



Chemical and Biological Evaluation

(Revised Scheme 4)

Q.P. CODE: 9360

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. Discuss ware house and vendor audit. Explain briefly the handling of returned pharmaceutical products.
2. Explain WHO certification for export of pharmaceuticals.
3. Write about tests for effectiveness of antimicrobial preservatives.
4. Explain the applications and validation of computers in quality control laboratory.
5. Explain the procedure for the calibration of HPLC and FT-IR.
6. Discuss cleaning and personnel validation in pharmaceutical industry.
7. Write the properties and tests for Bacterial pyrogen and Endotoxins.
8. Explain chemical and biological analysis of water for injection.
9. Explain the concept, methodology involved in microbiological assay of antibiotics.
10. Explain biological sample preparation for Liquid-liquid extraction and solid phase micro extraction.
11. How is cleaning limits for cleaning validation set?
12. Explain the limits for residual solvents for drug substances as per ICH guidelines.

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