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	**Introduction** Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12	20
2	**Role of quality systems and audits in pharmaceutical manufacturing environment** Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.	12	20
3	**Auditing of vendors and production department** Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	12	20
4	**Auditing of Microbiological laboratory** Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	12	20
5	**Auditing of Quality Assurance and engineering department** Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	12	20
	Total	60	100

Suggested Distribution Of Theory Marks Using Bloom's Taxonomy

Level	Remembrance	Understanding	Application
Weightage	40	30	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	Understanding the importance and methodology of auditing
CO2	Understanding the planning and process to carry out the audit
CO3	Understanding Audit report and checklist for audit

Reference Books

1.	**QUALITY AUDIT (TextBook)** By SOHRAB | 1996
2.	**Handbook of Microbiological Quality Control** By ROSAMUND M. BAIRD NORMAN A. HODGES STEPHEN P. DENYAR | 2000
3.	**Pharmaceutical Quality Assurance** By MANOHAR A. POTDAR | 2006 | I
4.	**Compliance Auditing for Pharmaceutical Manufacturers (TextBook)** By KAREN GINSBURY AND GIL BISMITH | 1994
5.	**Pharmaceuticals Manufacturing Handbook: Regulation and Quality (TextBook)** By SHAYNE COX GAD | 2008