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	M. Pharmacy
Department	Pharmacology
Course Title	Pharmacological & Toxicological Screening Methods-II

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

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

3. **DEPARTMENT** : PHARMACOLOGY

4. **PROGRAM TITLE** : M. PHARM.

4.1. Program Specific Outcome:

After completing the program, the student will be able to:

PSO 01: Highlight advancement in knowledge associated with advance pharmacology, toxicology, molecular pharmacology, drug discovery, clinical research and pharmacovigilance.

PSO 02: Independently carry out research and development work in pharmacology and interdisciplinary areas utilizing modern tools and employing problem analysis skills to solve practical problems.

PSO 03: Build the professional skills, computational, analytical and critical thinking skills.

PSO 04: Build protocols to test efficacy, safety and toxicity of the new chemical entities as per the guidelines.

PSO 05: Apply the GLP concepts, CCSEA and OECD guidelines in animal studies.

5. COURSE SPECIFICATION :

5.1.Course Identification and General Information

a. Course Title:	**Pharmacological & Toxicological Screening Methods-II**	
b. Course Number/Code	**MPL 202T**	
c. Credit Hours	Theory	Practical
	04	NA
d. Study level/semester at which this course is offered	Sem II	
e. Pre-requisite	M. Pharm Pharmacology	
f. Co-requisite	Toxicology, Pharmacology	
g. Program in which the course is offered	M Pharm	
h. Language of teaching the course	English	
i. Prepared by	Dr. Syed Ayaz Ali Dr. Hemant D. Une	
j. Approved by HOD	Dr. Syed Ayaz Ali	

5.2.Course Description:

The subject imparts the knowledge on preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

5.3.Course Objectives:

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

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

(Use Bloom's Taxonomy words)

CO Code	Course outcome
CO-104.1	Discuss the various regulatory guidelines for toxicity studies and good laboratory practice.
CO-104.2	Demonstrate various toxicity studies as per the OECD guidelines.
CO-104.3	Demonstrate various advanced toxicity studies such as reproductive, teratogenicity, genotoxicity and carcinogenicity.
CO-104.4	Demonstrate various IND studies needed for IND submission, safety pharmacological studies (Tier 1 and Tier 2 studies).
CO-104.5	Demonstrate various Toxicokinetic studies, their importance and application. Demonstrate alternative methods to animal toxicity testing.

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-104.1	**3**	**2**	**3**	**3**	**3**
CO-104.2	**3**	**2**	**3**	**3**	**2**
CO-104.3	**3**	**2**	**2**	**3**	**2**
CO-104.4	**3**	**3**	**2**	**3**	**2**
CO-104.5	**3**	**3**	**2**	**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** • **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**	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	**03**	**12**
2	**Unit II**	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	**03**	**12**
3	**Unit III**	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	**03**	**12**
4	**Unit IV**	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	**03**	**12**
5	**Unit V**	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	**03**	**12**
TOTAL			**15**	**60**

6.2.Practical Aspects - NA

Order	Name of Experiment	Number of Weeks
1		

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	**ayazpharm@gmail.com** **hemantune@gmail.com**

9.0.TEACHER'S AVAILABILITY FOR STUDENT SUPPORT:

Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time	**10:00-5:00**	**20:00-5:00**	**10:00-11:00**	**10:00-1:00**	**4:00-5:00**	**4:00-5:00**

10.0. LEARNING RESOURCES:

Sr. No.	Title of Learning Material	Details
1	Text books	1.
2	Reference material	Text books in college library
3	E-materials and websites	You tube videos, e-books, slide share
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. Syed Ayaz Ali (SAA)**
Location	Department of Pharmacology
Contact Detail (e-mail &cell no.)	9960883737 (ayazpharm@gmail.com)
Office Hours	10:00 AM to 5:00 PM

Name	Dr. Hemant D. Une (HDU)
Location	Department of Pharmacology
Contact Detail (e-mail & Cell No.)	9823015556 (hemantune@gmail.com)
Office Hours	10:00 AM to 5:00 PM