

3 X 10 = 30 Marks

- Explain scope of validation and master plan.
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- 2. Explain in detail about analytical instrument UV-Visible spectrophotometer.
- 3. Briefly explain validation of facilities in sterile and non sterile plants.
- 4. Explain in detail about analytical instrument HPTLC.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

- 5. Write a note on loan license auditing.
- 6. Briefly explain Site Acceptance Test (SAT).
- 7. Explain the working process of analytical instrument FTIR.
- 8. Explain in detail about hardness tester.
- 9. Describe validation process of Aerosols.
- 10. Write a note on computerized system validation.
- 11. Explain ICH guidelines in analytical method of validation.
- 12. Write a note on tap density tester.
- Describe validation process of liquid orals. 13.
- Explain about Factory Acceptance Test (FAT). 14.

