

Exam Date & Time: 14-Dec-2022 (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) Explain with examples the sources of organic impurities. Discuss the rationale for reporting, identification and qualification of an organic impurity as per ICH guidelines. (10)
- 2) a) What are Q3D ICH guidelines? List out the analytical procedures available for the identification of elemental impurities. 4 marks (10)
b) Give the working principle of ICP-OES and Graphite Furnace-AAS 6 marks
- 3) a) Explain the importance of accelerated stability testing of pharmaceuticals. 03 marks
b) Discuss the guidelines for accelerated stability testing as per ICH guidelines. 07 marks (10)
- 4) a) Briefly explain the bioassay of Heparin. 5 marks (10)
b) Discuss the basic steps involved in PCR studies. 5 marks
- 5) Explain the principle of immunoassay with a neat labelled diagram and enlist the important applications of immunoassay. (10)

SECTION - B

Answer all the questions.

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

- 6) Write a note on analytical method development. (5)
- 7) Write the principle and procedure involved in radio-immunoassay. (5)
- 8) Define the following terms as per ICH guidelines:
i) reporting threshold ii) new drug product (5)
iii) identification threshold iv) qualification threshold
- 9) Comment on the following:
a) HPTLC fingerprinting and its importance (5)
b) Use of markers in the standardization of herbal drugs
- 10) What are the protocols for stability testing of phytopharmaceuticals? (5)

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