Draw neat, labeled diagrams wherever necessary.

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

1. What are the contents of Investigational New Drugs Application (IND)?
2. Write in detail about Pre-formulation protocol for tablet dosage form.
3. Explain various parameters to be considered during selection of containers closure systems for parenteral formulation.
4. What controls need to be ensured when technical process is transferred from development site to client site?

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

5. Discuss the requirement of Supplemental New Drug Application (SNDA).
6. Discuss Product registration guidelines as per CDSCO.
7. Write a note on stability testing during product development.
8. How pre-formulation study for purity, impurity profiling is carried out?
9. What is Pilot Plant? Explain the factors to be considered in the organization of Pharmaceutical pilot plant.
10. Explain how development of Master Formula and Batch Formula manufacturing records play in important role in pilot plant scale up for tablets production.
11. Define and explain QC tests for blister packaged products.
12. List and explain QC tests for parentral products.
13. Explain metal as the container for the Pharmaceutical Packaging.
14. Explain various Qualitative and Quantitative models of technology transfer.

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