INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**BACHELOR OF PHARMACY**
SEMESTER	**7**
COURSE TITLE	**QUALITY ASSURANCE**
COURSE CODE	**13PH0705**
COURSE CREDITS	**4**

Objective:

1 This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

2 This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

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

1 Understand the cGMP aspects in a pharmaceutical industry.

2 Appreciate the importance of documentation.

3 Understand the scope of quality certifications applicable to pharmaceutical industries.

4 Understand the responsibilities of QA & QC departments.

Pre-requisite of course: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
3	1	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	**Quality Assurance and Quality Management concepts:** Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP. Total Quality Management (TQM): Definition, elements, philosophies. ICH Guidelines: purpose, participants, the process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines. Quality by design (QbD): Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration. NABL accreditation: Principles and procedures.	10

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Contents : Unit	Topics	Contact Hours
2	**Organization and personnel:** Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. Equipment and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.	10
3	**Quality Control:** Quality Control: Quality control test for containers, rubber closures and secondary packing materials. Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities.	10
4	**Complaints:** Complaints: Complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal. Document maintenance in the pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.	8
5	**Calibration and Validation:** Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. Warehousing: Good warehousing practice, materials management	7
Total Hours		**45**

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
1	**Tutorials will be based on the above syllabus.** TUTORIAL-1, TUTORIAL-2, TUTORIAL-3, TUTORIAL-4, TUTORIAL-5, TUTORIAL-6, TUTORIAL-7, TUTORIAL-8, TUTORIAL-9, TUTORIAL-10, TUTORIAL-11, TUTORIAL-12, TUTORIAL-13, TUTORIAL-14, TUTORIAL-15	15
Total Hours		**15**

Textbook :

1 Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials:, World Health Organization, World Health Organization, 1997

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References:

1 Good Laboratory Practice Regulations, Good Laboratory Practice Regulations, SandyWeinberg, CRC Press, 1995

2 A compendium of Guidelines and Related Materials , A compendium of Guidelines and Related Materials , World Health Organization, World Health Organization, 1997

3 Total Quality Management, Total Quality Management, Kushik Maitra and Sedhan K Ghosh., New Age International, 2013

4 Good manufacturing Practices, Good manufacturing Practices, P P Sharma., Vandana Pub, 2015

5 Total Quality Management, Total Quality Management, Sadhank G. Ghosh., Singh, S K, 2018

6 General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms., General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms., World Health Organization , CBS PUBLISHERS AND DISTRIBUTORS PVT LTD Publication date, 2018

7 GLP, GLP, Marcel Deckker Series., Marcel Dekker Inc, 1989

8 ICH and ISO guidelines, ICH and ISO guidelines, ISO, ISO, 2017

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**
10.00	20.00	25.00	25.00	10.00	10.00

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 black board 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.

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

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