Program	Master of Pharmacy (M.Pharm)	**Semester - 2**
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	**UNIT 1** Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location Factors influencing. Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.Production planning: General principles, production systems, calculation of standard cost, process planning,routing, loading, scheduling, dispatching of records, production control.	12	20
2	**UNIT 2** Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.	12	20
3	**UNIT 3** Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and palletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.	12	20
4	**UNIT 4** Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.	12	20

Course Content

T - Teaching Hours | **W** - Weightage

Sr.	Topics	T	W
5	**UNIT 5** Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.	12	20
	Total	**60**	**100**

Suggested Distribution Of Theory Marks Using Bloom's Taxonomy

Level	Remembrance	Understanding	Application
Weightage	40	40	20

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	Understanding regulatory requirements for pharmaceutical industry development and its approaches
CO2	Understanding of advanced manufacturing process and automization for pharmaceutical dosage forms
CO3	Understanding different type of packaging system in pharmaceutical industry

Reference Books

1. **Martin's physical pharmacy and pharmaceutical sciences**
   By PATRICK J. SINKO | Lippincott Williams and Wikins | 5, Pub. Year 2006
2. **Pharmaceutical Packaging Technology (TextBook)**
   By Dr.Rabindranath Pal | Nirali Prakashan, Pub. Year 2016
3. **Aulton's Pharmaceutics**
   By Michael Aulton | Churchill Living Stone | 3, Pub. Year 2007
4. **The Theory and Practice of Industrial Pharmacy (TextBook)**
   By Herbert Lieberman, Leon Lachman, J.L.Kanig | Varghese Publishing House | 2, Pub. Year 1976
5. **Modern Pharmaceutics (TextBook)**
   By Gilbert S. Banker,Christopher Rhodes | MDI DEKKER,New York | 2, Pub. Year 1990
6. **Pharmaceutical Dosage forms, Tablets, .**
   By LACHMEN/LIBERMAN'S | Marcel Dekkar Inc. | volume 1-3
7. **How to Practice GMP's**
   By P P Sharma | Vandana Publications | 1st Edition, Pub. Year 1991