**M. PHARM. (Regulatory Affairs) SEM – II (CBCS – 2019 COURSE) : Winter-2021**
**SUBJECT : REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS**

Day : Thursday | Time : 02:00 PM-05:00 PM
Date : 02-12-2021 | **W-20801-2021** | Max. Marks : 75

**N. B. :**

1) **Q. No. 1** and **Q. No. 5** are **COMPULSORY**. Out of the remaining answer **ANY TWO** question from each Section.
2) Figures to the right indicate **FULL** marks.
3) Answers to both the sections should be written in **SEPARATE** answer books.

## SECTION – I

**Q. 1** Discuss NSF standards for food and dietary supplements. **(08)**

**Q. 2** Explain NSF certification. **(15)**

**Q. 3** Answer the following: **(15)**

**a)** Discuss the scope and opportunities in nutraceutical market.
**b)** What are nutraceuticals?
**c)** Describe good manufacturing practices for nutraceuticals with respect to equipment.

**Q. 4** Write notes on **ANY TWO** of the following: **(15)**

**a)** Process for registration of dietary supplements in India.
**b)** WHO guidelines on neonatal 'Vitamin – A' supplementation.
**c)** Finished product testing (under NSF role in dietary supplements and nutraceuticals industries).

## SECTION – II

**Q. 5** Discuss the US regulations for manufacture and sale of nutraceuticals and dietary supplements. **(07)**

**Q. 6** Discuss the enforcement of Food Safety and Standards Act. **(15)**

**Q. 7** Answer the following: **(15)**

**a)** What are the labelling requirements and label claims for dietary supplements in US?
**b)** Describe the process for clearance of imported food by the Food Safety and Standards Authority of India.
**c)** What is front-of-pack nutrition labelling? Also explain EU law on food information to consumers.

**Q. 8** Write notes on **ANY TWO** of the following: **(15)**

**a)** Analysis of food as per Food Safety and Standards Act.
**b)** European regulations on novel foods and novel food ingredients.
**c)** Recommended Dietary Allowances (RDA) in the USA.

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