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	Pharmaceutics
Course Title	Industrial Pharmacy

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

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

3. **DEPARTMENT** : **PHARMACEUTICS**

4. **PROGRAM TITLE** : B. PHARM.

4.1. 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:	Industrial Pharmacy

b. Course Number/Code	BP702T	
c. Credit Hours	Theory	Practical
	45(3 Hrs/Week	60 (4Hrs. / Week)
d. Study level/semester at which this course is offered	Sem VII	
e. Pre-requisite	Formulative Pharmacy, Physical Pharmaceutics I, Physical Pharmaceutics II, Pharmaceutics I	
f. Co-requisite	N/A	
g. Program in which the course is offered	B Pharm	
h. Language of teaching the course	English	
i. Prepared by	Chishti Nahid Anjum Hafizuddin	
j. Approved by HOD	Dr.S.R.Lahoti	

5.2.Course Description:

This course is designed to impart fundamental knowledge on pharmaceutical product commercialization from laboratory to market.

5.3.Course Objectives:

1. **To know the process of pilot plant scale up of pharmaceutical dosage forms**
2. **To understand the process of technology transfer from lab scale to production batch**
3. **To know different laws and acts that regulate pharmaceutical industry in India and US**
4. **To understand the approval process and regulatory requirements for drug products**

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

(Use Bloom's Taxonomy words)

CO Code	Course outcome
CO 702.01	Explain the pilot Plant Scale Up Techniques in industries and various aspects of quality control and quality assurance aspects of pharmaceutical industries.
CO 702.02	Describe the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.
CO 702.03	Understand the scope of quality certifications applicable to pharmaceutical industries .
CO 702.04	Understand the principle involved in formulation of various pharmaceutical dosage forms
CO 702.05	Understand the responsibilities of Regulatory Affairs department
CO 702.06	Describe the drug regulatory approval process for investigational new drug, new drug and abbreviated new drug.

CO 702.07	Understand Quality Management System and ISO certification.
CO 702.08	Describe Technology Development and Transfer.

6.1. 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 702.01	**3**	**--**	**--**	**---**	**1**	**---**	**----**	**----**	**----**	**2**	**2**
CO 702.02	**3**	**--**	**3**	**3**	**---**	**---**	**1**	**2**	**----**	**2**	**3**
CO 702.03	**3**	**--**	**3**	**3**	**----**	**---**	**1**	**2**	**----**	**3**	**3**
CO 702.04	**3**	**3**	**3**	**3**	**2**	**1**	**1**	**2**	**----**	**3**	**3**
CO 702.05	**3**	**--**	**3**	**3**	**--**	**--**	**--**	**--**	**1**	**3**	**1**
CO 702.06	**3**	**--**	**3**	**1**	**--**	**--**	**--**	**3**	**3**	**3**	**1**
CO 702.07	**3**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**
CO 702.08	**3**	**3**	**3**	**3**	**3**	**1**	**1**	**1**	**-**	**-**	**2**

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**	**Pilot plant scale up techniques:** General considerations - including	**3 and Half week**	**10**

		significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to Platform technology		
2	**Unit II**	**Technology development and transfer:** WHO guidelines for Technology Transfer: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation - confidentiality agreements, licensing, MoUs, legal issues	**3 and Half week**	**10**
3	**Unit III**	**Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals **Regulatory requirements for drug approval:** Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions,	**3 and Half week**	**10**

		Management of Clinical Studies.		
4	**Unit IV**	**Quality management systems:** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP	**2 and half week**	**8**
5	**Unit V**	**Indian Regulatory Requirements**: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Common Technical Document (CTD), Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.	**2 and half week**	**7**
	TOTAL			**45**

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	10%
2	Sessional (Internal Theory exam)	As per scheduled examination	15	15%
3	Final exam (theory)	As per University at end of course	75	75%
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	**1:00-2:00**	**1:00-2:00**	**1:00-2:00**	**1:00-2:00**	**1:00-2:00**	**1:00-2:00**

10.0.

LEARNING RESOURCES:

Sr.No.	Title of Learning Material	Details
1	Text books	**N. K. Jain, Pharmaceutical product development, CBS Publishers** **Leon L., Herbert A. L, The theory and practice of industrial pharmacy, CBS publishers** **E. A. Rawlins, Bentley's Textbook of pharmaceutics, ELBS.** **Ansel H., Allen L., Popovich N., Pharmaceutical dosage forms and drug delivery systems, Lippincott Williams & Wilkins.** **Aulton E., The design and manufacture of medicine, Churchill Livingstone.**
2	Essential references (as per syllabus)	**Govt. of India, Indian Pharmacopoeia, TheController of Publication** **B.P.Comission, British Pharmacopoeia, H.M.S.O.London** **LeonLachman, Leiberman, Pharmaceutical Dosage Form: Tablet ChurchillLivingston** **AlfonsaGennara, Remingtons,The Science Practice of Pharmacy, Lippincott** **Bankar Gilbert, Cristofer T.Rhods, Modern Pharmaceutics, MarcelDekker** **Keneth E.A, Leon L., Herbert A. L., Pharmaceutical dosage forms: parenteral medications , Marcell dekker.**

3	Reference material	
4	E-materials and websites	
5	Other learning material	

11.0. FACILITIES REQUIRED:

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

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	Chishti Nahid Anjum Hafizuddin
Location	Third Floor (Faculty Room)
Contact Detail (e-mail &cell no.)	7028092427, anjumnahid20@gmail.com
Office Hours	10:00 AM to 5:00 PM