SUPPLEMENTARY
MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-II REGULATORY AFFAIRS :SUMMER- 2022
SUBJECT : REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

Day : Wednesday | Time : 10:00 AM-01:00 PM

Date : 21-09-2022 | **S-20801-2022** | Max. Marks : 75

N.B.:

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

SECTION – I

Q.1 Write about scope and opportunities in Nutraceutical Market. **[08]**

Q.2 Discuss in detail good manufacturing practices for Nutraceuticals. **[15]**

Q.3 Explain the role of NSF international in the Nutraceuticals Industries. **[05]**

Q.4 Write short notes on **ANY TWO** of the following: **[15]**

a) Medical food testing

b) WHO guidelines on nutrition

c) Dietary supplements registration process in India

SECTION – II

Q.5 Describe EFSA and its role in regulating Food Supplements, who is responsible for safety and monitoring of food supplements in EU? **[07]**

Q.6 Explain **ANY TWO** of the following and describe the requirements to be fulfilled by the food business operator at all stages of manufacturing, packaging and labelling operations to Comply Food Safety and Standards Regulations, India. **[15]**

a) Food for Special Dietary Use

b) Nutraceuticals

c) Probiotic food

Q.7 Answer the following: **[15]**

a) What does Recommended Dietary Allowances (RDAs) and Dietary Reference Intakes (DRIs) mean as per US Regulations?

b) What are Dietary Reference Values (DRVs) as per EFSA?

c) What does Annex I and Annex II of Directive 2002/46/EC of EU signify?

Q.8 Write short notes on **ANY TWO** of the following: **[15]**

a) Claims for Dietary Supplements in US

b) Novel foods as defined under Food Safety and Standards Regulations, India

c) Labelling requirements for Food Supplements in EU

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