



**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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