

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.

CLINICAL RESEARCH AND PHARMACOVIGILANCE [PHA-MPL204T-S1]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Explain the battery of safety tests conducted for a test compound (10)
- 2) Explain the composition, roles and responsibilities of institutional ethics committees (10)
- 3) Classify the types of observational studies and write a brief description about each one (10)
- 4) What are the guidelines followed for preparation of clinical trial documents? (10)
- 5) Discuss the progress and development of pharmacovigilance with relevant timelines (10)

SECTION - B

Answer all the questions.

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

- 6) List the principles of ICMR guidelines on research involving human subjects (5)
- 7) Give a brief overview of all the stakeholders involved in a clinical study (5)
- 8) Write a short note on international nonproprietary names for drugs (5)
- 9) Describe the components of investigator's brochure (5)
- 10) Explain the role of pharmacoeconomics in healthcare system (5)

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