



Analytical Assurance

(Revised Scheme 4)

Q.P. CODE: 9363

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. What are Stability Indicating Assay Methods (SIAM)? Discuss the methodology for development and validation of SIAM.
2. Write the production, chemistry and properties of Bacterial Pyrogens and Endotoxins.
3. Explain in detail the various ICH guidelines for validation of LC method.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Discuss the WHO guidelines for standardization of Herbal drugs.
5. Explain the different sources and types of impurities.
6. Write the Principle, Methodology and Applications of ELISA.
7. Explain in detail the Qualification of UV-Visible spectrometer.
8. Discuss the statistical principles involved in bioassay.
9. Explain the USP Methodology for testing Preservative Efficacy.

SHORT NOTES

2 X 5 = 10 Marks

10. GC-MS
11. Applications of Near IR Spectroscopy

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