

Exam Date & Time: 09-Sep-2021 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Modern Bioanalytical Techniques [PCH-MPA202T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Explain solid phase extraction as sample preparation method in biopharmaceutical analysis (5)
 - A)
 - B) Explain how stability is established during bioanalytical method validation as per FDA (5)
- 2) Discuss the various alternative methods in dissolution testing and their applications. (10)
- 3) Explain in vivo measurement of active moiety in biological fluid and in vivo pharmacodynamic comparison methods for assessing Bioavailability and Bioequivalence? (5)
 - A)
 - B) Explain the rate limiting steps like disintegration, solubility and dissolution in drug absorption. Add a note on conditions that may affect drug dissolution and release (5)
- 4) Explain the objectives and classification of good cell culture practice principles. (10)
- 5) Discuss kinetic solubility and thermodynamic solubility (10)

SECTION - B

Answer all the questions.

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

- 6) Discuss the various drug considerations in the design of a drug product (5)
- 7) Explain techniques for measurement of plasma protein binding including its advantage and disadvantages (5)
- 8) Discuss various methods to study the permeability of drug by in-situ. (5)
- 9) Explain general principles to be considered in toxicokinetic studies in preclinical stage. (5)
- 10) Explain the aim, components and applications of a flow cytometer (5)