Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. Explain in detail various phases of clinical trials.
2. Write the principles of ICH-GCP guidelines.
3. Explain in detail the process of designing study protocol in clinical trials.
4. Explain the spontaneous reporting of adverse drug reactions with suitable examples. Write the merits and demerits of spontaneous reporting. (6+4)

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Explain the application of Pharmacoeconomics.
6. Explain the various measures of outcome in a Pharmacoepidemiological study.
7. Define Pharmacovigilance. Write in brief in scope of Pharmacovigilance.
8. Write the role of pharmacist in prevention, monitoring and management of adverse drug reactions.
9. Write the composition and responsibilities of Institutional Review Board.
10. Write a note on case control studies.
11. Explain designing of Case Report Form with suitable example.
12. Explain the role of investigators in clinical trials.
13. Define and classify adverse drug reactions with examples.
14. Write a note on VigiFlow.

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