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Analytical Assurance (Revised Scheme 4) **Q.P. CODE: 9363**

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Your answers should be specific to the questions asked. Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any TWO)

[Time: 3 Hours]

- 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.
- 3. Write a note on Residual Solvents identification, characterization and quantification by LC-MS/MS.

SHORT ESSAY (Answer any FIVE)

- 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.

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- 8. How Antimicrobial Effectiveness Testing is performed as per USP?
- 9. How is the Performance Qualification of a HPLC done?

SHORT NOTES

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

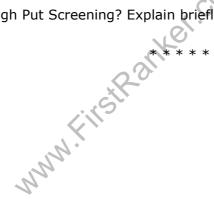
5 X 10 = 50 Marks

2 X 5 = 10 Marks

 $2 \times 20 = 40$ Marks

[Max. Marks: 100]

2016



(15+5)