

Preformulation and Production Management**(Revised Scheme 4)****Q.P. CODE: 9337**

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 the validation of manufacturing process for sterile and non-sterile products including brief protocols and reports.
2. Explain the various techniques to study the crystal properties and polymorphism.
3. Write a note on compression and consolidation of powders. Explain the influence of compression force on the properties of tablets.

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

4. List-out and explain preliminary evaluation tests required before preformulation studies.
5. Give the difference between ICH and WHO guidelines for stability studies.
6. Give all the general considerations required for setting up a pilot-plant.
7. Explain classical optimization and simplex method.
8. Give the detailed procedure to obtain a patent.
9. Classify material handling equipments and explain in detail.

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

10. Explain briefly the various levels of inventory.
11. Mechanical hazards

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