

Question Paper

Exam Date & Time: 09-May-2018 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES

END SEMESTER THEORY EXAMINATIONS - MAY 2018

PROGRAM: MPHARM SEMESTER 2 (PHARMACEUTICAL REGULATORY AFFAIRS)

DATE: 09/05/2018

TIME: 02:00 PM - 5:00 PM

Regulatory Aspects of Food and Nutraceuticals [PQA-MRA204T]

Marks: 50

Duration: 180 mins.

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

- 1) Explain the ambiguity of nutraceutical nomenclature. (5)
- 2) Write a note on the process of WHO guideline development. (5)
- 3) Write a note on food equipment certification by NSF. (5)
- 4) Write a note on "Sampling Procedure" by food safety officers as per FSSA. (5)
- 5) Write a note on NSF certification. (5)
- 6) Write a note on dietary supplement labelling requirements as per USFDA. (5)
- 7) Explain the types of Dietary Reference Values in Europe in brief. (5)
- 8) Write the methods for deterring the nutritional requirements. (5)

b

Answer all the questions.

Answer the following with specific answers (2 marks x 5 = 10 marks)

- 9) What is SWIFT? (2)
 - A) (2)
 - B) What is fortification of food as per FSSA? (2)
 - C) What are the compliance dates for dietary supplement GMP rules in US? (2)
 - D) (2)

Name any two minerals which have a significant difference in recommended allowance in India and European Union? Why?

E)

Name any four functions of US food GMP inspector.

(2)

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