



[Time: 3 Hours]

[Max. Marks: 75]

**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? Why is it essential? Explain in detail.
2. Explain the validation of a Fluidized Bed Dryer.
3. Explain in detail the qualification of a HVAC system intended for a sterile manufacturing area.
4. With a representative flow chart explain the process validation of a film coated tablet.

**SHORT ESSAY (Answer any Nine)**

**9 X 5 = 45 Marks**

5. List the factors checked during Design Qualification.
6. Differentiate Qualification and Validation.
7. Write a note on FAT.
8. How will you test the bio-burden of a pharmaceutical sterilization cycle?
9. Briefly explain the validation of a product manufacture.
10. List different analytical methods used in analytical procedures in cleaning validation.
11. Write a note on 21 CFR part 11.
12. Write a note on different types of sampling techniques employed in cleaning validation?
13. Write a note on validation of air handling systems.
14. Explain the process of performing the Qualification of Pharmaceutical water systems.

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