UKA TARSADIA UNIVERSITY
M. Pharm. (QA) 2nd Semester
040030202. Modern Pharmaceutical Analysis (Theory)

Duration: 3 hours   **Max. Marks: 70**

Section – I   35 marks

Q.1   a). How analysis of protein products differs from that of small synthetic molecules? Enlist analytical techniques used for standardization of biotechnology-derived articles.   **04 marks**

OR

      a). What is the importance of solid state analysis? Discuss the properties associated with molecular level.   **04 marks**

      b). Describe in brief ICH Quality guidelines.   **07 marks**

Q.2   a). What are impurities? Give types of impurities. Give general scheme/flow chart for drug impurities profiling.   **04 marks**

OR

      a). What are the requirements for Acid/Base stress testing and Photostability studies as per ICH guidelines.   **04 marks**

      b). What is preformulation analysis? Why it is required? Enlist pre-formulation parameters for drug substances. Justify – "Selection of suitable solid form for crystalline API is most important step during preformulation studies".   **08 marks**

Q.3   Write short notes on **ANY TWO.**   **12 marks**
      a). Peptide sequencing by Edman degradation
      b). Isoelectric focusing technique.
      c). Protein Content Assays

Section – II   35 marks

Q.4   a). What are the acceptance criteria for dissolution testing of capsules as per IP?   **03 marks**

OR

      a). What do you mean by sterility testing? Give different steps involved in it.   **03 marks**

      b). Describe methods used for evaluation of cosmetic preparations.   **08 marks**

Q.5   a). Explain the principle of Radioimmuno Assay.   **04 marks**

OR

      a). Write about compendial tests for hard gelatin capsule shells.   **04 marks**

      b). Discuss different standardization parameters used for evaluation of herbal drugs.   **08 marks**

Q.6   Write shot notes on **ANY THREE**.   **12 marks**
      a). Automated analysis
      b). Quality control of radiopharmaceuticals
      c). LAL test for pyrogen
      d). IP Dissolution testing apparatuses