



[Time: 3 Hours]

[Max. Marks: 100]

CHEMICAL AND BIOLOGICAL EVALUATION

PAPER IV

(RS 2 & RS 3)

Q.P. CODE: 9224

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

LONG ESSAY (Answer any TWO)

2 X 20 = 40 Marks

1. What is method validation? Explain the parameters determined for validating an analytical method
2. Give the principle and methods involved in the bioassay of any three hormone preparations
3. Give an account of the various factors that are to be considered for the layout, environment and water supplies and others for the establishment of a pharmaceutical manufacturing unit

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Write a note on sterility testing and interpellation in a formulation unit
5. Give the procedures for the assay of diphtheria and Tetanus vaccines
6. Explain how computers are useful in a quality control laboratory
7. Give the SOP for a HPLC instrument
8. How do you determine the effectiveness of an antimicrobial preservative
9. Discuss in detail about salvaging of returned goods and reprocessing

SHORT NOTES

2 X 5 = 10 Marks

10. Give the method of microbial assay of vitamin B₁₂
11. How do you test a parenteral preparation for the presence of pyrogens

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