Dr. Rafiq Zakaria Campus
Maulana Azad Educational Trust's
Y. B. CHAVAN COLLEGE OF PHARMACY
(B. Pharm, M. Pharm & Research Centre)
ISO 21001:2018 & ISO 14001:2015 CERTIFIED | NIRF-2022 ALL INDIA RANK 65TH
NAAC ACCREDITATION "A" GRADE WITH 3.23 CGPA SCORE

COURSE MODULE

Program Title	B. Pharmacy
Department	Quality Assurance and Pharmaceutical Analysis
Course Title	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** : B. PHARM.

Program Outcomes (PO):

PO 01: Pharmacy Knowledge: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.

PO 02: Planning Abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

PO 03:Problem analysis: Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.

PO 04:Modern tool usage: Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.

PO 05:Leadership skills: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and wellbeing.

PO 06: Professional Identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).

PO 07: Pharmaceutical Ethics: Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

PO 08:Communication: Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

PO 09:The Pharmacist and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

PO 10:Environment and sustainability: Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

PO 11:Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

5. COURSE SPECIFICATION :

5.1.Course Identification and General Information

a. Course Title:	Quality Assurance	
b. Course Number/Code	**BP606T**	
c. Credit Hours	Theory	Practical
	45(3 Hrs/Week	NA
d. Study level/semester at which this course is offered	B. Pharmacy VI semester	
e. Pre-requisite	Pharmaceutical Analysis-I	
f. Co-requisite	---	
g. Program in which the course is offered		
h. Language of teaching the course	English	
i. Prepared by	Dr. Rana Zainuddin, Dr. Barrawaz Aateka	
j. Approved by HOD	Dr. J.N. Sangshetti	

5.2.Course Description:

The subject basically deals with:

1. Quality Assurance and management tools.
2. Good manufacturing Practices, Good Laboratory Practices, ICH guidelines.
3. Quality by design (QbD)
4. ISO 9000 & ISO 14000 and NABL accreditation
5. Documentation and records
6. Calibration and Validation

5.3. Course Objectives:

1. Know the components of Quality management system.
2. Understand GMP GLP ICH guidelines and their implementation, with special emphasis on Q series.
3. Quality control of packaging material.
4. Create documents and records eg BMR, MFR, SOP.
5. Know methods for calibration and validation of common instruments.

Course Outcomes (COs) : (Min. 4 and Max. 6)

(Use Bloom's Taxonomy words)

CO Code	Course outcome
1	Ability to understand and apply cGMP principles in a pharmaceutical industry.
2	Appreciate value of Total Quality Management and QbD for Pharma industry.
3	Explain various regulatory guidelines such as ICH, GLP, GWP and their implementation.

4	Ability to address complaints and produce documents like SOPs, Audit reports, Batch Formula Record, Master Formula records, distribution records etc.
5	Appreciate quality certifications applicable to pharmaceutical industries including ISO , NABL.
6	Describe analytical tests, calibration and validation.

Knowledge and Understanding

(Alignment of POs to COs)

CO Code	**Program Outcome (PO)**										
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO. BP606T.01	3	3	3	2	2	3	3	1	3	1	1
CO. BP606T.02	2	3	3	3	3	3	3	3	3	2	3
CO. BP606T.03	2	3	3	2	1	2	1	3	3	2	2
CO. BP606T.04	3	3	2	2	2	3	3	3	1	1	1
CO. BP606T.05	2	3	2	2	2	3	3	2	1	3	2
CO. BP606T.06	3	3	3	3	-	-	-	-	1	1	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) **Collaborative learning (Discussion)** **Project based Learning** **Blended learning** **Inquiry based learning** **Flash cards** **Video** **Equipment models**	**Formative Assessment** **Case study** **Class test** **Multiple choice questions** **Assignments** **Seminar** **Viva Voce** **Synopsis** **Tutorials** **Summative Assessment**

Tools for the Teaching and learning

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

COURSE CONTENT

Theoretical Aspect:

Order	Topic list/units	Subtopics list	Number of Weeks	Contact Hours
1	**Unit I**	Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP Total Quality Management (TQM): Definition, elements, philosophies **ICH Guidelines**: (International council for harmonization) 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** : (National accreditation board for testing and calibration laboratories) Principles and procedures	**3 and Half week**	**10**
2	**Unit II**	**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. **Warehousing**: Good warehousing practice, materials management	**3 and Half week**	**10**

3	**Unit III**	**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 aNonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	**3 and Half week**	**10**
4	**Unit IV**	**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.	**2 and half week**	**7**
5	Unit V	**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	2 and half week	8
	TOTAL			45

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 University at end of course	75	50%
5	Final exam(practical)		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
2	Essential references (as per syllabus)	1. ICH guidelines 2. GMP guidelines 3. GLP guidelines

		4. Schedule M
3	Reference material	Inian Pharmacopoeia, 2011, the Controller of Publications Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th Edition
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

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