Draw neat, labeled diagrams wherever necessary.

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

1. List and explain the objectives to be attained during compliance audits of pharmaceutical facilities.
2. Give a brief overview of auditing pharmaceutical production and process controls in a cGMP environment.
3. Give an overview of auditing procedure of a supplier of API.
4. Explain the procedure of auditing water quality in a pharmaceutical production facility.

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

5. With a flow chart explain the auditing procedure of control of drug product containers and closures.
6. Explain the auditing procedure of holding and release of finished products to the market.
7. Explain how granulation procedures of a pharmaceutical product are audited against the BMR.
8. Explain the auditing of a HCG capsule filling line.
9. Write a short note on the audits of active and inactive raw material control.
10. How do you audit the efficacy of a pharmaceutical product by PET?
11. Write a note on auditing ETPs by pollution control authorities.
12. Give a brief overview of management responsibilities during a regulatory audit.
13. Explain the methodological perspective of a pharmaceutical audit.
14. Why are audits essential in assuring pharmaceutical quality?

* * * * *