

QP CODE: 112329

Reg. No:.....

First Semester M.pharm Degree Examinations March 2019

M.Pharm (Pharmaceutical Analysis)

Paper II: Advanced Pharmaceutical Analysis (MPA 102T)

Time: 3 Hours

Total Marks: 75

- Answer all Questions.
- Draw Diagrams wherever necessary.

Essays

(3x10=30)

1. What are the biological test and assay of tetanus anti toxin.
2. Describe the stability testing protocols for sampling frequency and test parameters.
3. Describe the sources, identification and analytical procedures of elemental impurities

Short Notes

(9x5=45)

4. Discuss the ICH guidelines for stability of biological products.
5. The basic principles and production of antibodies in IA.
6. Impurity profiling and degradant characterization of method development.
7. What are the regulatory requirements for stability testing of phytopharmaceuticals.
8. Discuss the characterization and specifications in listing of degradation products
9. Assay of heparin sodium IP.
10. Luminescence IA.
11. Calculation of shelf life.
12. PCR studies for gene regulation.
