

MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)

M.Pharm. Sem-II : SUMMER : 2022

SUBJECT : REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

Day : Wednesday

Time : 10:00 AM-01:00 PM

Date : 11/5/2022

S-20801-2022

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** What are Dietary supplements, Functional foods and Medical foods? **(08)**
- Q. 2** Discuss NSF standards for food and dietary supplements. **(15)**
- Q. 3** Answer the following: **(15)**
- a) What are Nutraceuticals?
 - b) What is NSF international?
 - c) Describe good manufacturing practices for nutraceuticals with respect to personnel.
- Q. 4** Write notes on **ANY TWO** of the following: **(15)**
- a) NSF certification.
 - b) WHO guideline on iron and folic acid supplementation in menstruating women.
 - c) Finished product testing (under NSF role in dietary supplements and nutraceuticals industries).

SECTION – II

- Q. 5** Explain the EU regulations for manufacture and sale of nutraceuticals and dietary supplements. **(07)**
- Q. 6** Discuss the regulations for import, manufacture and sale of nutraceutical products in India. **(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 food imported for specific purposes in India.
 - c) Which nutrition information is mandatory on food labels as per EU regulations?
- Q. 8** Write notes on **ANY TWO** of the following: **(15)**
- a) Offences and penalties under Food Safety and Standards Act.
 - b) Recommended Dietary Allowances (RDA) in Europe.
 - c) USFDA Food Safety Modernization Act.

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