Draw neat, labeled diagrams wherever necessary.

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

1. Discuss Regulatory requirement of ANDA generic drug approval in US.
2. Explain the *In vitro* drug product performance and its limitations.
3. Describe the regulatory guidelines for approval of biologics.
4. Discuss development of clinical trial protocol and add a note on working of institutional review board for clinical trials.

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

5. What are the amendments of Hatch – Waxman Act?
6. Discuss the importance of informed consent in clinical trial.
7. Discuss ICH guidelines related to maintenance.
8. Write a note on Master formula record and distribution records.
9. Discuss the regulatory requirements of investigator brochure.
10. Explain non clinical development related to global submission of NDA.
11. Discuss about CMC in regulations.
12. Explain the Regulatory requirements of ROW countries.
13. Write a note on post approval regulatory affairs.
14. Discuss regulation of combination products.

* * * * *