Dr. Rafiq Zakaria Campus
Maulana Azad Educational Trust
Y.B. Chavan College of Pharmacy
An ISO 9001:2008 Certified Institute
(B. Pharm., M. Pharm & Research Center)

COURSE MODULE

Program Title	M. Pharmacy
Department	Pharmaceutics
Course Title	CADD (Computer aided drug development)

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

1. AFFILIATED UNIVERSITY : DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

2. DEPARTMENT : Pharmaceutics

4. PROGRAM TITLE : M. PHARM

4.1. Program Outcomes (PO):

PO 01: Ability to independently carry out research/ investigation and development work to solve practical problems.

PO 02: Ability to write and present a substantial technical report/ documents.

PO 03: Ability to demonstrate a degree of mastery over the area as per the specialization of the program.

PSO1: Ability to independently develop the business proposal in the specialized area.

PSO2: Ability to use software and technology in research analysis and product/ process design.

5. COURSE SPECIFICATION :

5.1.Course Identification and General Information

a. Course Title:	Regulatory Affairs		
b. Course Number/ Code	**MPH 203T**		
c. Credit Hours	Theory	Practical	Total
	4	------	4
d. Study level/ semester at which this course is offered	Semester III		
e. Pre-requisite	Computer Application and Statistics (B.Pharm)		
f. Co-requisite	--------		
g. Language of teaching the course	English		
h. Prepared by	Dr. M. H. Dehghan		
i. Approved by	Head of Department Pharmaceutics		

5.2.Course Description/Scope:

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

5.3. Course Objectives

Upon completion of the course, student shall be able to understand:

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

Code	Course outcome
CO S2- MP203T-01	Ability to comprehend the concept of QbD and Computer-aided formulation development and the ethics of computing.
CO S2- MP203T -02	Application of computers in Pharmaceutical Research and Development and Market Analysis.
CO S2- MP203T -03	Knowledge about Computer aided modeling in drug disposition, clinical research, biopharmaceutics and computer simulations in Pharmacokinetics and pharmacodynamics.
CO S2- MP203T -04	Ability to understand pharmaceutical applications of Artificial Intelligence (AI), Robotics and Computational fluid dynamics

5.4.1 CO-PO Matrix: (PO: Program Outcome; CO: Course Outcome)

Course code (CO)	Program Outcome (PO)				
	PO1	PO2	PO3	PSO 1	PSO2
CO S2- MP203T-01	H	M	M	M	H
CO S2- MP203T -02	M	S	M	-	M
CO S2- MP203T -03	H	S	H	S	S
CO S2- MP203T -04	H	M	H	S	M

Correlation levels 1, 2 or 3 as defined below:
S: Slight (Low); M: Moderate (Medium); H: Substantial (High); If there is no correlation, put '-'

6. Teaching and Assessment Methods for achieving learning outcome:

Teaching Strategies /methods used	Methods of Assessment
Lectures Group Discussions Demonstrations Problem Solving Sessions	Assignments Oral Presentations Written Examinations Laboratory Experimental Reports (daily assessment).

6. COURSE CONTENTS:

6.1. Theoretical Aspect:

Order	Topic list/units	Subtopics list	Number of Weeks	Contact Hours
1a	Computers in Pharmaceutical Research and Development	I a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling	4	6
1b	Quality-by-Design In Pharmaceutical Development:	Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - 12 23 examples of application	4	6
II	Computational Modeling Of Drug Disposition:	Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	4	12
III	Non clinical drug development	Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical	4	12

		emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis		
IV a	Computer-aided biopharmaceutical characterization:	Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro-in vivo correlation, Biowaiver considerations	4	6
b.	Computer Simulations in Pharmacokinetics and Pharmacodynamics:	Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems	4	6
V	Artificial Intelligence (AI), Robotics and Computational fluid dynamics:	General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	4	12

6.2. Practical Aspect (If Any):-------

6.3. Assignments/Tutorials:

Assignments are given as questions on the respective chapters.

7. LEARNING RESOURCES:

Sr. No.	Title of Learning Material	Details
1	Text books	**1.** Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2	Essential references (as per syllabus)	1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins,2006, JohnWiley&Sons. 2. Computer-Aided Applications in

		Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing 3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel DekkerInc,NewYork,1996.
3	Reference material	1. Guidance for Industry: Q8(R2) Pharmaceutical Development 2. Guidance for Industry: Q9 Quality Risk Management 3. Guidance for Industry: Q10 Pharmaceutical Quality System 4. G A Lewis, Didier Mathieu, Roger Phan-Tan-Luu. Pharmaceutical Experimental Design, publishers Informa Healthcare, New York.
4	E-materials and websites	www.ich.org/ www.fda.gov/ www.uspto.gov
5	Other learning material	---

8. STUDENT SUPPORT:

Office Hours/Week	Other Procedures
Two hours minimum	WhatsApp, e-mail.

9. SCHEDULE OF ASSESSMENT TASKS DURING THE SEMESTER:

Sr. No.	Assessment Method	Week due	Marks	Proportion of Final Assessment
01	Assignments, Exercises & tutorials/Attendance		10	10%
02	Sessional (Internal Theory exam)		15	15%
04	Final exam (theory)	As per University at end of course	75	75%
Total			100	100%

10. FACILITIES REQUIRED:

Sr. No.	Particular of Facility Required
01	Lecture/ Tutorial Rooms (capacity for 60 students)
02	Laboratory (capacity for 20 students)
03	Computing resources: P-IV-PCs with recent hardware/ utilization of open source and licensed application software

04	Other resources: Appropriate laboratory tools, Chemicals, Glass ware, Apparatus, Instrumentation

11. COURSE IMPROVEMENT PROCESSES:

11.1. Strategies for obtaining student feedback on effectiveness of teaching:

Course delivery evaluation by students using: Questionnaire forms and online questionnaires

11.2. 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.

11.3. Process for improvement of teaching:

Use of ICT tools, teaching aids, Simultaneous practical orientation and theory classes (SPOT), Adoption of reflective teaching.

11.4. Describe the planning procedures for periodically reviewing of course effectiveness and planning for improvement:

Procedure for periodic planning and reviewing includes: periodic review by departmental review committee, review of course delivery and outcome through assessment and feedback from all stake holders.

11.5. Course development plans:

Provide inputs for course improvement and update to University Course development Committees (Board of Studies)

12. INFORMATION ABOUT FACULTY MEMBER RESPONSIBLE FOR THE COURSE:

Name	Dr Dehghan M H
Location	Dept of Pharmaceutics- M.Pharm,
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Office Hours	10:00 AM to 5:00 PM