

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.
 - a) Discuss the Environmental control in the factory
 - b) Give the qualification, experience, hygiene and training of recruit
2.
 - a) Elaborate the utilities and facilities required by bulk drug industry
 - b) Controls to be imposed for Drug substance
3.
 - a) How to handle the complaints received. Detail its evolution and discuss the rectification
 - b) Quality audit of manufacturing plant
 - c) Discuss the phases of certification of ISO 9000 series

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

4. In a manufacturing unit they are supposed to receive chloroform, ether, pesticides and MORTEIN RAT KILLER, how to handle it. Explain
5. Explain the certificate for stability testing of pharmaceuticals
6. Describe the requirements for animal testing facility
7. What are the differences present between FDA guidelines and schedule M proposed by Govt. of India?
8. What is statutory certificate of suitability? Explain the trade mark act
9. Describe in detail about the applications of modern equipments in practical GLP

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

10. Discuss the ICH guidelines for efficacy
11. Write short notes on construction and maintenance of material store room

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