

PREFORMULATION AND PRODUCTION MANAGEMENT**(RS2 & RS3)****Q.P. CODE: 9282**

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. List-out and explain preliminary evaluation tests required before preformulation studies. Explain preformulation studies.
2. Discuss in detail Q1A (R2) stability testing for drug substances.
3. Write the primary functions and significance of the pharmaceutical pilot plant and explain in detail about the general considerations of pilot plant design.

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

4. Define safety stock. What are its advantages? Give the method of calculation. What is meant by stock out position? Explain the reasons and implications.
5. Give the differences between ICH and WHO guideline for stability.
6. Write the objectives of material management. Discuss the factors to be considered while selecting material handling equipments.
7. What are the various protective measures for keeping machine intact? Give examples. What are the benefits of preventive maintenance?
8. What are the two optimization parameters? Explain. What are the various applications of optimization?
9. Write the formulation aspects of medicated lozenges

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

10. Write a note on GATT and TRIPS.
11. Explain process validation.

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