



Your answers should be specific to the questions asked.
Draw neat labeled diagrams wherever necessary. Answer all questions

LONG ESSAY (Answer any TWO)**2 X 20 = 40 Marks**

1. Explain the concept of GLP. Outline the procedure for dealing with recovered materials and reprocessing.
2. Write in detail about the layout and good warehousing practices in pharmaceutical industries.
3. What is patent? What are the procedures to be followed while obtaining a patent? What is meant by infringement? What are the laws governing the patent?

SHORT ESSAY (Answer any FIVE)**5 X 10 = 50 Marks**

4. Explain in detail about the procedures involved in GMP certification.
5. Write briefly on:
(a) Recent amendments in Drugs and Cosmetic Act.
(b) Selection of vendors.
6. Explain the following with reference to a pharmaceutical formulation units:
(a) Master formula record.
(b) Quality audits.
7. Discuss the role of quality policy and management approach in "Total Quality Management".
8. Discuss in brief about ISO 9000 series of quality assurance standard.
9. Write short notes on:
(a) Material management.
(b) Line Clearance.

SHORT NOTES**2 X 5 = 10 Marks**

10. Briefly enumerate the recall procedures.
11. Write notes on scrap disposal procedures.

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