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	Formulative 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 assessment 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:	Formulative Pharmacy
b. Course Number/Code	BP502T

c. Credit Hours	Theory	Practical
	45(3 Hrs/Week	60 (4Hrs. / Week)
d. Study level/semester at which this course is offered	Sem V	
e. Pre-requisite	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	Dr. M.N.CHISHTI	
j. Approved by HOD	Dr. S.R.LAHOTI	

5.2.Course Description:

Formulative Pharmacy is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms, cosmetics and packaging. An understanding of formulative pharmacy is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient

5.3.Course Objectives:

1. To understand various pharmaceutical dosage forms and cosmetical products.
2. To imbibe the concept of manufacturing techniques and various preformulation principles involved in dosage form development.
3. To impart the knowledge regarding production methodology of sterile and non sterile dosage forms.

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

CO Code	Course outcome
CO 502.01	**Describe formulation principles, methodology and evaluation for various cosmetic preparation**
CO 502.02	**Formulate various dosage forms and differentiate them on the basis of advantages, disadvantages, route of administration, usability and methodology of manufacturing.**
CO 502.03	**List out raw materials and machinery requirement in manufacturing of different dosage forms.**
CO 502.04	**Select, use and operate testing process to evaluate various drug dosage forms.**
CO 502.05	**Explain the appropriateness of packaging material required in line to various dosage forms and knowledge about latest packaging trends.**
CO 502.06	**Structure out the labeling instructions as per official compendia's and list out**

CO Code	Course outcome
	examples of various official formulations.
CO 502.07	**Appreciate the importance of GLP in manufacturing of dosage forms.**

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 502.01	**3**	**--**	**--**	**---**	**1**	**---**	**----**	**----**	**----**	**2**	**2**
CO 502.02	**3**	**--**	**3**	**3**	**---**	**---**	**1**	**2**	**----**	**2**	**3**
CO 502.03	**3**	**--**	**3**	**3**	**----**	**---**	**1**	**2**	**----**	**3**	**3**
CO 502.04	**3**	**3**	**3**	**3**	**2**	**1**	**1**	**2**	**----**	**3**	**3**
CO 502.05	**3**	**--**	**3**	**3**	**--**	**--**	**--**	**--**	**1**	**3**	**1**
CO 502.06	**3**	**--**	**3**	**1**	**--**	**--**	**--**	**3**	**3**	**3**	**1**
CO 502.07	**3**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**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
01	**UNIT-I**	**Preformulation Studies:** Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances. a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.	**$2^{1/3}$**	**7**
02	**UNIT-II**	**Tablets:** a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling. b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. c. Quality control tests: In process and finished product tests **Liquid orals:** Formulation and	**$3^{1/3}$**	**10**

Order	Topic list/units	Subtopics list	Number of Weeks	Contact Hours
		manufacturing consideration of solutions, suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia		
03	**UNIT-III**	**Capsules:** a. Hard gelatin capsules: Introduction, Extraction of gelatin and production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules. In process and final product quality control tests for capsules. b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minimum/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules **Pellets:** Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets	**$2^{2/3}$**	**8**
04	**UNIT-IV**	**Parenteral Products:** a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity b. Production procedure, production facilities and controls. c. Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals and lyophilized products, Sterilization. d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests. **Ophthalmic Preparations:** Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations	**$3^{1/3}$**	**10**
05	**UNIT-V**	**Cosmetics:** Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens. **Pharmaceutical Aerosols:** Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies. **Packaging Materials Science:** Materials	**$3^{1/3}$**	**10**

Order	Topic list/units	Subtopics list	Number of Weeks	Contact Hours
		used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.		
	Total		**15**	**45**

6.2.Practical Aspects

Order	Name of Experiment	Number of Weeks
1	Preformulation study for prepared granules	**2**
2	Preparation and evaluation of Paracetamol tablets	**2**
3	Preparation and evaluation of Aspirin tablets	**2**
4	Coating of tablets	**1**
5	Preparation and evaluation of Tetracycline capsules	**1**
6	Preparation of Calcium Gluconate injection	**1**
7	Preparation of Ascorbic Acid injection	**1**
8	Preparation of Paracetamol Syrup	**1**
9	Preparation of Eye drops	**1**
10	Preparation of Pellets by extrusion spheronization technique	**1**
11	Preparation of Creams (cold / vanishing cream)	**1**
12	Evaluation of Glass containers	**1**
13	**Total**	**15**

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%

Sr. No.	Assessment Mechanism	Week due	Marks	Proportion of Final Assessment
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	**marzuka.kazi@ybccpa.ac.in**

9.0.TEACHER'S AVAILABILITY FOR STUDENT SUPPORT:

Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time	2:00-3:00	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	**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**

Sr.No.	Title of Learning Material	Details
		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)
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:

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)

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13.0. INFORMATION ABOUT FACULTY MEMBER RESPONSIBLE FOR THE COURSE:

Name	Dr. M.N.CHISHTI
Location	Dr. M.N.Chishti., Third floor, F-4, M.Pharm. Pharmaceutics Lab.
Contact Detail (e-mail &cell no.)	9975145944, marzuka.kazi@ybccpa.ac.in

Office Hours	10:00 AM to 5:00 PM