

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
6	15	30	45	02	30

Course Objectives: Students will be able to-

1. Understand the material management process.
2. Know the different methods, documents required for material management.

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

Unit		No. of Lectures
Unit I	Material Management	8
	Introduction, purchasing, raw materials, packaging materials, Intermediates and bulk product, finished products, rejected and recovered materials, recalled products, return goods, reagents and culture media, Waste materials, references standards, miscellaneous materials.	
Unit II	Documents and formats	7
	SOP and record of vendor certification, SOP on receipt storage and sampling raw material and product material, SOP on dispensing of materials, SOP and releasing of finished product, SOP on handling on rejected materials.	

Course outcomes: Students should be able to-

1. Prepare standard operating process
2. Explain waste management process.

Credits 1	List of Practicals	
	<ol style="list-style-type: none">1. Prepare inventory of the chemicals in the department according to barcode and CAS Number.2. Check the material data sheet for the above listed chemicals and segregate according to their safe nature.3. Prepare SOP for the newly arrived equipment in the laboratory.4. Fire extinguishing techniques uses.5. Measure least count and handling micropipettes.6. Sampling technique used for dilution.7. Visit to manufacturing unit.	

References:-

Pharmaceutical quality assurance by Manohar. A. Potdar. NiraliPrakashan

1. Subcommittee for draft syllabi of Quality Control & Quality Assurance Analyst (Drug Chemistry)

Sr. No.	Name of Member	Designation	Address
1	Dr. R. V. Hangarge	Chairman	Y.C.I.S. Satara
2	Ms. A. S. Choudhari	Member	Y.C.I.S. Satara
3	Dr. S. S. Gilda	Academic Expert	GES College of Pharmacy, Satara
4	Dr. S. S. Birajdar	Industrial Expert	Group Leader, Workhardt Research Centre, Aurangabad