Draw neat, labeled diagrams wherever necessary.

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

1. How are ICH guidelines organized by scope? List and explain briefly the Q series guidelines of ICH.
2. With a floor plan the layout of a production facility for solid oral dosage forms as mandated by Schedule M.
3. What is a Drug Master File? List its contents.
4. Explain the process of IPQC. Why is it essential? Illustrate the IPQ process for manufacturing process of a capsule formulation.

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

5. What details should the protocol for a GLP study encompass?
6. Compare the scope of QA and QC
7. Explain the environmental control requirements for various production areas.
8. Give the IPQC requirements for topical dosage forms as per IP.
9. Explain the QC tests prescribed for ophthalmic products.
10. How do you audit your vendor for ensuring your purchase specifications?
11. Explain the weight variation test for solid oral dosage forms as per IP.
12. Explain the Common Technical Documentation triangle and it's modules.
13. Explain how you will compute expiry date of a drug product as per ICH requirements.
14. How will you handle disposal of waste products incurred during a pharmaceutical production process?

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