Exam Date & Time: 07-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 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) Explain the approval process of new CEP and sister file. (5)

a.)

b.) Explain the risk based selection of inspection site by European Directorate for the Quality of Medicines & HealthCare. (5)

2) Write the relationship between the approval application of the pharmaceutical product and master file application. (2)

a.)

b.) Explain the re-examination and re-evaluation system in the post marketing surveillance of Japan. (8)

3) Explain the components of registration of drugs through WHO prequalification programme. (10)

4) Discuss in detail the approval process for Investigational New Drug (IND) and New Drug Application (NDA). (10)

5) Explain the cosmetic registration requirement in Malaysia. (10)

SECTION - B

Answer all the questions.

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

6) Explain the process of obtaining CoPP for marketing products to US. (5)

7) Explain legislation and regulations for the import, manufacture, distribution, and sale of cosmetics in the United States of America (USA). (5)

8) Explain the notification and assessment of industrial chemicals in cosmetics as per ICNA Act. (5)

9) Explain the different types of variation application in ASEAN countries with examples. (5)

10) Write the registration requirement and approval process of drugs in United Arab (5)

Emirates.

-----End-----