

Question Paper

Exam Date & Time: 05-May-2018 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

**MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS- MAY 2018
PROGRAM: MPHARM SEMESTER 2 (PHARMACEUTICAL ANALYSIS)**

DATE: 05/05/2018

TIME: 2:00 PM - 5:00 PM

Modern Bioanalytical Techniques [PCH-MPA202T]

Marks: 50

Duration: 180 mins.

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

- 1) Explain solid phase extraction as sample preparation method in biopharmaceutical analysis (5)
- 2) Discuss any three alternative methods of dissolution testing and their applications (5)
- 3) Explain in detail the saturation shake flask method for solubility determination (5)
- 4) Explain how stability is established during bioanalytical method validation as per FDA (5)
- 5) Write note on storage facilities of a cell culture lab (5)
- 6) With suitable examples, explain the implications of Pharmacodynamic interactions (5)
- 7) Explain the ICH recommendation with regard to single and repeated dose toxicity studies as per its guideline on Toxicokinetics. (5)
- 8) Explain the implications of protein binding. (5)

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

- 9) Enlist the various biopharmaceutical considerations in drug (2)

- A) product design
- B) Explain cross over study design in bioequivalence studies (2)
- C) Explain Biosafety level I and III (2)
- D) Under what circumstances metabolite concentration must be determined as per ICH guideline on Toxicokinetics? (2)
- E) Mention the models used during metabolite identification studies. (2)

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