



**NG ESSAY (Answer any Three)**

**3 X 10 = 30 Marks**

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1. Explain in detail Schedule Y.
2. Explain in detail genotoxicity studies.
3. Explain in detail about IND studies and enlist the IND submission parameters.
4. Describe alternative methods of animal toxicity testing.

**SHORT ESSAY (Answer any Nine)**

**9 X 5 = 45 Marks**

5. Briefly explain acute oral toxicity studies (OECD-425 TGs).
6. Briefly explain segment I and II female reproductive toxicity studies.
7. What are the objectives and importance of safety pharmacology studies?
8. Describe hERG assay.
9. Briefly explain absorption and distribution aspects of toxicokinetic studies.
10. Briefly write about types of toxicology.
11. Explain any one in vivo anticancer study.
12. Briefly explain Tier 2-GI, renal and other studies.
13. What are the applications of toxicokinetic studies?
14. Briefly narrate about personnel and organization aspects of GLP studies.

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