



[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. Explain Ames test and chromosomal aberrations studies.
2. Explain in detail Schedule Y.
3. Explain safety pharmacology studies.
4. Explain toxicokinetic studies.

**SHORT ESSAY (Answer any Nine)**

**9 X 5 = 45 Marks**

5. Write briefly about the role of personal and study director in GLP studies.
6. Write briefly about *in-vivo* carcinogenicity study.
7. Write about dermal toxicity studies as per OECD.
8. Write about segment II teratogenicity studies.
9. List of studies needed for IND submission.
10. Briefly explain Tier 1-CVS, CNS and respiratory safety pharmacology studies.
11. Write the principle of any two alternative methods of animal toxicity studies.
12. What are the applications of toxicokinetic studies?
13. Briefly explain the salient points of ICH guidelines.
14. Describe hERG assay.

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