

Exam Date & Time: 27-Mar-2021 (01:30 PM - 04:30 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Advanced Pharmaceutical Analysis [PCH-MPA102T - S3]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Classify elemental impurities with examples. List out the analytical instruments used for determining elemental impurities. Give the working principle involved in any one of them. (10)
- 2) What is meant by forced degradation study in new drug products? What is the rationale for the reporting and control of degradation products? Give the applications of mass spectrometry. (10)
- 3) What is photo stability of drugs and pharmaceuticals? Explain the guidelines for conducting it (10)
Write a note on impurity profiling and degradant characterisation
- 4) Explain testing frequencies and different storage conditions in stability testing guidelines of Pharmaceuticals (10)
Brief the bioassay procedure of Diphtheria vaccine.
- 5) Write a note on essential components of PCR technique (10)
Discuss the production of antibodies and separation of bound and unbound complexes in immunoassay

SECTION - B

Answer all the questions.

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

- 6) Write a note on evaluation and stability testing of phytopharmaceuticals. (5)
- 7) What are the different types of analytical procedures available for determining residual solvents? How do you report the levels of residual solvents? (5)
- 8) Give the structure, objectives and categories of ICH guidelines. (5)
- 9) Explain Radioimmunoassay in terms of its principle and general methodology (5)
- 10) Explain the basis of RTPCR and its applications (5)

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