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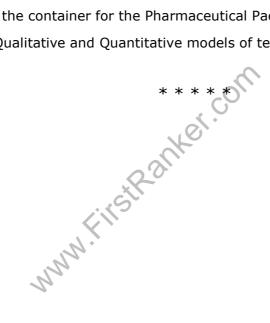
LONG ESSAY (Answer any Three)www.FirstRanker.com

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- 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)

- 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.



9 X 5 = 45 Marks