Title of Skill Course: Quality Control And Quality Assurance Analyst

1. Department: Department of Drug Chemistry
2. Title: Quality Control and Quality Assurance Analyst
3. Sector: Chemical Sciences
4. Eligibility: 12th Pass
5. Year of implementation: 2022-2023

Course Structure

Skill Level	Theory Hours	Practical Hours	Total Hours	Credits	No. of students in batch
5	15	30	45	02	30

Syllabus

Course Objectives: Students will be able to...

1. Appreciate the importance of validation and qualification
2. Understand about qualification of manufacturing equipment and analytical instruments.

Theory Syllabus (Contact Hrs: 15, Credits: 01)

1. Introduction To Concept Of Validation And Qualification: (9 L)

Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. **Qualification:** User requirement specification, Design qualification, Installation qualification, Operational qualification, Performance qualification, Requalification

2. Qualification Of Manufacturing And Analytical Equipment: (8 L)

Qualification of manufacturing equipment : Dry Powder Mixers, Tray dryers, Tablet Compression (Machine), Autoclaves, Membrane filtration, Capsule filling machine. **Qualification of analytical instruments:** UV-Visible spectrophotometer, FTIR.

Course Outcomes: Students will be able to...

1. Differentiate calibration and validation
2. Understand different qualification methods of manufacturing equipments

Practical Syllabus (Contact Hrs: 30, Credits: 01)
Course Objectives: Students will be able to...

1. Calibrate various analytical instruments
2. Validate analytical methods for drug
3. Evaluate assay of drug by using TLC
4. Perform Qualification of various equipments

List of Experiments ---------- 30 hrs

1. Calibration of pH meter and measure pH of different sample solutions
2. Calibration of analytical balance
3. Calibration of conductivity meter and measure conductance of given sample
4. Calibration of glass wares.
5. Calibration of UV Spectrophotometer and measure the absorbance of given sample
6. Assay of drug by using TLC.
7. Qualification of Autoclave
8. Qualification of Hot air oven
9. Validation of an analytical method for assay of paracetamol
10. Validation of an analytical method for assay of aspirin, sulphonamides, ibuprofen (any one)

    Case study/ Field Visit/ Industrial Visit

Course Outcomes: Student should be able to...

1. Calibrate and Validate various analytical instruments
2. Analyse various raw materials used in drug formulations
3. Perform Assay of drugs
4. Validate an analytical method for drug assay

References

1. IPC “Indian Pharmacopiea” (2018)

2. D. A. Skoog, D. M. West and F. J. Holler, “Fundamentals of Analytical Chemistry”, 2nd Ed, Saunders College Publishing (1991)

3. Larry Hargis, “Analytical Chemistry- Principles and Techniques”, Prentice-Hall (1987)

4. S. M. Khopkar, “Basics of Analytical chemistry”, New Age International (2004)

5. M. A . Potdar, “Pharmaceutical Quality Assurance”, Nirali Prakashan (2020)

BOS Sub Committee:

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2. Member: Ms. A. S. Choudhari
3. Member: Ms. T. J. Sabale

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