



Pharmacological Screening Methods and Clinical Evaluation

(Revised Scheme 4)

Q.P. CODE: 9350

Your answers should be specific to the questions asked.

Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any TWO)

2 X 20 = 40 Marks

1. Explain about preparation of drug master files – NDA and ANDA. Add a note on salient features of ICH guidelines for efficacy testing of drugs.
2. Write a note on various laboratory animals employed for preclinical research and write the merits/demerits of transgenic and genetically proven animal models.
3. Enumerate and explain various methods available to screen analgesic and anti-inflammatory drugs.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. What are nootropic agents? Name the synthetic/herbal nootropic agents. Explain the principle and method employed in evaluation of nootropic agents.
5. Explain the applicability of cell culture techniques in drug discovery process.
6. Write a note on individualization of pharmacokinetic parameters.
7. Enumerate and explain the various clinical trial designs.
8. Explain the CFR-USFDA and CDSCO for clinical research regulations.
9. Give the composition, roles and responsibilities of Institutional Ethics and Review committee.

SHORT NOTES

2 X 5 = 10 Marks

10. What is biomarker analysis? Write its applications.
11. Write a note on ethics of clinical trial.
