COURSE MODULE

Program Title	M. Pharmacy
Department	Quality Assurance and Pharmaceutical Analysis
Course Title	Quality Control and Quality Assurance

1. **NAME OF INSTITUTION** : Y. B. CHAVAN COLLEGE OF PHARMACY, AURANGABAD

2. **AFFILIATED UNIVERSITY** : DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

3. **DEPARTMENT** : **QUALITY ASSURANCE**

4. **PROGRAM TITLE** : M. PHARM.

5. Program Outcomes (PO):

M. Pharm in Quality Assurance Techniques:After completing the program, student will be able to:

PSO-1:Highlight advancement in knowledge associated with the quality assurance of Pharmaceuticals, regulatory requirements, Industry associated hazards, audit methodology, product development & technology transfer.

PSO-2:Perform validation of analytical methods, processes, equipment, facilities and prepare documentation as per the Regulatory Standards Leading to Compliance of cGMP.

PSO-3: Independently carry out research work utilizing modern tools, problem analysis skills and analytical skills.

PSO-4:Apply the Quality control and Quality assurance concepts throughout product life cycle.

PSO-5:Analyze the application-based of emerging quality building concepts (QbD) in drug development.

5. COURSE SPECIFICATION :

5.1.Course Identification and General Information

a. Course Title:	Quality Control and Quality Assurance	
b. Course Number/Code	**MQA 103T**	
c. Credit Hours	Theory	Practical
	60 (4 Hrs/Week)	NA
d. Study level/semester at which this course is offered	M. Pharmacy I semester	
e. Pre-requisite	Instrumental methods of Analysis VII Sem Quality Assurance VI Sem	
f. Co-requisite	---	
g. Program in which the course is offered	M. Pharmacy	
h. Language of teaching the course	English	
i. Prepared by	Dr. Rana Zainuddin	
j. Approved by HOD	Dr. J.N. Sangshetti	

5.2. Course Description:

The subject basically deals with:

1. Quality management system
2. Regulatory agencies and guidelines
3. Documentation, records and reports
4. Guidelines used in Pharma industry
5. Manufacturing operations and control of mixup and cross contamination
6. IPR concept

5.3. Course Objectives:

1. Know the components of Quality management system.
2. Understand GMP GLP Schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA ,ICH guidelines and their implementation, with special emphasis on Q3 and Q 6
3. Analysis of raw materials, finished products, packaging materials, in process quality control(IPQC), developing specification.
4. Documentation in Pharmaceutical industry : making policy, formats, records, reports
5. Manufacturing operations and controls.
6. Introduction, scope and importance of intellectual property rights.

Course Outcomes (COs) :

CO Code	Course outcome
1	Ability to understand and apply Quality management system , regulatory guidelines and tools in a pharmaceutical industry.
2	Quality control evaluation of materials
3	Ability to address manufacturing operation and control over post manufacturing operations

Knowledge and Understanding

(Alignment of POs to COs)

CO Code	Program Outcome				
	PO1	PO2	PO3	PO4	PO5
1	3	3	1	3	1
2	1	2	3	3	1
3	1	2	2	2	1

Correlation levels 1, 2 or 3 as defined below:

1: Slight (Low); 2: Moderate (Medium); 3: Substantial (High); If there is no correlation, put '-'

Teaching and Assessment Methods for achieving learning outcome:

Teaching Strategies(methods)/Tools used	Methods of Assessment
Lectures (Constructivist learning)	**Formative Assessment**
Collaborative learning (Discussion)	**Case study**
Project based Learning	**Class test**
Blended learning	**Multiple choice questions**
Inquiry based learning	**Assignments**
Flash cards	**Seminar**
Video	**Viva Voce**
Equipment models	**Synopsis**
	Tutorials
	Summative Assessment

Tools for the Teaching and learning

Theory subjects	Practical Subjects
• **Power Points presentation**	• **White boards**
• **Videos**	• **Glassware**
• **Flash Card**	• **Chemicals**
• **Models**	• **Instruments**
• **Software**	• **Equipment**
• **Charts**	• **Software**
• **Smart Boards**	• **Models**
• **White boards**	• **Plants/Crude Drugs**
• **Online Platform**	• **Animal**

COURSE CONTENT

Theoretical Aspect:

Order	Topic list/units	Subtopics	Number of Weeks	Contact Hours
1	**Unit I**	Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	**3 and Half week**	**12**
2	**Unit II**	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	**3 and Half week**	**12**

3	**Unit III**	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. 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).	**3 and Half week**	**12**
4	**Unit IV**	Documentation in pharmaceutical industry: Three tier documentation, Policy, 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. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common	**2 and half week**	**2**

		Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.		
5	Unit V	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.	2 and half week	12
	TOTAL			60

Practical Aspects

Order	Name of Experiment	Number of Weeks
1	NA	-

7.0 ASSESSMENT MECHANISM :

Sr. No.	Assessment Mechanism	Week due	Marks	Proportion of Final Assessment
1	Assignments, Exercises & Home works	2nd week of every month	10	6%
2	Sessional (Internal Theory exam)	As per scheduled examination	15	10%
3	Continuous Practical Assessment (Sessional Practical exam)	Weekly during practicals	15	10%
4	Final exam (theory)	As per	75	50%

5	Final exam(practical)	University at end of course	35	24%
Total			150	**100%**

8.0 STUDENT SUPPORT:

Office hours/week	Other procedures
Two hours minimum	

9.0 TEACHER'S AVAILABILITY FOR STUDENT SUPPORT:

Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time	**10:00-1:00**	**10:00-1:00**	**4:00-5:00**	**12:00-1:00**	**11:00-1:00**	**4:00-5:00**

10.0 LEARNING RESOURCES:

Sr. No.	Title of Learning Material	Details
1	Text books	1. Quality Assurance of Pharmaceuticals, Vol. 2, Updated Edition, World Health Organization, Geneva. 2. M.A. Potdar, Pharmaceutical Quality Assurance, Nirali Prakashan, Pune. 3. S. H. Willing, GMP for Pharmaceuticals, Latest Edition, Marcel Dekker. 4. Lachman/Liebermans The Theory and Practice of Industrial Pharmacy : 4th Edition
2	Essential references (as per syllabus)	1. ICH guidelines 2. GMP guidelines 3. GLP guidelines 4. Schedule M
3	Reference material	Indian Pharmacopoeia 1996 volume 1 and 2
4	E-materials and websites	**www.ich.org, www.fda.gov, www.iso.org**
5	Other learning material	-

11.0 FACILITIES REQUIRED:

Sr.No.	Particular of Facility Required
1	Lecture Rooms (capacity for 60 students)

2	Laboratory (capacity for 20 students)
3	Computing resources: PC with latest version and hardware/software and utilization of open source and licensed application software
4	Other resources: Appropriate laboratory tools, Chemicals, Glass ware, Apparatus, Instrumentation

12.0 COURSE IMPROVEMENT PROCESSES:

Strategies for obtaining student feedback on effectiveness of teaching:

Course delivery evaluation by students using: Questionnaire forms and online questionnaires

Other strategies for evaluation of teaching by the instructor or by the department:

Periodic review by Academic Planning & Monitoring Committee and departmental review committee, Observations and assistance of colleagues, External assessments by advisors/ examiners and auditors.

Process for improvement of teaching:

Use of ICT tools, teaching aids, Simultaneous practical orientation and theory classes (SPOT), Adoption of reflective teaching.

Describe the planning procedures for periodically reviewing of course effectiveness and planning for improvement:

Periodic review by departmental meeting, Review of course delivery and outcome through assessment and feedback from all stake holders.

Course development plans:

Provide inputs for course improvement and update to University Course development Committees (Board of Studies)

13.0 INFORMATION ABOUT FACULTY MEMBER RESPONSIBLE FOR THE COURSE:

Name	Dr. Rana Zainuddin
Location	M. Pharm. Q. A. Lab.
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Office Hours	10:00 AM to 5:00 PM