

[Time: 3 Hours]

[Max. Marks: 75]

Pharmaceutical Validation**Q.P. CODE: 5113**

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. Define validation? Discuss about validation process and validation master plan.
2. Discuss briefly about Design qualification? Describe the qualification of FTIR.
3. Explain validation of HVAC system, pharmaceutical water system.
4. Describe the various phases of drug development and drug approval.

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

5. Explain about qualification of manufacturing equipments.
6. Discuss about the qualification of beakers and burette.
7. Discuss about requirements of new IND.
8. Write a brief note on validation of utility system.
9. Discuss about ICH guidelines regarding validation of analytical method.
10. Explain about cleaning validation.
11. Discuss about regulatory aspects Loan License auditing.
12. Explain the qualification of U.V-Visible Spectrophotometer apparatus.
13. Write calibration procedure for HPTLC.
14. Discuss about site acceptance test.

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