



**Pharmaceutical Validation -II**

**Q.P. CODE: 5162**

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 is Validation? Explain in detail. Write a detailed note on Validation and Calibration of Analytical equipment.
2. Explain the Qualification of dissolution apparatus.
3. Explain methods to validate Air Handling system for air supply for sterile area.
4. Explain the validation procedures for aseptic filling.

**SHORT ESSAY (Answer any Nine)**

**9 X 5 = 45 Marks**

5. Write about Validation of Tablet Compression.
6. Explain in detail Cleaning Validation.
7. Explain the Qualification Process and documentation of Fluid Bed Drier.
8. Write in brief Re-Validation Process.
9. Differentiate between calibration and validation.
10. Write note on calibration preventive maintenance.
11. Write note on qualification of dry heat sterilization.
12. Write note on scope of validation.
13. Explain the qualification of LC-MS.
14. Write note on process validation of aerosols.

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