NIRMA UNIVERSITY
Institute of Pharmacy

(B. Pharm)
(Semester - VI)

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Course Code	**BP606T**
Course Title	**Pharmaceutical Quality Assurance - Theory**

Scope:
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.

Objectives:
Upon completion of the course, the student shall 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

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -

1. Understand the aspects of quality assurance, total quality Management, ICH guidelines ,QbD, relevant ISO and accreditation process in a pharmaceutical industry
2. Describe the importance of organization, personnel, premises, equipment and raw material as per cGMP guideline
3. Explain the quality control and GLP practices followed in Pharmaceutical Industry **S**
4. Appreciate the importance of documentation and complaint procedure
5. Apply the principles of calibration and validation and follow good warehousing practices

Syllabus: **Teaching hours: 45 Hours**

UNIT I **10 Hours**

- **Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP
- **Total Quality Management fjTQM):** Definition, elements, philosophies

- **ICH Guidelines:** purpose, participants, 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

UNIT II **10 Hours**

- **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.
- **Equipments and raw materials:** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT III **10 Hours**

- **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

UNIT IV **08 Hours**

- **Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.
- **Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNITV **07 Hours**

- **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

Suggested Readings/\: (Latest edition)

1. Quality Assurance Guide by Organisation of Pharmaceutical Producers oflndia.
2. Weinberg, S. (Ed.). Good laboratory practice regulations. CRC Press.
3. World Health Organization. Quality assurance of pharmaceuticals: A compendium of guidelines and related materials. Good manufacturing practices and inspection (Vol. 2). World Health Organization.

4. Maitra, K. and Ghosh, S.K. A guide to total quality management. Oxford Publishing House.
5. Sharma, P. P. How to practice GMPs. Vandana publications.
6. Ghosh, S.K. Introduction to ISO 9000 and Total Quality Management. Oxford Publishing House.
7. World Health Organization .. International Pharmacopoeia. Vol. 1-4.
8. Good laboratory Practices - Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 4000 guidelines

L= Lecture, T= Tutorial, P= Practical, C= Credit

" this is not an exhaustive list