Exam Date & Time: 13-Jul-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Regulatory Aspects of Drugs and Cosmetics [PQA-MRA201T]

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

SECTION - A

Answer all the questions.

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

1) Write the conditions when a pharmaceutical company can apply for Sister CEP.

a.) (2)

b.) What is the validity of CEP and write the approval process for renewal of CEP. (8)

2) Name the type of application, content and filling procedure for conducting clinical trials in one or more EU member states. (10)

3) Latam Labs, an Indian Pharma company is planning to market a product in Ukraine. This product is manufacturing but not for sale in India.
a. Write the drug approval process in Ukraine. (5 M)
b. Write the document requirement for approval process in Ukraine. (5 M) (10)

4) Discuss in detail about reporting categories in Supplemental New Drug Application mainly focusing on manufacturing site, manufacturing process and specifications (10)

5) Explain the significance of Phase I and Phase II validation in drug approval process in Saudi Arabia. (10)

SECTION - B

Answer all the questions.

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

6) Explain the role of QUEST system in drugs and cosmetics registration in Malaysia. (5)

7) Explain any 5 types of combination products with suitable examples (5)

8) Explain the notification and permit system for cosmetic regulations in Australia. (5)

9) Explain the safety and labelling requirement of cosmetics in Dubai. (5)

10) What are the difference between class I and class II cosmetics in Brazil?

a.) (2)

b.) Explain the sanitary registration application process of class II cosmetics in Brazil. (3)