



Pharmaceutical Technology and Validation

(Revised Scheme 4)

Q.P. CODE: 9362

Your answers should be specific to the questions asked.

Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any TWO)

2 X 20 = 40 Marks

1. Explain the effects of Physicochemical and Biopharmaceutical characteristics of a Drug Substance on Preformulation with suitable examples.
2. Classify IVIVC (In-Vivo In-Vitro Correlation). Explain in detail.
3. Write a note on Water System Validation in a Sterile Manufacturing Unit.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Write a note on Stress Testing of Drug Substances.
5. Write a note on Post Approval changes of a Bulk Active Chemical.
6. Explain the testing of Plastic Containers used for Sterile Dosage Forms.
7. Write a note on Role of Validation in GMP.
8. Prepare a Master Validation Plan for the Manufacturing of Paracetamol IP 500mg Tablets.
9. Explain the Qualification of a Moist Heat Sterilizer.

SHORT NOTES

2 X 5 = 10 Marks

10. Write a note on Accelerated Stability Testing of Drug Substances.
11. What is a Commercial Off the Shelf Software? List the Validation Parameters for the same.

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