INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE)**
SEMESTER	**1**
COURSE TITLE	**QUALITY ASSURANCE PRACTICAL-1**
COURSE CODE	**13MQ0105**
COURSE CREDITS	**6**

Objective:

1 This course is designed to equip students with the practical skills and knowledge required to excel in the field of Quality Assurance.

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

1 Develop and implement protocols for conducting validation studies, including analytical method validation and process validation.

2 The students will know about an industry's organization, personnel, and regulatory requirement to develop and manufacture quality pharmaceuticals.

3 Develop critical thinking and problem-solving skills to identify and resolve quality-related issues in the pharmaceutical industry.

Pre-requisite of course:B.Pharm. Degree holder from an Indian university established by law in India from an institution approved by the Pharmacy Council of India and has scored not less than 55 percent of the maximum marks (aggregate of 4 years of B.Pharm.).

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
0	0	12	0	0	20	100	30

Contents : Unit	Topics	Contact Hours
Total Hours		

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
1	**Practical-1** Analysis of Pharmacopeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV-Visible spectrophotometer.	1

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Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
2	**Practical-2** Simultaneous estimation of a multi-drug component containing formulations by UV spectrophotometry.	1
3	**Practical-3** Experiments based on HPLC.	1
4	**Practical-4** Experiments based on Gas Chromatography.	1
5	**Practical-5** Estimation of riboflavin/quinine sulfate by fluorimetry.	1
6	**Practical-6** Estimation of sodium/potassium by flame photometry or AAS.	1
7	**Practical-7** Case studies	1
8	**Practical-8** Development of Stability study protocol.	1
9	**Practical-9** Estimation of process capability.	1
10	**Practical-10** In-process and finished product quality control tests for tablets, capsules, parenteral, and semisolid dosage forms.	1
11	**Practical-11** Assay of raw materials as per official monographs.	1
12	**Practical-12** Testing of related and foreign substances in drugs and raw materials.	1
Total Hours		**12**

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.

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Instructional Method:

2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.

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

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