



**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. Write in detail the Principle, Different Methods and Applications of Immunological Assays.
2. Write the Production, Chemistry and Properties of Bacterial Pyrogens and Endotoxins.
3. Discuss in detail the validation parameters for bioanalytical methods as per USFDA.

**SHORT ESSAY (Answer any FIVE)**

**5 X 10 = 50 Marks**

4. Discuss the different types of Stability Indicating Assay Methods.
5. Explain the methodology involved in qualification of HPLC.
6. Discuss the requirements for testing Heavy Metals and Pesticides as per WHO and EU.
7. Write a note on sterility testing.
8. Write briefly the Statistical Principles involved in bioassay.
9. Discuss the methodology for Determination of Preservative Efficacy.

**SHORT NOTES**

**2 X 5 = 10 Marks**

10. Scanning Electron Microscopy
11. High throughout Screening in Bioassay

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