



1. What do you understand by the term preformulation? Explain in detail physical and chemical characterization of a new drug molecule.
2. Explain steps involved in Product Validation.
3. Explain the physics of tablet compression.
4. What are SMEDDs? Explain in detail composition and stability aspects of SMEDDs.

**SHORT ESSAY (Answer any Nine)**

**9 X 5 = 45 Marks**

5. Add a note on compaction profiles and explain graphically.
6. Explain significance of Higuchi and peppas model.
7. Explain essential components of TQM.
8. Explain fragmentation/deformation at point of bonding.
9. Explain retrospective validation and re-validation.
10. Define inventory management. Explain in detail.
11. Explain in brief solubility enhancement techniques.
12. Explain phases in production planning.
13. Explain the concept of TQM.
14. Explain factors such as applied pressure and lubricant on tablet.

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