



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-I |

- 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-I | |
| b. Course Number/Code | MPL 103T | |
| c. Credit Hours | Theory | Practical |
| | 04 | NA |
| d. Study level/semester at which this course is offered | Sem I | |
| e. Pre-requisite | M. Pharm Pharmacology | |
| f. Co-requisite | Pathophysiology, 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 evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject contents helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes.

5.3.Course Objectives:

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Explain the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals.
- Explain the various newer screening methods involved in the drug discovery process.
- Discuss and correlate the preclinical data to humans.

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

(Use Bloom's Taxonomy words)

| CO Code | Course outcome |
|-----------------|---|
| CO-104.1 | Discuss the experimental animal handling, production, guidelines and good laboratory practice. |
| CO-104.2 | Demonstrate various screening models used for Central Nervous System acting drugs. |
| CO-104.3 | Demonstrate various screening models used for drugs acting on respiratory, reproductive, analgesics, anti-inflammatory and Gastrointestinal drugs. |
| CO-104.4 | Demonstrate various screening models used for drugs acting on cardiovascular system, metabolic disorders and cancer. |
| CO-104.5 | Demonstrate various screening models used for drugs acting on Immune system, immunoassay methods evaluation, limitation to animal experimentation and alternate animal experiments, extrapolation of invitro data to preclinical to humans. |

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 | 1 |
| CO-104.3 | 3 | 2 | 2 | 3 | 1 |
| CO-104.4 | 3 | 2 | 2 | 3 | 1 |
| CO-104.5 | 3 | 2 | 2 | 3 | 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 |
|---|---|
| <ul style="list-style-type: none"> • PowerPoints presentation • Videos • Flash Card • Models • Software • Charts • Smart Boards | <ul style="list-style-type: none"> • White boards • Glassware • Chemicals • Instruments • Equipment • Software • Models |

| | |
|---|--|
| <ul style="list-style-type: none"> • White boards • Online Platform | <ul style="list-style-type: none"> • 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 | Laboratory Animals Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animal Good laboratory practice. Bioassay-Principle, scope and limitations and methods | 03 | 12 |
| 2 | Unit II | Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System. | 03 | 12 |
| 3 | Unit III | Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: anti-ulcer, anti -emetic, anti- diarrheal and laxatives. | 03 | 12 |
| 4 | Unit IV | Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, | 03 | 12 |

| | | | | |
|--------------|---------------|---|-----------|-----------|
| | | and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods. | | |
| 5 | Unit V | Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Immunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans | 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) | 2 nd 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 | <ol style="list-style-type: none"> 1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin 2. Screening methods in Pharmacology by Robert Turner. A 3. Evaluation of drugs activities by Laurence and Bachrach 4. Methods in Pharmacology by Arnold Schwartz. 5. Fundamentals of experimental Pharmacology by M.N.Ghosh 6. Pharmacological experiment on intact preparations by Churchill Livingstone |

| | | |
|---|--------------------------|--|
| | | 7. Drug discovery and Evaluation by Vogel H.G. 8. Experimental Pharmacology by R.K.Goyal. 9. Preclinical evaluation of new drugs by S.K. Gupta 10. Handbook of Experimental Pharmacology, SK.Kulkarni 11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3 rd Edition. 12. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK. 13. Screening Methods in Pharmacology, Robert A. Turner. 14. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee. 15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author) |
| 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:

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|---|----------------------------------|
| 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 |

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|---|----------------------------------|
| 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 |