



1. Define validation. What are the advantages of qualification? Discuss about validation master plan.
2. Explain about calibration of HPLC.
3. Discuss in detail about compressed air and Nitrogen in validation of utility system.
4. Describe the various phases in drug development and drug approval.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Explain about calibration of pH meter.
6. Explain the qualification of volumetric flask.
7. Write a note on loan license.
8. Write a note on cleaning in place.
9. Discuss about analytical method validation by ICH guidelines.
10. Explain about validation of pharmaceutical water system.
11. Write a note on NDA review process.
12. Illustrate the qualification of dissolution apparatus.
13. What are IQ, OQ and PQ? Explain by taking suitable example.
14. Describe about site acceptance test.
