

Question Paper

Exam Date & Time: 09-May-2018 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS- MAY 2018
PROGRAM: MPHARM SEMESTER 2 (PHARMACOLOGY)

DATE: 09/05/2018

TIME: 2:00 PM - 5:00 PM

Clinical Research and Pharmacovigilance [PHA-MPL204T]

Marks: 50

Duration: 180 mins.

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

- 1) Describe the roles and responsibilities of pharmacovigilance team (5)
- 2) Explain the guidelines for ADR reporting (5)
- 3) Discuss the principles and applications of pharmaco-economics (5)
- 4) Explain the ways in which pharmacists can contribute to pharmaco-epidemiology (5)
- 5) Explain the roles and responsibilities of principal investigator in clinical trials (5)
- 6) Describe the WHO scale of causality assessment of ADR (5)
- 7) Write the composition of Institutional Review Board and its role in clinical trials (5)
- 8) Discuss the ethical principles involved for human subjects in the conduct of clinical trials (5)

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

- 9) What is a CAPA plan? (2)
 - A) (2)
 - B) List the sources for safety information (2)
 - C) Write the ICH definition of clinical trials (2)

- D) What is the difference between an ADR and an AE? (2)
- E) What do you mean by Informed consent in clinical trials? (2)

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