Question Paper

Exam Date & Time: 04-Dec-2017 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM : MPHARM SEMESTER I
DATE : 04-12-2017
TIME : 2:00PM - 5:00PM

Clinical Research [PPR-MPP104T]

Marks: 50 **Duration: 180 mins.**

Answer all the questions.

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

1) Explain the principles of ICH GCP guidelines. (5)

2) Explain female reproduction and developmental toxicity studies as per Schedule Y. (5)

3) Discuss therapeutic exploratory trials and therapeutic confirmatory trials in detail. (5)

4) Explain the roles and responsibilities of Sponsor according to FDA. (5)

5) Explain the importance of regulatory authority in the conduct of Clinical Trials with the emphasis on FDA inspection. (5)

6) With Appropriate regulations explain NDA process to FDA. (5)

7) Explain various concepts of clinical data Management in the conduct of Clinical Trial process with appropriate regulations. (5)

8) Discuss contents of Investigator's Brochure in detail. (5)

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

9) Differentiate between a "hit" and a "lead" (2)

A)

B) What is a clinical hold. Mention its types. (2)

C) What is meant by "Nuremberg code". Mention its significance. (2)

D) What is Paragraph IV? (2)

E) What are "FDA Observations" during an inspection ? Which is the form used to list the observations? (2)

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