

2018-19

Makeup - II Sem

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)

- 3) 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)

-----End-----

Question Paper

Makeup

Exam Date & Time: 11-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 : 11/06/2019

Regulatory Aspects of Food and Nutraceuticals [PQA-MRA204T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) What is the scope of nutraceutical market in India? (10)
- 2) Write a note on NSF certification. (10)
- 3) Who is an implementation partner in "Clean Street Food"? What are the steps of CSF implementation? (10)
- 4) A label on ascorbic acid lozenges reads as "cures scurvy and prevents common cold". Can the manufacturer be sued under DSHEA? Justify. (10)
- 5) Explain the general principles for deriving dietary recommendations as per European Union. (10)

SECTION - B

Answer all the questions.

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

- 6) Compare Indian and US scenario of nutraceuticals. (5)
- 7) Write a note on universal salt iodization. (5)
- 8) What are the training contents of street food vendors as a part of CSF? (5)
- 9) India has lesser recommended dietary allowance of vitamins than US. Comment on this statement by comparing RDA values of both countries. (5)
- 10) Write the role of dietary reference values for nutrients. (5)

-----End-----