



[Time: 3 Hours]

[Max. Marks: 75]

Clinical Research

Q.P. CODE: 5140

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. Discuss the submission process of IND application in detail.
2. Discuss about the requirements to conduct clinical trial as per schedule Y.
3. Describe the various approaches of health outcome research.
4. Write a note on clinical data management in clinical trials.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Explain briefly the inclusion and exclusion criteria for selection of clinical trial subjects.
6. Discuss various drug characterization techniques in drug development process.
7. Write a note on randomized techniques in clinical trials.
8. Procurement and storage of investigational products.
9. Write a note on clinical trial close out visit.
10. Enumerate the roles and responsibilities of contract research organizations.
11. Write a short notes on Investigator's brochure.
12. Write briefly about case report forms.
13. What is ADE and ADR, differentiate between ADE and ADR.
14. Preparation of audit report for FDA inspection.

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