

**Title of Skill Course: Quality Control Analyst**

1. Department: Department of Drug Chemistry
2. Title: Quality Control Analyst
3. Sector: Chemical Sciences
4. Eligibility: 12<sup>th</sup> Pass
5. Year of implementation: 2021

**Course Structure**

Skill Level	Theory Hours	Practical Hours	Total Hours	Credits	No. of students in batch
4/5/6/7	15	30	45	02	30

**Syllabus****Learning Objectives:**

1. To Understand the GMP aspects and the responsibilities of QC & QA departments
2. To appreciate the importance of documentation

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

Unit I: Introduction to Quality Control and Quality Assurance : Concept and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, cGMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias). (10 L)

Unit II: Introduction to Documentation in pharmaceutical industry: Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. (05 L)

**Practical Syllabus (Contact Hrs: 30, Credits: 01)**

List of Experiments ----- 30 hrs

1. Introduction to different Pharmacopoeias
2. Assay of raw materials as per official monographs
3. Preparation of SOP of various instruments
4. Training of writing various records- Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports
5. Introduction and analysis of organic compounds by using TLC
6. Introduction and analysis of organic compounds by using UV Vis spectrophotometer

7. Demonstration of dissolution test apparatus
8. Preparation of buffers and recording its pH  
Case study/ Field Visit/ Industrial Visit
9. Calibration of instruments as pH meter, analytical balance, conductivity meter, etc (minimum 02)
10. Calibration of glass wares

(**Note:** For Skill Level 6 and 7 total experiment is 08 with Case study/ Field Visit/ Industrial Visit)

**Learning Outcomes:**

1. Should be able to know the SOP of various instruments
2. Should be able to analyse various raw materials

**Reference Books:**

1. Indian Pharmacopoeia, IPC, 2018
2. D. A. Skoog, D. M. West and F. J. Holler, Fundamentals of Analytical Chemistry, 2<sup>nd</sup> Ed, Saunders College Publishing 1991
3. Larry Hargis, Analytical Chemistry- Principles and Techniques.

**BOS Sub Committee:**

1. Chairman: Dr. P. A. Bharad
2. Member: Ms. A. S. Choudhari

**Expert:**

1. Name of Academic Expert: Dr. S. S. Gilda,  
GES College of Pharmacy, Satara
2. Name of Industrial Expert: Dr. S. S. Birajdar,  
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