COURSE MODULE

Program Title	M. Pharmacy
Department	Pharmaceutics
Course Title	Modern Pharmaceutics

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** : M. PHARM.

4.1. Program Specific Outcome:

PSO-1: Independently carry out research and development work by utilizing modern tools like Artificial Intelligence (AI), Computer based Informatics and Simulations Models.

PSO-2: Highlight advancement in knowledge associated with novel as well as conventional drug delivery systems

PSO-3: Build professional, Statistical, computational, analytical, critical thinking and Problem-solving skills.

PSO-4: Apply Good manufacturing Practices and Regulations to Drugs and Cosmetics.

PSO-5: Explain and apply the concepts of Biopharmaceutical, Molecular and Biological aspects in formulation development and drug targeting

5.1.Course Identification and General Information

5.2.Course Description:

a. Course Title:	**M.Pharmacy Pharmaceutics**	
b. Course Number/Code	**MPH 103 T**	
c. Credit Hours	Theory	Practical
	4	-
d. Study level/semester at which this course is offered	Semester I	
e. Pre-requisite	Knowledge of Dosages Forms, Formulations, Physical Pharmacy	
f. Co-requisite	Quality aspects of Pharmaceuticals, Basic Mathematics	
g. Program in which the course is offered	M. Pharm	
h. Language of teaching the course	English	
i. Prepared by	Dr. S.R. Lahoti and Dr. Maria Saifee	
j. Approved by HOD	Dr. S.R. Lahoti	

5.3.

The course is designed to impart advanced knowledge and skills required to learn various aspects and concepts at Pharmaceutical Industries.

5.4.Course Objectives:

Upon completion of this course it is expected that students will be able understand,

1. The elements of pre-formulation studies.

2. Active Pharmaceutical ingredient band Generic product development.

3. Industrial Management and GMO Consideration.

4. Optimization and pilot plant scale up techniques.

5. Stability testing, Sterilization process and packaging of dosage forms.

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

(Use Bloom's Taxonomy words)

CO Code	Course outcome
CO 202.01	Apply the knowledge for pre-formulation studies of various formulations.
CO 202.02	Understand and apply the optimization techniques and statistics in formulation research.
CO 202.03	Ability to professionally manage various activities in industry
CO 202.04	To understand various concepts and principal in dosage form design
CO 202.05	Ability to validate various processes in pharmaceutical industry

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 202.01	**H**	**H**	**M**	**M**	**H**
CO 202.02	**H**	**H**	**H**	**H**	**M**
CO 202.03	**M**	**M**	**H**	**M**	**S**
CO 202.04	**H**	**H**	**H**	**M**	**H**
CO 202.05	**M**	**M**	**M**	**M**	**S**

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**	**a. Preformation Concepts –** Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion	**3 Weeks**	**20**

		and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. **b. Optimization techniques in Pharmaceutical Formulation**: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation		
2	**Unit II**	**Validation**: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	**3 Weeks**	**10**
3	**Unit III**	**cGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	**3 Weeks**	**10**
4	**Unit IV**	**Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	**3 Weeks**	**10**
5	**Unit V**	**Study of consolidation parameters;** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas	**3 Weeks**	**10**

		plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.		
	TOTAL		**15 Weeks**	**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	4%
2	Sessional (Internal Theory exam)	As per schedule of examination	15	6%
3	Continuous Practical Assessment (Sessional Practical exam)	Weekly during practical	20	8%
4	Sessional (Internal Practical exam)	As per schedule of examination	30	12%
5	Final exam (theory)	As per University at end of course	75	30%
6	Final exam(practical)		100	40%
Total			150	**100%**

8.0.STUDENT SUPPORT:

Office hours/week	Other procedures
Two hours minimum	**Sharing of Study materials/ Question Bank**

9.0.TEACHER'S AVAILABILITY FOR STUDENT SUPPORT:

Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time	**1 -2 pm**	**1 -2 pm**	**1 -2 pm**	**1 -2 pm**	**1 -2 pm**	**1 -2 pm**

10.0. LEARNING RESOURCES:

Sr.No.	Title of Learning Material	Details
1	Text books	1) Modern Pharmaceutics; By Gillbert and S. Banker
2	Reference material	1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann 2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann. 3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann. 4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann. 5. Modern Pharmaceutics; By Gillbert and S. Banker. 6. Remington's Pharmaceutical Sciences. 7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett. 8. Physical Pharmacy; By Alfred martin 9. Bentley's Textbook of Pharmaceutics – by Rawlins. 10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig. 11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India. 12.Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi. 13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra. 14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash. 15. Pharmaceutical Preformulations; By J.J. Wells. 16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams. 17. Encyclopaedia of Pharmaceutical technology, Vol I – III.
3	E-materials and websites	1) https://www.fda.gov/ 2) All websites of various drug regulatory bodies
4	Other learning material	ICH and CGMP guidelines, Schedule M

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 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	Dr. S.R. Lahoti
Location	Industry Institute Interaction cell
Contact Detail (e-mail &cell no.)	9823371119 , pharmalahoti@gmail.com
Office Hours	10:00 AM to 5:00 PM

Name	Dr. Maria Saifee
Location	Academic Incharge Cabin
Contact Detail (e-mail &cell no.)	9970070232
Office Hours	10:00 AM to 5:00 PM