

# Question Paper

Exam Date & Time: 18-May-2023 (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 -S2]

Marks: 75

Duration: 180 mins.

#### SECTION - A

Answer all the questions.

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

- 1) Define the term 'biological standardization'. Discuss the indirect methods for carrying out Bioassays. (10)
- 2) Explain the principle involved in microbiological assay of antibiotics. Describe the method used to perform the two-level factorial assay. (10)
- 3) How are cleanrooms classified? With necessary diagrams, explain the operation and applications of Type II B2 biosafety cabinet (10)
- 4) When are two drug products shown to be bioequivalent? Discuss the factors influencing bioequivalence studies. (10)
- 5) Write a detailed note on New Drug application (NDA) and guidance documents needed for submission of NDA. (10)

#### SECTION - B

Answer all the questions.

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

- 6) Describe the Kendrick test used for determination of vaccine potency. (5)
- 7) Describe the principle involved in LAL test. (5)
- 8) Write the source, mechanism of action and therapeutic application of insulin (5)
- 9) Write a note on advantages and application of non-compartment models. (5)
- 10) Explain the composition, role and function of Central Drugs Standard Control Organization. (5)

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