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

1. Explain in detail the ANDA submission.

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2. Explain in detail the various study designs of BA/BE studies.
3. Explain in detail the principles of ethics in conducting biomedical research and write the challenges in implementing the ethical guidelines.
4. Explain the different phases of clinical trial and write the requirements to conduct clinical trials as per schedule Y.

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

5. Explain in detail the composition of IRB. Add a note on different types of review.
6. Write a short notes on lead optimization.
7. Write a note on CDSCO guidelines.
8. Discuss the roles and responsibilities of sponsor in a study.
9. Explain in detail the prospective and retrospective studies.
10. Explain the roles and responsibilities of contract research organization.
11. Write a short notes on guidelines to develop Investigator's brochure.
12. Discuss the clinical trial document preparation.
13. Define IND. Discuss the different types of IND.
14. Write a note on data mining and warehousing and write its advantages in clinical trial data management.

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