Question Paper

Exam Date & Time: 04-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 - Pharmaceutical regulatory affairs
MPharm Semester II - End Semester Examination, May 2019
Date : 04/05/2019

Regulatory Aspects of Herbal and Biologicals [PQA-MRA202T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

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

1) Discuss the data requirements for preclinical studies for approval of "similar biologics" in India. (10)

2) Explain the manufacturing process of biologic drug substance. Add a note on cell lines used in biologics production. (10)

3) Describe the requirements for IND for Phase III clinical trials for botanicals as per USFDA (10)

4) Discuss the EU guideline on stability of biologicals (ICH Q5C) (10)

5) What are the objectives and strategic goals of International Haemovigilance Network (IHN)? (10)

SECTION - B

Answer all the questions.

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

6) Discuss the guidelines on "selection of reference biologic" and "manufacturing process" for approval of similar biologics in India. (5)

7) What are "biosimilars"? Write any five differences between "biosimilar law" and "Hatch Waxman act. (5)

8) Discuss the guidelines on data requirements for "waiver of safety and efficacy study" and "immunogenicity" for clinical trial application of similar biologics in India. (5)

9) Discuss the contents and submission procedures for "FDA Form 2253" (5)

10) Discuss the key requirements to establish a blood bank in India. (5)

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