



[Time: 3 Hours]

[Max. Marks: 75]

**Pharmacological and Toxicological Screening Methods - II**

**Q.P. CODE: 5178**

Your answers should be specific to the questions asked.

Draw neat, labeled diagrams wherever necessary.

**LONG ESSAY (Answer any Three)**

**3 X 10 = 30 Marks**

1. What is IND? Describe its importance and list of studies required for the IND submission.
2. Describe in detail about acute, sub acute and chronic oral studies as per OECD guidelines.
3. Describe in detail the ICH guidelines for conducting toxicity studies.
4. Write in detail the segment I and III female reproductive studies.

**SHORT ESSAY (Answer any Nine)**

**9 X 5 = 45 Marks**

5. Discuss Tier 1 respiratory safety pharmacology.
6. Explain the toxicokinetic evaluation in preclinical studies.
7. What is GLP? Write its importance in drug development.
8. Describe EPA guidelines for conducting toxicity studies.
9. Write a note on acute eye irritation studies.
10. Write about the origin and importance of safety pharmacology studies.
11. Briefly write on in vivo carcinogenicity studies.
12. Explain skin sensitization studies.
13. Describe in vitro micronucleus genotoxicity study.
14. Explain alternative methods to animal toxicity testing.

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