

INSTITUTE	FACULTY OF PHARMACY
PROGRAM	MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE)
SEMESTER	2
COURSE TITLE	QUALITY ASSURANCE PRACTICAL-II
COURSE CODE	13MQ0205
COURSE CREDITS	6

Objective:

- 1 To equip students with practical competencies and regulatory insights in quality assurance by training them in analytical method validation, equipment qualification, environmental monitoring, contaminant analysis, and quality systems implementation, with applied understanding through checklists, plant layouts, and case studies based on Quality by Design (QbD) and Process Analytical Technology (PAT).

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

- 1 Demonstrate expertise in analytical methods, including HPLC, TLC, flame photometry, and colorimetry, for detecting and quantifying organic, metallic, and environmental pollutants in pharmaceutical environments.
- 2 Implement qualification and validation protocols for pharmaceutical equipment, processing areas, and analytical methods according to ICH and GMP requirements.
- 3 Establish and review documentation practices, encompassing checklists and plant layouts, while implementing QbD and PAT principles using case studies.

Pre-requisite of course: Nil

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 Organic contaminants residue analysis by HPLC	1
2	Practical-2 Estimation of Metallic contaminants by Flame photometer	1

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
3	Practical-3 Identification of antibiotic residue by TLC	1
4	Practical-4 Estimation of Hydrogen Sulphide in Air.	1
5	Practical-5 Estimation of Chlorine in Work Environment.	1
6	Practical-6 Sampling and analysis of SO ₂ using Colorimetric method	1
7	Practical-7 Qualification of following Pharma equipment A. Autoclave B. Hot air oven C. Powder Mixer (Dry) D. Tablet Compression Machine	1
8	Practical-8 Validation of an analytical method for a drug	1
9	Practical-9 Validation of a processing area	1
10	Practical-10 Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)	1
11	Practical-11 Check list for Bulk Pharmaceutical Chemicals vendors	1
12	Practical-12 Case study on application of QbD	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.
- 2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.

Instructional Method:

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