Exam Date & Time: 15-Jul-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal MPharm
Theory End-Semester Examinations. July-2022
Department of Pharmaceutical Quality Assurance
Specialization- Pharmaceutical Regulatory Affairs
Sub title: REGULATORY ASPECTS OF HARBAL AND BIOLOGICS
Sub code: PQA-MRA202T

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS [PQA-MRA202T-S1]

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

SECTION - A

Answer all the questions.

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

1)	Analyse the CDSCO guidance on the data requirements for the pre-clinical development of similar biologics.	(10)
2)	What are the regulatory guidance of FDA on process development of Biopharmaceuticals?	(10)
3)	Describe the steps in "Recombinant DNA technology" and the "Biopharmaceutical production process" with necessary diagrams.	(10)
4)	What are the ICH Q5C guidance on the stability testing of biopharmaceutical products?	(10)
5)	Explain the clinical evaluation, marketing authorisation and pharmacovigilance regulations for vaccines in the India.	(10)

SECTION - B

Answer all the questions.

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

6)	What are "Biologics"? Give the classification with one example each.	(5)
7)	What are "Biosimilars"? Differentiate the drug approval guidance of "biosimilar" and "small molecule generics".	(5)
8)	Classify the scientific guidelines of EMA on Biologics.	(5)
9)	Mention the ISBT Standing Committees with their roles	(5)
10)	What are the Quality and Safety regulations implemented in the US for herbal products. Explain in brief?	(5)

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