Makeup

Paper

Time: 10-Jun-2019 (09:30 AM - 12:30 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 June 2019
Date : 10 / 06 / 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 in detail about legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union. (10)

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

3) Write a comparative chart for the marketing authorization requirement for drug in GCC countries. (10)

4) a. Write briefly about the registration process phase of drugs in Australia.(5) (10)
b. Prepare a label for Moisturizing cream as per the labelling requirement in Australia. (5)

5) Discuss in detail about history and publication procedure of Code of Federal Regulations (CFR). (10)

SECTION - B

Answer all the questions.

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

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

7) a. Write drug approval process of Singapore (3) (5)
b. Write the structure of ACTD. (2)

8) Aether pharmaceuticals, an Indian company plans to market NOVIR, an anti-retroviral product in Indonesia. (5)
a. Write the procedure for marketing authorization for NOVIR. (3)
b. Write the documents required for marketing authorization. (2)

9) Write briefly the EDQM inspection programme for CEP application. (5)

10) Explain the application for MF registration for foreign manufacturers in Japan. (5)

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