

Product Development and Technology Transfer

Q.P. CODE: 5104

Your answers should be specific to the questions asked.

Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three)

3 X 10 = 30 Marks

1. Define Solubility. Discuss different methods to improve the solubility.
2. What are the contents of Investigational New Drugs Application (IND)?
3. Discuss the various optimization parameters to be considered during technology transfer.
4. Explain various parameters to be considered during selection of container closure system for parenteral formulation.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Write a note on Bulk Active Chemical Post Approval Changes (BACPAC).
6. Discuss the product registration guidelines as per CDSCO.
7. How is a polymorphic form of drug deduced? Why it is essential in formulation development.
8. What is Pilot Plant? Explain the factors to be considered in the organization of pharmaceutical Pilot Plant.
9. Explain how the development of Master Formula Records and Batch Manufacturing records play an important role in Pilot Plant Scale Up Studies.
10. Discuss the various issues faced during modern drug packaging system.
11. List and explain QC tests for Blister packaged products.
12. Define and explain Primary and Secondary packing materials
13. Write a note Development Report.
14. Explain metal as the container for the Pharmaceutical Packaging.

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