

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

Regulatory Affairs [PMA-MPD103T]

Marks: 50

Duration: 180 mins.

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

- 1) Explain medicines regulatory functions. (5)
- 2) Write a brief note on global regulatory agencies and professional societies. (5)
- 3) Describe approval procedure to market a new drug in Europe. (5)
- 4) Explain steps involved in drug discovery and development process. (5)
- 5) Define and classify medical devices as per Indian regulatory system. (5)
- 6) Describe bioavailability and bioequivalence. Why BA and BE studies are often required? (5)
- 7) Define nutraceuticals and novel food. Add a note on categorization of cosmeceuticals in a few major markets. (5)
- 8) Explain required and additional elements of Informed consent. (5)

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

- 9) Enlist regulatory ICH parties. (2)
 - A)
 - B) What are the objectives of Good Laboratory Practice. (2)
 - C) Write a note on Drug Master File. (2)

- D) Write in brief about post marketing surveillance. (2)
- E) Write a note on Investigator brochure. (2)

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