

**THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY**

**[M.PHARM 0823]**

**AUGUST 2023  
(APRIL 2023 EXAM SESSION)**

**Sub. Code: 3008**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER - II (PCI New Regulations 2016)  
PHARMACEUTICAL REGULATORY AFFAIRS - MRA  
PAPER IV – REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS**

*Q.P. Code: 263008*

**Time : Three hours**

**Answer ALL Questions**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. History of nutraceuticals regulation in INDIA.
2. NSF Standards for Food and Dietary Supplements.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Differentiate between functional foods and medicinal foods.
2. US FDA Food safety Modernization Act.
3. Organisation structure of FSSAI.
4. Recommended Dietary Allowances (RDA) in US.
5. Regulations for import of nutraceuticals in INDIA.
6. European Food Safety Authority (EFSA) organisation structure.
7. Manufacturing and labeling of nutraceuticals.

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