COURSE MODULE

Program Title	M. Pharmacy
Department	All Departments
Course Title	Research Methodology & Biostatistics

1. **NAME OF INSTITUTION** : Y. B. CHAVAN COLLEGE OF PHARMACY, AURANGABAD
2. **AFFILIATED UNIVERSITY** : DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD
3. **DEPARTMENT** : All Departments
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 Description:

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in themanufacturing industry. It also aids in understanding the quality evaluation in thepharmaceutical industries.

5.2.Course Objectives:

a. To familiarize students regarding teaching methodology & research projects.
b. To teach students preparation of are search projects & different aspects associated withit.
c. To acquaint students with experimental data analysis.
d. To impresss upon students the importance of ethical issues in the profession & plagiarism.
e. To train the students for applications of various statistical methods available for analysis of data.

5. COURSE SPECIFICATION :

5.3.Course Identification and General Information

a. Course Title:	Research Methodology & Biostatistics	
b. Course Number/Code	MRM 301 T	
c. Credit Hours	Theory	Practical

	60	-
d. Study level/semester at which this course is offered	Semester III	
e. Pre-requisite	Basic Knowledge of Pharmacy, Mathematics	
f. Co-requisite	-	
g. Program in which the course is offered	M Pharm	
h. Language of teaching the course	English	
i. Prepared by	Dr. S.R. Lahoti, Dr. J. N. Sangshetti, , Dr. Ayaz Ali, Mrs. Shaikh Sabina Meraj	
j. Approved by Academic In-Charge	Dr. Mrs. Maria Saifee	

5.4.Course Description:

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

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

(Use Bloom's Taxonomy words)

CO Code	Course outcome
CO-1	To understand basic concept and methodology of research
CO-2	Ability to use statistical techniques in data interpretation and analysis.
CO-3	To understand various ethical aspects in Medical Research
CO-4	To create appropriate research design
CO-5	To apply standard Operating Procedures for medical research

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-1	3	3	3	2	2
CO-2	3	1	3	--	2
CO-3	3	1	2	1	2
CO-4	3	3	3	2	3
CO-5	3	1	3	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 '-'

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**	• **White boards** • **Glassware** • **Chemicals**

• **Models** • **Software** • **Charts** • **Smart Boards** • **White boards** • **Online Platform**	• **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**	General R esearch Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.	**03**	**12**
2	**Unit II**	Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	**03**	**12**
3	**Unit III**	Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships,	**03**	**12**

		fatality.		
4	**Unit IV**	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	**03**	**12**
5	**Unit V**	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**02**	**12**
	TOTAL		**15**	**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	10%
2	Sessional (Internal Theory exam)	As per schedule of 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	12:00-1:00	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	1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork. 2. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam, 3. Research Methodology by Kothari
2	Reference material	-
3	E-materials and websites	https://ccsea.gov.in/WriteReadData/userfiles/file/Compendium%20of%20CPCSEA.pdf https://www.vlifesciences.com, https://www.wma.net/
4	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)

13.0. INFORMATION ABOUT FACULTY MEMBER RESPONSIBLE FOR THE COURSE:

Name	Dr S.R. Lahoti
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