

BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE-PILANI, HYDERABAD CAMPUS
SECOND SEMESTER 2023-2024

Course Handout

Date: 09/01/2023

In addition to Part I (General Handout for all courses appended to the time table) this portion gives further specific details regarding the course.

Course No. : PHA G 624
Course Title : Principle of Toxicology
Instructor in charge : Dr. Abhijeet Joshi
Team of Instructors : Dr. Srinivas Prasad

1) Scope & Objective of the Course:

The course will cover all aspects of the rationale and purpose of preclinical toxicology studies of new drugs under development. It gives in depth understanding to the basic principles and mechanisms of toxicology, different class of toxicants, dose and the concept of dose-response relationship, Toxicokinetics and toxicodynamics, OECD guidelines for toxicological study, International Council for Harmonization (ICH) guidelines, toxicity testing methods in organ systems

Learning Outcomes (course benefits): Students who have undergone the course are expected to

- Understand the molecular mechanisms of chemical toxicity
- Understand the guidelines and methods of testing for chemical toxicity
- Understand the regulatory requirements of preclinical toxicological studies
- Understand the ICH and OCED guidelines for preclinical toxicity testing and safety Pharmacology

2) Text book:

1. Casarett & Doull's Toxicology: The Basic Science of Poisons, 9th Edition
2. A textbook of modern toxicology, by Ernest Hodgson, 4th edition, Wiley publication
3. Fundamentals of Toxicology, 1st edition, Elsevier

Reference Books:

1. Drug Discovery and Evaluation Pharmacological Assays Second Completely Revised, by H. Gerhard Vogel
2. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines
3. Organisation for Economic Co-operation and Development (OECD) Guidelines for the Testing of Chemicals (TGs)
4. Principles of Toxicology Testing By *Frank A Barile: CRC press, 2014*

3) Course Plan:

Lect. No.	Module No.	Lecture Session	References
1-6	Introduction, scope and history of Toxicology	Introduction to toxicology, Principles of Toxicology, general Terms used in toxicology-Toxicant/poisons	TB1- Chapter 2, 3 Class notes
		Mechanisms of toxicity, mechanisms of cell death Types and Classifications of Toxicants, Sub-disciplines of Toxicology, Common Toxic Mechanisms and Sites of Action	
7-12	Toxicity Testing, Dose Response, risk Assessment	Toxicological testing: In vivo systems: In vivo tests or bioassays: Drug toxicity mechanisms and methods to detect toxicity In vitro tests: genotoxicity, Mutagenicity, Chronic, dermal, inhalational, reproductive and developmental toxicology	TB1- Ch2, 4 TB2- Ch 20 Class notes
13-19	To understand the mechanism of Target Organ Toxicity	Drug toxicity mechanisms and methods to detect toxic Responses of the nervous system, liver, lungs, kidney and Heart	TB1- Ch 13 and 14, 15
20-23	To understand the importance of Toxicodynamics Toxicokinetics in pharmaceutical development	Introduction to toxicodynamics and toxicokinetics and toxicokinetic Concepts Disposition of toxicants ADME of toxicants Biotransformation of Xenobiotics	TB1- Ch 5-7; TB2- Ch 5-9 and Class notes
24-26	R3 and Replace Animal Use for Toxicity Testing	In vitro assay: EPIDERM™, EPISKIN™, Embryonic stem cell test, 3T3 NRU phototoxicity test	Class notes
27-30	Molecular and Immunochemical Techniques in Toxicology	Molecular Cloning, cDNA and Genomic Libraries, PCR Evaluation of Gene Expression, Regulation, and Function Proteomics, Metabolomics, epigenomics	Class notes
31-34	Introduction to ICH and OECD guidelines	Introduction to ICH and OECD guidelines for toxicity testing	Self study, Class notes
35-40	Preclinical toxicological investigations of pharmaceutical and Biotechnology products	Regulatory Considerations Specific Poison, Drugs, diagnosis and treatment Therapeutics drugs and antidote	TB1- Ch 12, ICH guidelines

4) Evaluation Scheme:

No.	Evaluation Component	Duration	Weight-age (%)	Date & Time	Nature of Component
1	Surprise quizzes	30 min each	20	Continuous	CB
2	Mid-Sem Examination	90 min	25	As announced in the Timetable	CB
3	Seminar	variable	20	Continuous	OB
4	Comprehensive Exam	180 min	35	As announced in the Timetable	CB (15)/OB (20)

5) **Mid-Semester Grading:** Will be announced after Mid-term test.

6) **Make-up:** Prior approval or intimation to take a make-up is mandatory. It is solely at the discretion of the instructor-in-charge, depending upon the genuineness of the circumstances, to allow or disallow a student to appear for a make-up evaluation component. No makeup will be granted for Assignments/Quizzes under any circumstances.

- **Grading Procedure:** Grading will be done by “bunching” procedure. Total marks obtained by the students will be arranged in descending order, ‘bunches’ will be identified and grades awarded accordingly. Fine grading system (A, A-, B, B-....) will be followed.
- It is not mandatory for the instructor-in-charge to award all the grades (A to E); subjective judgment will be used for awarding the grades.
- As specified in Handout – Part I, appended to the timetable, the instructor in-charge reserves the right to award a NC report in case the student does not make himself/ herself available for any of the evaluation component mentioned above.
- Borderline cases during grading will be judged on the basis of regularity to classes and consistency or progress in the performance in evaluation components.

7) **Chamber Consultation Hours:** will be announced in class

8) **Notices:** All the notices pertaining to this course will be displayed only on google classroom.

Instructor-in-charge