

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

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

1. Explain in detail the design of the product, facilities, requirements and equipment validation for a unit dosage solid preparation.
2. Explain the factors considered in production planning and inventory control measures followed in Pharmaceutical Manufacturing.
3. Draw a sketch of layout for Parenteral manufacturing and explain the service facilities incorporated in it.

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

4. Explain the safety precautions followed for drugs and chemicals during manufacturing.
5. Discuss ICH Guidelines for stability testing of Drugs.
6. Explain how the Effluent and other wastes are managed in industry.
7. Explain the Optimization methods followed in the production Department.
8. Describe the service facilities provided in Pharmaceutical Units.
9. Explain the Compilation procedure followed for Biological Production as per D & C Act.

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

10. Salient features of Intellectual property rights.
11. Salient features of ISO 9001.

* * * * *