

**PARUL UNIVERSITY**  
**FACULTY OF PHARMACY**  
**M. Pharm. Winter 2022- 23 Examination**

**Semester: 1****Subject Code: MPA102T****Subject Name: Advanced Pharmaceutical Analysis****Date: 15/03/2023****Time: 10:00am to 1:00pm****Total Marks: 75****Instructions:**

1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

**Q.1 Essay Type Questions. (any 2 out of 3) (15 Marks Each) (30)**

1. Give a detailed note on classification, limits and analytical procedure for reporting of residual impurities. Write in detail about Elemental Impurities its classification, control and potential source.
2. Write a note on WHO stability studies and explain in detail about biological test and assay of Adsorbed Tetanus vaccine.
3. The regulatory requirements for HPTLC finger printing in stability testing of Phytopharmaceuticals. Explain basic principles and production of antibodies.

**Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Marks Each) (25)**

1. Write note on listing of degradation products in specifications.
2. Describe the methods of C, H, N and S analysis with principle.
3. Write a note on accelerated stability testing & shelf-life calculation as per ICH.
4. Write a note on impurity profiling with respect to photostability.
5. Write a note on PCR.
6. Write a note on Enzyme IA.

**Q.3 Short Answers. (2 Marks Each) (20)**

1. Classify Impurities in drug substances.
2. What is HPLC finger printing?
3. What is stability study protocol?
4. Write about test parameters and sampling frequency in long-term stability studies.
5. State any two guidelines for photosensitivity testing.
6. Describe about Stability zones.
7. Write biological test of Oxytocin.
8. What is Heparin sodium I.P? Explain its assay.
9. Write application of IA.
10. Write principle of Radioimmunoassay.