

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

**[M.PHARM 1223]**

**DECEMBER 2023  
(OCTOBER 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. Scope and Opportunities in Nutraceuticals Market in India.
2. Good manufacturing Practices for Nutraceuticals.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Define nutraceuticals. Add a note on dietary supplements and functional foods.
2. WHO guidelines on nutrition.
3. Functions of FSSAI.
4. Recommended Dietary Allowances (RDA) in India.
5. Labeling requirement for dietary supplements in US.
6. European Food Safety Authority (EFSA) functions.
7. European Novel food regulations.

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

**[M.PHARM 0524]**

**MAY 2024  
(APRIL 2024 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. Define NSF. Write down the steps involved in NSF Certification Process.
2. Manufacturing and sale of nutraceuticals in INDIA.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Scope and opportunity of nutraceuticals in INDIA.
2. Nutritional labeling in Europe.
3. Food Safety and Standards Act.
4. Labeling claim for Dietary Supplements.
5. Dietary Supplement Health and Education Act.
6. Recommended Dietary Allowance in Europe.
7. EU Directives and regulation for manufacture and sale of nutraceutical.

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

**[M.PHARM 1025]**

**OCTOBER 2025**

**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. Compare the regulations for sale of nutraceuticals and dietary supplements between India and US.
2. Elaborate on EU directives and regulations for manufacture and sale of nutraceuticals and dietary supplements.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Discuss the Regulations for import of Nutraceuticals in India.
2. Brief on US FDA Food Safety Modernization act.
3. RDA in India vs US. Compare and differentiate between them.
4. What are the steps involved in NSF certification and benefits of NSF certification.
5. European Regulation on Novel food ingredients.
6. Regulation for the manufacture of nutraceuticals in USA.
7. Nutrition labelling in nutraceuticals in European Union and dietary supplements.

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