COURSE MODULE

Program Title	M. Pharmacy
Department	Quality assurance
Course Title	Pharmaceutical Validation

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.

4.1. Program Specific Outcome:

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 Qualitycontrol 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:	PHARMACEUTICAL VALIDATION	
b. Course Number/Code	MQA 202T	
c. Credit Hours	Theory	Practical
	4	-
d. Study level/semester at which this course is offered	Sem II	
e. Pre-requisite	Basic knowledge of qualification, calibration and validation of pharmaceutical instruments.	
f. Co-requisite		
g. Program in which the course is offered	M Pharm	
h. Language of teaching the course	English	
i. Prepared by	Dr. Furquan khan	

j. Approved by HOD	Dr. Jaiprakash Sangshetti

5.2.Course Description:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application. The subject also gives a brief outline of general principles of Intellectual Property Rights.

5.3.Course Objectives:

At completion of this course, it is expected that students will be able tounderstand the concepts of calibration, qualification and validationof various equipment and instruments. Process validation of different dosage forms. Validation of analytical method for estimation of drugs. Cleaning validation of equipment employed in the manufacture ofpharmaceuticals. General principles of Intellectual Property Rights.

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

(Use Bloom's Taxonomy words)

CO Code	Course outcome
CO-1	Discuss about the concept and types of validation
CO-2	Demonstrate qualification and calibration of instruments and equipment.
CO-3	Explain the concepts of process validation of dosage forms.
CO-4	Explain the procedure of analytical method validation and cleaning validation.
CO-5	Discuss the concepts of Intellectual Property Rights.

6.1. Knowledge and Understanding

(Alignment of PSOs to COs)

Course Code	Program Specific Outcome				
	PSO-1	**PSO-2**	**PSO-3**	**PSO-4**	**PSO-5**
CO-1	**3**	**3**	**1**	**3**	**1**
CO-2	**3**	**3**	**3**	**3**	**1**
CO-3	**1**	**-**	**-**	**1**	**-**
CO-4	**-**	**3**	**3**	**3**	**-**
CO-5	**-**	**-**	**-**	**-**	**-**

Correlation levels 1, 2 or 3 as defined below:

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

6.2.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**

6.3.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**

6.4.COURSE CONTENT

6.1. Theoretical Aspect:

Order	Topic list/units	Subtopics list	Number of Weeks	Contact Hours
1	**Unit I**	Introduction to validation and Qualification	**2.5**	**10**
2	**Unit II**	Qualification of manufacturing equipment and analytical instruments	**2.5**	**10**
3	**Unit III**	Qualification of laboratory equipments and Validation of Utility systems	**2.5**	**10**
4	**Unit IV**	Process Validation and Analytical method validation	**2.5**	**10**
5	**Unit V**	Cleaning Validation and Computerized system validation	**2.5**	**10**
6	**Unit VI**	General Principles of Intellectual Property	**2.5**	**10**
	TOTAL		**15**	**60**

7.0. ASSESSMENT MECHANISM:

Sr. No.	Assessment Mechanism	Week due	Marks	Proportion of Final Assessment
1	Continuous Assessment (Theory)	2nd week of every month	10	10%
2	Sessional (Internal Theory exam)	As per schedule of examination	15	15%
3	Continuous Practical Assessment (Sessional Practical exam)	Weekly during practical	-	-
4	Sessional (Internal Practical exam)	As per schedule of examination	-	-
5	Final exam (theory)	As per University	75	75%

6	Final exam(practical)	at end of course	-	-
Total			100	**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	**12:00-1:00**	**12:00-1:00**	**12:00-1:00**	**12:00-1:00**	**12:00-1:00**	**12:00-1:00**

10.0. LEARNING RESOURCES:

Sr.No.	Title of Learning Material	Details
1	Text books	• B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs andPharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y. • The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman,Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay. • Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
2	Reference material	• Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
3	E-materials and websites	https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf
4	Other learning material	Power point presentation, Notes

11.0. FACILITIES REQUIRED:

Sr.No.	Particular of Facility Required
1	Lecture Rooms (capacity for 60 students)
2	Computing resources: PC with latest version and hardware/software and utilization of open source and licensed application software

12.0. COURSE IMPROVEMENT PROCESSES:

12.1. **Strategies for obtaining student feedback on effectiveness of teaching:** Course delivery evaluation by students using: Questionnaire forms and online questionnaires.

12.2. **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.

12.3. **Process for improvement of teaching:** Use of ICT tools, teaching aids, Simultaneous practical orientation and theory classes (SPOT), Adoption of reflective teaching.

12.4. **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.

12.5. **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. Furquan khan
Location	Department of Quality Assurance
Contact Detail (e-mail &cell no.)	e-mail: furkhankhan11@gmail.com. Cell no:9730076135
Office Hours	10:00 AM to 5:00 PM