

**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. Explain the process of salvaging of returned goods and WHO certification for export of pharmaceuticals.
2. Draw a neat outline of QC lab and explain in detail its planning, design and layout.
3. Explain in detail the methodology and interpretation of Bacterial Enumeration Test (BET).
4. Explain the various applications, advantages and disadvantages of computers in quality control laboratory.
5. Give an elaborate note on calibration procedure of UV – Visible spectrophotometer and analytical balance.
6. What is technology transfer and method verification?
7. Explain chemical and bacteriological analysis of purified water and potable water.
8. Define bioassay. Explain the principle and procedure for the bioassay of Streptokinase.
9. Explain the principle, methodology involved in microbiological assay of antibiotics by turbidimetric method.
10. Mention the various parameters for stability studies and impurity profiling of Q3A and Q3B.
11. Explain the methodology of microbiological assay of antibiotics.
12. Write a note on sample preparation of biological samples.

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