

Question Paper

Exam Date & Time: 08-May-2019 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

MPharm - Pharmacology

MPharm Semester II - End-Semester Examination May 2019

Date : 08/05/2019

Clinical Research and Pharmacovigilance [PHA-MPL204T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Certain components and capabilities are important for the functioning of a pharmacovigilance system. Explain (10)
- 2) A researcher's responsibility is to educate the subjects about the study purpose in a clinical trial. Identify the document required and its process (10)
- 3) Mention the most common cause of hospital admissions, which comprise a significant economic burden. Discuss the reporting methods (10)
- 4) How do you determine the likelihood of whether an adverse event is actually due to a drug or not. Explain. (10)
- 5) Explain the different methods of randomization. (10)

SECTION - B

Answer all the questions.

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

- 6) Write a short note on vaccine safety surveillance (5)
- 7) Explain the purpose of international classification of diseases (5)
- 8) Which study would you develop to give an estimate of beneficial and adverse effects of a drug for a population? List the types. (5)
- 9) List the components of an informed consent. (5)
- 10) Explain clinical trial profile with the help of an example. (5)

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