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				
				Theory Marks		Practical Marks		
Lecture	Tutorial	Lab	Credit	External Marks (T)	Internal Marks (T)	External Marks (P)	Internal Marks (P)	Total Marks
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	**Principles of Drug discovery and development** Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application(NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.	12	20
2	**Pre-formulation studies** Introduction/concept, organoleptic properties, purity, impurity profiles,particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.	12	20
3	**Pilot plant scale up** Concept, Significance, design, layout of pilot plant scale up study, operations,large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	12	20
4	**Pharmaceutical packaging** Pharmaceutical dosage form and their packaging requirements,Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.	12	20
5	**Technology transfer** Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.	12	20
	Total	60	100

Suggested Distribution Of Theory Marks Using Bloom's Taxonomy				
Level	Remembrance	Understanding	Application	Analyze
Weightage	35	35	20	10

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	Basic knowledge of new product development process and its preformulation studies
CO2	Understanding the concept of pilot plant scale up, pharmaceutical packaging and technology transfer

Reference Books

1.	**THE SCIENCE AND PRACTICE OF PHARMACY** By REMINGTON- | LIPPINCOTT WILLIAMS and WIKINS | 21ST, Pub. Year 2005
2.	**THE THEORY AND PRACTICE OF INDUSTRIAL PHARMACY (TextBook)** By LACHMEN/LIBERMAN'S | CBS PUBLISHER and DISTRIBUTORS | 4TH, Pub. Year 2009
3.	**THE PHARMACEUTICAL REGULATORY PROCESS** By ROBERT.P.MARTIN | INFORMA HEALTHCARE | 2ND, Pub. Year 2008
4.	**AULTON'S PHARMACEUTICS-THE DESIGN AND MANUFACTURE OF MEDICINES (TextBook)** By MICHAEL E.AULTON KEVIN M.G.TAYLOR | ELSEVIER | 4TH, Pub. Year 2013
5.	**Cooper and Gunn's Tutorial pharmacy (TextBook)** By S.J. Carter | CBS PUBLISHERS AND DISTRIBUTORS | 6TH, Pub. Year 2005
6.	**GOOD MANUFACTURING OF PHARMACEUTICALS** By Sidney H. Willing ,Murray M,Tuckerman | Bhalani Publishing House | 3rd, Pub. Year 2008