 4
3.	BIOPHARMACEUTICS & PHARMACOKINETICS: A TREATISE (TextBook) By D.M. BRAHMANKAR, S.B. JAISWAL VALLABH PRAKASHAN, Pub. Year 2009
4.	Pharmaceutical Dosage Forms: Disperse Systems Volume 1-2 By Herbert A. Lieberman, Martin M. Rieger Gilbert S. Banker Marcel Dekker Inc 2
5.	Pharmaceutical Dosage Forms: Tablets 1 - 3 By Herbert Lieberman, Leon Lachman, Joseph B. Schwartz CRC Press 2, Pub. Year 1989
6.	Pharmaceutical Process Validation (TextBook) By Fra. R. Berry & Robert A. Nash CRC Press 3, Pub. Year 2014
7.	Computer Aided application in Pharmaceutical technology By Jelena Djuris Woodhead Publication 1, Pub. Year 2013