

Exam Date & Time: 20-Jul-2022 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Biological Evaluation of Drug Therapy [PBT-MPB204T]

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'. Describe the direct and indirect methods used in bioassays. (10)
- 2) Describe the protocol of the microbial limit tests for a water-soluble substance regarding - Preliminary testing, Total aerobic microbial count and Tests for specified microorganisms. (10)
- 3) Define cleanroom. How do you classify them based on their operational state? Discuss the mechanisms behind in filtration of air. (10)
- 4) Enlist the different pharmacokinetic models for a drug administered through extravascular route. Describe the one and two compartment models. (10)
- 5) Outlining the goals, describe the process of submission for a successful New Drug Application. (10)

SECTION - B

Answer all the questions.

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

- 6) Explain the biological standardization of Pertussis vaccine. (5)
- 7) What are pyrogens? Describe the in-vitro test for detection of pyrogens. (5)
- 8) Describe biosafety levels of containment (5)
- 9) Explain the factors influencing Bioequivalence studies. (5)
- 10) Write a note on composition and functions of FDA. (5)

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