Question Paper

Exam Date & Time: 01-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 : 01-12-2017
TIME : 2:00PM - 5:00PM

Clinical Research Regulations [PQA-MRA103T]

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

a

Answer all the questions.

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

1) Briefly describe the regulations of pediatric investigation of medicinal products as per ICMR and ICH (5)

2) List the modules of GVP (Good Vigilance Practices) and explain Module II and Module V in detail. (5)

3) Define medical devices and classify them according to USFDA. Write a short note on approval procedure of medical devices followed under European Union (5)

4) What are audits? Mention the types of audits and steps involved in certification audit as per ISO (5)

5) Write a brief note on Clinical Trial Site management and Clinical trial management. (5)

6) Write a brief note on phase III clinical trials (5)

7) Describe the contents of ANDA in brief. (5)

8) Discuss the regulatory requirements for the conduct of pharmacokinetic study to establish bioequivalence (5)

b

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

9) List the regulatory bodies governing medicinal products in US under USFDA (2)

A)

B)	Enlist the contents of Schedule Y as per Drugs and cosmetics act 1940.	(2)
C)	Differentiate between single ascending and multiple ascending trials	(2)
D)	Write the Title I and Title II of Hatch Waxman Act	(2)
E)	Enlist the contents of a NDA application (CTD format)	(2)

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