Question Paper

Exam Date & Time: 02-May-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm - Pharmaceutical Regulatory Affairs
MPharm Semester 2 - End-Semester Examination May 2019
Date : 02/05/2019

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 steps involved in the submission and approval process of MAA to the Saudi Food and drug authority. (10)

2) Eddison pharmaceutical company has replaced the manufacturing site of ATORVA, anti-hypertensive drug without any change in the manufacturing process. (10)
a. What type of variation is the above case as per ASEAN regulation. (2 marks)
b. Write the documents required for the approval of this variation. (8 marks)

3) Explain in detail about legislation and regulations for import, manufacture, distribution and sale of cosmetics in CIS countries. (10)

4) a. Write the documents required for variation filling for Type II variations in EU. (5 marks) (10)
b. Explain the processing timeline for Type II variation notification by EU health authority. (5 marks)

5) Discuss in detail about 21CFR-PART-316. (10)

SECTION - B

Answer all the questions.

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

6) Explain in detail about lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity. (5)

7) Explain the J-NDA drug regulatory approval process. (5)

8) a. Do a change in name / address of the marketing authorization holder is categorised as reason for MA transfer? (5)
b. If yes / no, justify the answer?
c. Write the application for transfer of marketing authorization.
(1+1+3 marks)

e the organization chart for EDQM and responsibility of each (5)

(PTO)