

[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 Qualification and Validation? Explain the process of Qualification and Validation. Write a note on Validation Master Plan.
2. Explain the significance of Qualification for analytical instruments. Describe the qualification of HPLC.
3. Elaborate on validation of utility systems with emphasis on Pharmaceutical water system and pure steam.
4. Write a detailed note on Validation of Analytical method as per ICH guidelines.

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

5. Explain FAT and SAT.
6. Explain the Qualification of Volumetric flask and Burette.
7. Write the scope of Cleaning Validation.
8. Explain the various phases of drug development and drug approval.
9. Write a note on ANDA.
10. Write salient features of Consumer Protection Act.
11. Write a note on Regulatory aspects of Bulk drug manufacture.
12. Explain Validation of HVAC system in Pharmaceutical Industry.
13. Elaborate on DQ and IQ of Pharmaceutical Equipments.
14. Write a note on Qualification of pH meter.

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