COURSE MODULE

Program Title	M. Pharmacy
Department	Quality Assurance and Pharmaceutical Analysis
Course Title	**Pharmaceutical Manufacturing Technology**

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.

Program Specific Outcomes (PSO):

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:	Pharmaceutical Manufacturing Technology	
b. Course Number/Code	**MPA204T**	
c. Credit Hours	Theory	Practical
	60 (4 Hrs/Week)	NA
d. Study level/semester at which this course is offered	M. Pharmacy II 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	MPharmacy	
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. Developments in Pharmaceutical industry. Legal requirements, plant layout and production planning
2. Aseptic process technology: Advanced sterile product manufacturing , Process Automation in Pharmaceutical Industry
3. Non sterile manufacturing process technology: Advance non-sterile solid product manufacturing technology, Coating technology.
4. Containers and closures for pharmaceuticals: Types and Testing
5. Quality by design (QbD) and process analytical technology (PAT):

5.3. Course Objectives:

1. Know the requirements of regulations, layout in Pharma industry.
2. Principles of planning layout, production systems and control.
3. Understand manufacturing process operations for non-sterile an sterile products and automation
4. Types of containers and closures, their performance and testing.
5. Current approaches in QbD and PAT .

Course Outcomes (COs) :

CO Code	Course outcome
1	Able to Interpret and apply knowledge in regulatory requirements, production planning and operations for manufacturing of product in a pharmaceutical industry.
2	Able to relate to technological advances and automation in manufacturing operations and packaging science.
3	Able to appreciate and implement concept of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

Knowledge and Understanding

(Alignment of PSOs to COs)

CO Code	Program Outcome				
	PO1	PO2	PO3	PO4	PO5
CO MQA103T.01	3	3	1	1	1
CO MQA103T.02	2	1	3	1	1
CO MQA103T.03	1	3	3	1	3

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**	1. Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.	**3 and Half week**	**12**
2	**Unit II**	2. Aseptic process technology: Manufacturing, manufacturing flowcharts, in process quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). **Advanced sterile product manufacturing technology** : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance**.**	**3 and Half week**	**12**

		Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). **Lyophilization technology**: Principles, process, equipment.		
3	**Unit III**	Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.	**3 and Half week**	**12**

		Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.		
4	**Unit IV**	**Containers and closures for pharmaceuticals:** Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.	**2 and half week**	**12**
5	Unit V	Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality	2 and half week	12

		by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.		
	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 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. Potdar, Manohar A. cGMP Current Good Manufacturing Practices for Pharmaceuticals Publisher : PharmaMed Press Pub-Year : 2012 2. Potdar, Manohar A. cGMP Current Good Manufacturing Practices for Pharmaceuticals Author Publisher : PharmaMed Press Pub-Year : 2018 3. Lachman L, Lieberman HA, Kanig JL. The theory and practice of Industrial Pharmacy,
2	Essential references (as per syllabus)	1. cGMP Current Good Manufacturing Practices for Pharmaceuticals Author : Potdar, Manohar A. Publisher : PharmaMed Press Pub-Year : 2012 2. cGMP Current Good Manufacturing Practices for Pharmaceuticals Author : Potdar, Manohar A. Publisher : PharmaMed Press Pub-Year : 2018
3	Reference material	1. The Drugs and Cosmetics Act, 1940 and Rules, 1945 Author : Deshpande, S. W. Susmit Publishers Pub-Year : 2004. 2. Pharmaceutical Packaging Technology Author : Dean, D. A., Taylor & Francis Pub-Year : 2006. 3. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996. 4. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008. 5. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA,
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.
Contact Detail (e-mail &cell no.)	ranazainy@gmail.com 8668215030
Office Hours	10:00 AM to 5:00 PM