Draw neat, labeled diagrams wherever necessary.

NG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. Write in detail about USGMP with reference to part 210 and part 211.
2. Write in detail about USFDA GLP regulations.
3. Write in detail about principles and requirements of GALP.
4. Write in detail principles and legal GDP requirements.

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Write briefly about WHO cGMP guidelines.
6. Write briefly about training documentation of GALP.
7. Write briefly about the concept of ISO.
8. Write a note on software evaluation checklist.
9. Write a note on stability testing principles.
10. Write a note on Total Quality Management.
11. Write briefly about cleaning validation.
12. Write briefly about cGMP guidelines related to medical devices.
13. Describe the goals of laboratory quality audit.
14. Write a note on validation master plan.

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