Exam Date & Time: 07-Dec-2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
Specialization: Pharmaceutical Regulatory Affairs
Date: 07-12-2018
Regulations and Legislation for Drugs and Cosmetics - Medical Devices - Biologicals and Herbals and [PQA-MRA104T]

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

SECTION - A

Answer all the questions.

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

1) What is patent? Explain the steps in filing a patent application in India. (10)

2) Explain the central regulatory governance and drug approval process in India. (10)

3) Write a note on Schedule Y under D&C act 1940 and briefly explain on clinical trial management systems (10)

4) Enlist the Table of Contents (TOC) of quality, animal and human data for regulatory filing. (10)

5) Write a note on various designs of stability testing of new drugs and products as per ICH with appropriate examples (10)

SECTION - B

Answer all the questions.

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

6) Differentiate between Drug Price Control Order and National Pharmaceutical Pricing Authority of India. (5)

7) Explain the provisions of bonded manufactory. (5)

8) Enlist the acts and regulations governing animal testing in India. (5)

9) Mention the responsibilities of drug inspector as per D&C act 1940. (5)

10) Mention the organogram of Medical Device regulations under CDSCO. (5)

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