

Question Paper

Exam Date & Time: 26-Dec-2023 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Clinical Research [PPR-MPP104T - S2]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Explain the essential components and processes of drug discovery and development. (10)
- 2) Define clinical trial. Discuss the importance of randomization in clinical research (10)
- 3) Describe the requirements for preparing a protocol in clinical research. (10)
- 4) Explain the essential documents required for the clinical trial. (10)
- 5) Explain the roles and responsibilities of auditor and monitor in clinical trial. (10)

SECTION - B

Answer all the questions.

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

- 6) Define clinical data management in research and explain its importance. (5)
- 7) Explain the roles and responsibilities of sponsor and investigator in clinical research? (5)
- 8) Describe the purpose and roles of Institutional Ethics Committee in clinical research. State the benefits to the society because of such committees. (5)
- 9) Define investigational drug product. How is the investigational drug products handled in clinical research. (5)
- 10) Explain the investigator's brochure and patient/subject diary in a clinical trial. (5)

-----End-----