



CHEMICAL AND BIOLOGICAL EVALUATION

PAPER IV

(Revised Scheme 2)

Q.P. CODE : 9224

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. Write a note on:
 - a) Vendor validation
 - b) Handling of returned pharmaceutical products
2. Explain the principle and procedure in the bioassay of Heparin sodium and Typhus vaccine as per IP 1996.
3.
 - a) Explain the principle and procedure in the bioassay of Tuberculin PPD as per IP 1996.
 - b) Explain the calibration of dissolution and disintegration apparatus.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Explain the applications, advantages and disadvantages of computers in QC lab.
5. Why personnel validation is important? Explain the steps in personnel validation.
6. Why calibration of volumetric apparatus is necessary? Write the important steps in calibration of volumetric apparatus by taking suitable examples.
7. Write a note on SOP for monograph analysis.
8. What are the responsibilities and duties of quality control personnel?
9. How do you check the effectiveness of the antimicrobial preservatives Thiomersal and Benzoic acid?

SHORT NOTES

2 X 5 = 10 Marks

10. Explain in brief the sterility testing procedure in various pharmaceutical preparations as per IP 1996.
11. Explain the various analytical standards of water for injection as per IP 1996 in brief.

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