INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE)**
SEMESTER	**2**
COURSE TITLE	**AUDITS AND REGULATORY COMPLIANCE**
COURSE CODE	**13MQ0203**
COURSE CREDITS	**4**

Objective:

1 This course deals with the understanding and process of auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

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

1 To understand the importance of auditing
2 To understand the methodology of auditing
3 To carry out the audit process
4 To prepare the auditing report
5 To prepare the checklist for auditing

Pre-requisite of course: Nil

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** Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12
2	**Unit-2** Role of quality systems and audits in a pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resources, Manufacturing operations, Evaluation activities, Transitioning to a quality system approach, Audit checklist for drug industries.	12

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Contents : Unit	Topics	Contact Hours
3	**Unit-3** 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
4	**Unit-4** Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, and Packaging materials.	12
5	**Unit-5** Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	10
Total Hours		**58**

Textbook :

1 Compliance auditing for Pharmaceutical Manufacturers, Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C., 2000

2 Pharmaceutical Manufacturing Handbook, Regulations and Quality, Shayne Cox Gad. , Wiley-Interscience, A John Wiley, and sons, Inc., Publications., 1989

3 Handbook of microbiological Quality control., Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. , CRC press, 2000

4 Laboratory auditing for quality and regulatory compliance. , Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden., Taylor and Francis , 2005

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.

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Instructional Method:

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

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