

Question Paper

Exam Date & Time: 24-Nov-2023 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Advanced Pharmaceutical Analysis [PCH-MPA102T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

- 1) What are residual solvents? Give the classification, analytical procedures, limits of residual solvents and reporting levels of residual solvents (10)
- 2) With neat labelled diagram, explain the principle, procedure, components and applications of Radioimmunoassay (10)
- 3) A) Explain the principle, procedure and application of Fluoroimmunoassay. (10)
B) Explain the biological tests and assay of Heparin sodium
- 4) Define Elemental impurities and give their detailed classification. How is their route of exposure estimated and controlled ? (5)
A)
B) Explain the potential sources and identification of potential elemental impurities. (5)
- 5) Explain the Scientific basis of herbal drug stability testing as well as the major challenges that make stability testing of an herbal drug/product a herculean task (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

- 6) How will you classify impurities in API and quantify them? (5)
- 7) Explain in detail the method development, stability studies, concepts of validation and application (5)
- 8) Explain with few examples how enzyme activity influences the degradation of phytopharmaceuticals during the shelf life. (5)
- 9) Write a note on impurity profiling (5)
- 10) Explain the biological Assay of rabies vaccine and adsorbed tetanus vaccine (5)

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