Exam Date & Time: 09-Sep-2021 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

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) You are submitting a clinical trial application to CDSCO. Discuss are the data requirements for this submission? (10)

2) Analyse the regulatory guidance of FDA on "process development" of biopharmaceuticals. (10)

3) What are the factors to be considered in performing the comparative analytical assessment during the development of therapeutic protein biosimilars as per the USFDA guidance? (10)

4) Discuss the EU guidelines on Specifications for biologics and biotechnology products. (10)

5) Analyse and discuss the blood and blood products regulations of EU (10)

SECTION - B

Answer all the questions.

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

6) Which are the competent authorities involved in the approval process of Similar Biologics in India? What are their responsibilities? (5)

7) Analyse and discuss the guidance of CDSCO on the analytical development of similar biologics. (5)

8) What are the data requirements for the "Technical information section" of PMF? (5)

9) What is Haemovigilance? Write briefly on International Haemovigilance Network. (5)

10) Discuss the FDA requirement of "Evidence to ensure therapeutic consistency" under the NDA for a botanical drug product. (5)

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