

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. With the help of a neat sketch explain the layout of the plant for large volume parenteral prepared by terminal sterilization. What different GMP regulations are to be followed in the design of the layout?
2. Explain the different techniques for the study of crystal properties and polymorphism with suitable examples
3. What different industrial hazards are possible in pharmaceutical industry? Explain the preventive measures

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

4. Explain the significance of pilot plant scale up studies. What are the parameters that influence these studies?
5. Explain the significance of human resource development in the pharmaceutical industry
6. Explain the forces involved in the tablet compression
7. What is your understanding of validation? Briefly describe the different techniques employed in the pharmaceutical industry
8. What different statistical methods are employed in the optimization techniques and briefly describe them
9. Explain the physico-chemical characteristics of a new drug molecule relevant to different dosage forms

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

10. What are the salient features of Trade Related Investment Measures (TRIMS)
11. Explain the significance of ISO 9000 series

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