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	**UNIT I** Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of nonclinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	12	20
2	**UNIT II** cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	12	20
3	**UNIT III** Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenteral, ophthalmic and surgical products (How to refer pharmacopoeias).	12	20
4	**UNIT IV** Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.	12	20
5	**UNIT V**	12	20

Course Content

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

Sr.	Topics	T	W
	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.		
		Total	**60**	**100**

Suggested Distribution Of Theory Marks Using Bloom's Taxonomy

Level	Remembrance	Understanding	Application	Analyze	Evaluate
Weightage	40	40	10	5	5

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 GMP, GLP and various regulatory authorities.
CO2	Understanding of IPQC parameters of various dosage form and documentation and legal procedures of Pharma industry.

Reference Books

1.	**Atextbook of Quality Control & Quality Assurance (TextBook)** By Deepanti Gajjar, Ashish Budhrani, Dr. Md. Rageeb Md. Usman, Dr. Dilpreet Singh | S. Vikas and Company (Medical Publisher) | 1st, Pub. Year 2021
2.	**Quality Assurance of Pharmaceuticals** World Health Organization Geneva | 3rd revised edition, Volume I & II, Pub. Year 1996
3.	**Quality Assurance Guide by organization of Pharmaceutical Procedures of India** Volume I & II, Mumbai | 3rd revised edition, Pub. Year 1996
4.	**Good Laboratory Practice Regulations** By Sandy Weinberg | Vol. 69, Marcel Dekker Series, | 2nd Edition, Pub. Year 1995
5.	**GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, (Volume 1 - With Checklists and Software Package).** By Steinborn L. | Taylor & Francis; 2003. | 6th Edition, Pub. Year 2003
6.	**Quality Systems and Controls for Pharmaceuticals** By Sarker DK | John Wiley & Sons, Pub. Year 2008
7.	**Good Manufacturing Practices for Pharmaceuticals a plan for total quality control** By Sidney H. Willig | Marcel Dekker Series. | Vol. 52- 3rd Edition
8.	**QA Manual (TextBook)** By D.H. Shah | Business Horizons | 1stedition, Pub. Year 2000
9.	**How to Practice GMP's (TextBook)** By P P Sharma | Vandana Publications | 1st Edition, Pub. Year 1991
10.	**Good laboratory Practice Regulations** By Allen F. Hirsch | Marcel Dekker Series | 1st Edition, Volume 38, Pub. Year 1989