INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (PHARMACEUTICS)**
SEMESTER	**1**
COURSE TITLE	**MODERN PHARMACEUTICS**
COURSE CODE	**13MC0103**
COURSE CREDITS	**4**

Objective:

1 The course is designed to impart advanced knowledge and skills required to learn various aspects and concepts in the pharmaceutical industry.

Course Outcomes: After completion of this course, student will be able to:

1 The elements of preformulation studies.
2 The Active Pharmaceutical Ingredients and Generic drug Product development
3 Industrial Management and GMP Considerations.
4 Optimization Techniques & Pilot Plant Scale-Up Techniques
5 Stability Testing, sterilization process & packaging of dosage forms.

Pre-requisite of course:B.Pharm. Degree holder from an Indian university established by law in India from an institution approved by the Pharmacy Council of India and has scored not less than 55 percent of the maximum marks (aggregate of 4 years of B.Pharm.).

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	**Unit-1** a. Preformation Concepts – Drug Excipient interactions - different methods, the 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 the formulation.	20

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Contents : Unit	Topics	Contact Hours
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 equipment, Validation of specific dosage form, and Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ, and PQ of facilities.	10
3	**Unit-3** cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, the layout of buildings, services, equipment, 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, and industrial and personal relationship. Concept of Total Quality Management.	10
4	**Unit-4** Compression and compaction: Physics of tablet compression, compression, consolidation, the effect of friction, distribution of forces, compaction profiles. Solubility.	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
Total Hours		**60**

Textbook :

1 Theory and Practice of Industrial Pharmacy , Lachmann and Liberman., Lachmann and Liberman., 2000

2 Quality Assurance Guide, Pharmaceutical producers of India., Pharmaceutical producers of India., 1996

3 Advances in Pharmaceutical Sciences Vol. 1-5; , H.S. Bean & A.H. Beckett., H.S. Bean & A.H. Beckett., 1997

4 Pharmaceutical Dosage Forms: Disperse Systems, , By Leon Lachmann., By Leon Lachmann., 1989

5 Bentley’s Textbook of Pharmaceutics , Rawlins., Rawlins., 1996

6 Pharmaceutical Process Validation, Fra. R. Berry and Robert A. Nash., Fra. R. Berry and Robert A. Nash., 2001

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	**Understand**	**Apply**	**Analyze**	**Evaluate**	**Higher order Thinking / Creative**
20.00	25.00	25.00	15.00	10.00	5.00

Instructional Method:

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

2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.

3 Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.

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