

Exam Date & Time: 09-Mar-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) Define impurity. Add a note on sources of impurities. Discuss the rationale for reporting, identification and qualification of an organic impurity as per ICH guidelines. (10)
- 2) What are residual solvents? Classify with examples. How do you analyse and report residual solvents as per ICH guidelines with examples? (10)
- 3) Explain the biological tests and assays for Adsorbed tetanus vaccine. (10)
- 4) Outline the method for the production of mono and poly clonal antibodies. Explain Radioimmunoassay with suitable illustrations. (10)
- 5) Explain ICH stability testing guidelines for API. (10)

SECTION - B

Answer all the questions.

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

- 6) Write a note on Arrhenius equation and calculation of shelf life. (5)
- 7) Write the biological tests and assay for rabies vaccine. (5)
- 8) (5)

Define the following terms as per ICH guidelines:

- i) reporting threshold
- ii) new drug product
- iii) identification threshold
- iv) qualification threshold

- 9) Discuss the challenges in the stability testing of phytopharmaceuticals.
Define the terms; Markers & Finger printing with regard to phytopharmaceuticals. (5)
- 10) Briefly discuss the stability testing guidelines for phytopharmaceuticals. (5)

-----End-----