

Question Paper

Exam Date & Time: 08-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 : 08/05/2019

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) Atlantic cod is a functional food where as Seven Seas® is a nutraceutical. Comment. (10)
- 2) What are the requirements of production and process control requirements of US GMP for dietary supplements subpart F and G? (10)
- 3) VSO (Voluntary Service Organization) of MAHE decides to implement clean street food - Manipal. They decide to fund it through "Pradhan Mantri Kaushal Vikas Yojana". Is it possible? Explain. (10)
- 4) Why DSHEA was passed by US Congress? (10)
- 5) Explain the functions of European Food Safety Authority. (10)

SECTION - B

Answer all the questions.

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

- 1) Define the following: (5)
 - a. Nutraceuticals.
 - b. Medical Foods
 - c. Dietary Supplements
 - d. Functional Foods
- 7) What is WHO recommendation on infant feeding in areas of Zika Virus transmission and why? (5)
- 8) A. Fragments of Mango seed is found in a product labelled as "Natural Mango Pulp". Is it considered as contaminant within the purview of Food Safety Standard Act 2006? Justify your answer. (5)
B. A chocolate cake was found to contain barley starch. Is the manufacturer punishable under Food Safety Standard Act 2006? Justify your answer
- 9) What is a dietary supplement as per DSHEA? (5)

(PTO)