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M.Pharmacy (Pharmaceutical Analysis) (2017 & Onwards) (Sem.–1)

ADVANCE PHARMACEUTICAL ANALYSIS

Subject Code : MPA-102T Paper ID : [74694]

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. a. Give classification of impurities in active pharmaceutical ingredients.
 - b. How to list and report the degradation product content of batches?
 - c. Give classification of residual solvents by risk assessment.
- 2. a. Give the classification of elements on the basis of toxicity and occurrence in the drug products.
 - b. Briefly describe various sources of elemental impurities in drug products.
 - c. Discuss role of mean kinetic temperature in determining stability of a pharmaceutical product.
- 3. Discuss in detail ICH stability testing guidelines.
- 4. a. Describe the role of appropriate selection of markers for stability studies of phytopharmaceuticals.
 - b. Describe fingerprint analysis approach using HPLC for quality control of phytopharmaceuticals.
- 5. a. Describe the assay procedure of oxytocin.
 - b. Give the principle of assay for tetanus vaccine.
 - c. Discuss the assay procedure for heparin sodium IP.
- 6. Describe various types of immunoassay. Discuss in detail enzyme linked immune sorbent assay.

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