



1. Explain the pilot plant design of tablet dosage form in detail.
2. Explain equipment qualifications of autoclave.
3. Define validation. Explain the process validation of liquid filling sealing.
4. Define industrial hazards. Explain different types of fire extinguishers.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Define technology transfer. Enlist the problems encountered during technology transfer.
6. Describe Validation Master Plan.
7. Explain the importance of installation and operational qualification.
8. Describe the process of validation of mixing.
9. Explain the importance of vendor qualification.
10. Write a note on chemical hazards in pharmaceutical industry.
11. Describe equipment qualification of rotary tablet compression machine.
12. Describe the protocol of cleaning validation.
13. Explain with a neat diagram of a pilot plant layout of parenteral dosage form.
14. Describe prospective validation and concurrent validation.

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