

INDIRA UNIVERSITY, PUNE

SCHOOL OF PHARMACY- MPHARM (Pharmacology)

Term End Examination (2025 Pattern) April- May – 2026- Semester – II

Course Name: Pharmacological and Toxicological Screening Methods-II
Course Code: MPL202T

Max. Marks: 75
Time: 3:00 Hrs.

Instructions

- All Questions are Compulsory. Write two sections on separate answer sheets.
 - Neat diagram must be drawn wherever necessary.
 - Figures to the right indicate full marks.
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Section : I

Q.1 Solve any ONE from the following

15 Marks

- Explain the importance and methods for test item characterization in regulatory toxicity study.
- Describe in detail acute oral toxicity studies as specified in the OECD guidelines.

Q.2 Solve any FOUR from the following

20 Marks

- Write a short note on OECD guidelines.
- Discuss principles and importance of GLP in drug development.
- Discuss acute eye irritation studies.
- Explain the types of toxicity studies with examples.
- Write a short note on skin sensitization studies.
- Write a short note on schedule Y.

Section : II

Q.3 Solve any ONE from the following

15 Marks

- Outline the most common testing methods for genotoxicity studies. Discuss bacterial reverse mutation test as per OECD guidelines.
- Explain in detail in vivo CNS safety pharmacology studies.

Q.4 Solve any TWO from the following

15 Marks

- a. Describe micronucleus assays for genotoxicity studies as per OECD guidelines
- b. Discuss *in-vivo* carcinogenicity studies.
- c. Write a short note on HERG assay.
- d. Explain alternative methods to animal toxicity testing.

Q.5 Solve any TWO from the following

10 Marks

- a. Explain male reproductive toxicity studies.
- b. Describe In Vitro chromosomal aberration assays for genotoxicity studies as per OECD guidelines.
- c. Write a note on Tier II safety pharmacology studies.
- d. Explain toxicokinetic considerations as per ICH guidelines.
