

[Time: 3 Hours]

[Max. Marks: 75]

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. What are the contents of New Drugs Application (NDA)?
2. Define Solubility. Discuss the different methods to improve the solubility.
3. Explain various parameters to be considered during selection of Glass as a primary container system for Pharmaceutical dosage form.
4. Discuss the various Optimization parameters to be considered during Technology transfer.

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

5. Write a note Bulk Active Chemical Post Approval Changes (BACPAC) Guidelines.
6. Write a note on Clinical research process.
7. How is a polymorphic form of drugs deduced? Why it is essential in formulation development?
8. Explain characterization techniques for determination of particle size and surface area.
9. Why is scale up of production processes essential?
10. Explain the protocol for pilot plant scale up for liquid dosage forms.
11. What are the parameters to be considered during mixing of solids during Pilot plant scale up?
12. Define and explain primary and secondary packing materials.
13. Discuss the various Issues faced during modern drug packaging system.
14. Write a note Development report.

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