

Question Paper

Exam Date & Time: 21-May-2024 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Biological Evaluation of Drug Therapy [PBT-MPB204T -S1]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Define the term 'Bioassay'. Explain the advantages and limitations of Bioassay. Describe the 3-3 Quantal Assay for standardization of Pertussis Vaccine. (10)
- 2) Explain the principle, and enlist methods involved in Microbial Limit Tests as per Indian Pharmacopoeia. Describe, the preliminary tests and tests for specific organisms in detail. (10)
- 3) Write the importance of Biosafety levels. With necessary diagrams explain the operation and applications of Type II B2 biosafety cabinet. (10)
- 4) Compare and contrast between one compartment and two compartment models after I.V. bolus administration of a drug. (10)
- 5) Describe in detail the regulatory considerations for preclinical and clinical testing of drugs. (10)

SECTION - B

Answer all the questions.

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

- 6) How does GHS define acute toxicity study? Explain the protocol used for carrying out acute toxicity testing. (5)
- 7) Describe the method for performing sterility testing of a large volume parenteral with a volume more than 100 mL. (5)
- 8) Explain the differences between HEPA and ULPA filters in terms of their efficiency and application in biosafety cabinets. (5)
- 9) Write a note on factors affecting Bioequivalence studies. (5)
- 10) Explain the factors that impact batch disposition decisions. (5)

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