Question Paper

Exam Date & Time: 05-May-2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - MAY 2018
PROGRAM: MPHARM SEMESTER 2 (PHARMACEUTICAL REGULATORY AFFAIRS)
DATE: 05/05/2018
TIME: 02:00 PM - 5:00 PM

Regulatory Aspects of Herbal and Biologicals [PQA-MRA202T]

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

a

Answer all the questions.

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

1)	Discuss the process development requirements for biologics as per USFDA.	(5)
2)	Discuss the difference between "generic drug" and "biosimilar drug".	(5)
3)	Explain the quality and safety requirements for herbal drugs necessitated by WHO.	(5)
4)	What are the "competent authorities" and "types of manufacturing licenses" for biologics approval in India?	(5)
5)	Briefly discuss the principles of development of similar biologics as per CDSCO.	(5)
6)	Explain the quality attributes in development and manufacturing process of biologics in EU.	(5)
7)	Discuss the development and registration process of vaccine in India.	(5)
8)	Discuss the labelling standards for blood and blood components as per US regulations.	(5)

b

Answer all the questions.

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

9)		(2)

A) What are the types of 510k applications?

B) What are "biological contaminants" in herbal drugs? (2)

C) Define "Specification". Enlist any four specifications for biologics as per EU. (2)

D) Write any two strategic goals of International Haemovigilance Network (IHN). (2)

E) What is VAERS? (2)

-----End-----