

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. Answer any ten questions.

LONG ESSAY (Answer any TEN)**10 X 10 = 100 Marks**

1. Explain different methods to enhance the solubility of a poorly soluble drug.
2. a) Write short note on parameters for physical stability testing.
b) Explain the different tools used in quality by design.
3. Compare and contrast the formulation variables between sublingual and buccal tablets.
4. Explain photostability and oxidative stability studies.
5. Explain safety stock, stock out, lead time and modern inventory management system.
6. Explain (a) Validation of HVAC system (b) Validation protocol for water system.
7. Explain (a) Centralized and decentralized purchasing (b) Different methods of buying techniques.
8. a) Define and explain trademark protection law.
b) Explain non-obviousness in patent law.
9. Explain in detail about mechanical hazards and its control and preventive measures.
10. Explain the general procedure for pilot plant scale up technique in pharmaceutical industries.
11. Discuss the role of (a) WIPO (b) TRIPS.
12. Define optimization. Explain about statistical design of experiment by simplex and factorial design.

* * * * *