

# Question Paper

Exam Date & Time: 04-May-2019 (02:00 PM - 05:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.  
MPharm - Pharmaceutical Analysis Specialization  
MPharm Semester II - End Semester Examination, May 2019  
Date :04/05/2019

### 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 and protein precipitation as sample preparation methods in biopharmaceutical analysis (10)
- 2) Discuss the various alternative methods in dissolution testing and their applications (10)
- 3) Write a note on different types and levels of bioanalytical method validation and explain how stability is established during bioanalytical method validation as per FDA (10)
- 4) What are the factors that can be determined with the help of toxicokinetic principles? (10)
- 5) Write in detail about safe laboratory practices to be followed in a cell culture lab. (10)

#### SECTION - B

Answer all the questions.

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

- 6) What are biosimilars? Write a note on FDA recommendation on factors that must be considered in assessing biosimilarity (5)
- 7) Explain the pH-solubility curve for a weak acid and a weak base. Add a note on BCS classification of drugs (5)
- 8) What are the implications of Pharmacokinetic interactions? Explain with suitable examples. (5)
- 9) Explain the different Biosafety levels. (5)
- 10) Write about different types of Cell Culture Hoods (5)

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