

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 a note on Validation of an Analytical method as per ICH E6 guidelines.
2. a) Explain different types of Stability Analysis in Bioanalytical method Validation along with their relevance.
b) Differentiate Herbal Substances, preparations and products. (15+5)
3. Write a note on Residual Solvents identification, characterization and quantification by LC-MS/MS.

SHORT ESSAY (Answer any FIVE)**5 X 10 = 50 Marks**

4. What are Forced Degradation Studies? Why and how are they performed?
5. Compare and contrast EU and WHO requirements for Herbal Products.
6. Explain the principle, advantages and disadvantages of RIA (Radio Immuno Assay).
7. Write a note on Statistics used in Bioassay.
8. How Antimicrobial Effectiveness Testing is performed as per USP?
9. How is the Performance Qualification of a HPLC done?

SHORT NOTES**2 X 5 = 10 Marks**

10. Enlist the Production and Research Applications of NIR (Near Infra Red) Spectroscopy.
11. What is High Through Put Screening? Explain briefly.

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