



DBZ-014-1102004 Seat No. _____

Master of Pharmacy (Sem. II) Examination

July - 2022

Regulatory aspects of food & Nutraceuticals : MRA-204T

**Faculty Code : 014
Subject Code : 1102004**

Time : 3 Hours] [Total Marks : 75

1 Answer the following questions : 20

- (1) How can we differentiate nutraceuticals and food ?
- (2) What is EFSA ? Enumerate its organization.
- (3) What are RDA and NSF in aspects of nutraceuticals ?
- (4) What is the purpose of US FDA Food Safety Modernization Act ?
- (5) Enlist different food safety and standards Acts of India.
- (6) What is Fees structure to get central license of sale of nutraceuticals in India ?
- (7) What is HACCP ?
- (8) Write about Recommended Dietary Allowances of nutraceuticals in India.
- (9) Enlist function of Food Safety Standards Authority of India.
- (10) Which Documents are required for FSSAI registration ?

2 Answer the following questions : (ANY TWO) 20

- (1) What is the purpose of Dietary Supplement Health and Education Act ? Explain U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements.
- (2) Explain in brief about WHO guidelines on nutrition.
- (3) Write a note on GMP for Nutraceuticals.

3 Answer the following questions : (ANY **SEVEN**) **35**

- (1) Differentiate Nutraceuticals, Dietary Supplements, Functional Foods, Medical Food with examples.
- (2) Explain organizations, functions of Food Safety and Standards Act.
- (3) Explain the regulation for import of nutraceuticals in India.
- (4) Explain Product and process development regulations for Manufacture and sale of nutraceuticals and dietary supplements in Europe.
- (5) Write about European Regulation on Novel Foods and Novel Food Ingredients.
- (6) Explain Role of NSF and its Certifications in the Nutraceuticals Industries.
- (7) Explain functions of EFSA.
- (8) Write about Labelling Requirements and Label Claims for Dietary Supplements as per US regulations.
- (9) Explain in brief about Scope and Opportunities in Nutraceutical Market.
