



[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 elaborately the OECD principles of Good Laboratory Practice (GLP).
2. Explain in detail male reproductive toxicity studies.
3. Describe the methods and importance of test item characterization in regulatory toxicity studies.
4. Describe in detail about HERG assay.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Write the applications of toxicokinetic studies.
6. Explain Tier -1 CNS safety pharmacology.
7. Explain the alternative methods to animal toxicity testing.
8. Explain the industry perspective of IND.
9. Explain in vivo micronucleus genotoxicity study.
10. Write about in vitro chromosomal aberrations study.
11. Explain the importance of saturation kinetics in toxicokinetic studies.
12. Explain dermal toxicity studies.
13. Write a note on dermal irritation studies.
14. Explain the importance of GLP in drug development.

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