



[Time: 3 Hours]

[Max. Marks: 100]

FORMULATION PRODUCTION MANAGEMENT

PAPER IV

(Revised Scheme 2)

Q.P. CODE: 9254

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. Discuss the role of pilot plant scale up techniques for various pharmaceutical products.
2. Explain the ICH guidelines, with respect to stability testing of API and finished products
3. Discuss various safety aspects including preventive system during pharmaceutical production.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Explain optimization technique for pharmaceutical formulation and processing.
5. Explain the importance of forecasting for pharmaceutical products.
6. State the procedure to manufacture any Biological product as per D and C act.
7. Give the details of materials handling for various pharmaceutical products.
8. Give the steps of Effluent treatment procedure used in a pharmaceutical manufacturing unit.
9. Give the outline of production, planning and scheduling for pharmaceutical products.

SHORT NOTES

2 X 5 = 10 Marks

10. Define validation explain different types of validation. Add a note on its importance
11. Different layouts with respect to a pharmaceutical industry

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