



2. Explain the details about ICH stability testing for new drug substances.
3. Briefly discuss about filling and sealing machines used in packaging of pharmaceutical products.
4. State design of experiments (DOE). Write note on concepts and optimization parameters in DOE.

**SHORT ESSAY (Answer any Nine)**

**9 X 5 = 45 Marks**

5. Discuss about factorial design in pharmaceutical optimization.
6. Brief note on WHO stability guidelines.
7. Write note on USFDA's aspects in quality by design.
8. Add a note on accelerated stability testing.
9. Discuss about classical of optimization.
10. Write possible interaction between container and product in pharmaceutical packing.
11. Write about the risk assessment in quality by design.
12. Brief note on modern packaging techniques.
13. List out the evaluation of pharmaceutical packaging materials and containers.
14. Give brief note on simplex design.

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