

**Roll No.**

**Total No. of Pages : 01**

**Total No. of Questions : 06**

**M.Pharmacy (Pharmaceutical Analysis) (Sem.-1)**

# ADVANCED PHARMACEUTICAL ANALYSIS

**Subject Code : MPA-102T**

**M.Code : 74694**

**Date of Examination : 17-01-2023**

**Time : 3 Hrs.**

**Max. Marks: 75**

**INSTRUCTIONS TO CANDIDATES :**

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

**1. Explain in brief :**

- a. Impurities
  - b. Principle of immunoassay
  - c. Importance of Finger printing in stability testing
  - d. Sampling frequency
  - e. Limits of residual solvents.
2. Give a detailed account of classification of impurities in drug substances and their quantification as per ICH guidelines.
  3.
    - a. Give a detailed account on sources, classification and methods for identification of potential elemental impurities in Pharmaceutical products.
    - b. Comment on the affect of buffering species ionic strength and dielectric constant.
  4.
    - a. Write note on WHO and ICH stability testing guidelines.
    - b. Elaborate on stability studies and concepts of validation accelerated stability testing and shelf life prediction.
  5. Give a detailed account on stability testing of Phyto-pharmaceuticals with special emphasis on protocols, finger printing and interactions with suitable examples.
  6.
    - a. Give the biological tests and assay of Rabies Vaccine and Heparin Sodium IP.
    - b. Give a detailed account on principle procedure and instrumentation of PCR studies for gene regulation.

**NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.**