

Question Paper

Date & Time: 08-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 Biotechnology
MPharm Semester II - End Semester Examination, May 2019
Date : 08/05/2019

Biological Evaluation of Drug Therapy [PBT-MPB204T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Discuss pyrogens as under: physiological effects of pyrogens; sources; LAL test; limitations of rabbit pyrogen test. (10)
- 2) Describe Erythropoietin(EPO) with respect to its functions, regulation of its production and therapeutic applications. (10)
- 3) Enlist the various competent authorities involved in the approval process for a similar biologic and describe the studies needed for its characterization. (10)
- 4) Describe the objectives, steps involved and parameters used in acute and chronic toxicity tests. (10)
- 5) Explain the factors which increase bioavailability of proteinaceous drugs (10)

SECTION - B

Answer all the questions.

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

- 6) Briefly outline the salient features of Class I BCS and Class II BCS products. (5)
- 7) Define the following as per the guidelines on similar biologics: Genetic Engineering; Drug substance; Immunogenicity. (5)
- 8) Briefly explain: Teratogenicity, LD50 and ED50. (5)
- 9) Write briefly on clinical significance of protein based contaminants. (5)
- 10) Write a note on importance of pharmacokinetic models. (5)

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