

INSTITUTE	FACULTY OF PHARMACY
PROGRAM	MASTER OF PHARMACY (REGULATORY AFFAIRS)
SEMESTER	2
COURSE TITLE	REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS
COURSE CODE	13MR0204
COURSE CREDITS	4

Objective:

- 1 This course is designed to impart fundamental knowledge on Regulatory Requirements, Registration, and Labeling Regulations of Nutraceuticals in India, USA, and Europe. It prepares the students to learn in detail on Regulatory Aspects of nutraceuticals and food supplements.

Course Outcomes: After completion of this course, student will be able to:

- 1 Know the regulatory Requirements for nutraceuticals.
- 2 Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA, and Europe.

Pre-requisite of course:--

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	Nutraceuticals Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.	12
2	Global Aspects WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food and Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.	12
3	India Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.	12

Contents : Unit	Topics	Contact Hours
4	USA US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for the manufacture and sale of nutraceuticals and dietary supplements, labeling requirements, and Label Claims for Dietary Supplements Recommended Dietary Allowance (RDA) in the U.S.	12
5	European Union European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for the manufacture and sale of nutraceuticals and dietary supplements. Nutrition labeling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.	12
Total Hours		60

Textbook :

- 1 Handbook of Nutraceuticals, by Yashwant Pathak , CRC Press, 2000

References:

- 1 Regulation of Functional Foods and Nutraceuticals: A Global Perspective, Regulation of Functional Foods and Nutraceuticals: A Global Perspective, by Clare M. Hasler , Wiley Online Library, 2005
- 2 Nutraceutical and Functional Food Regulations in the United States and Around the World , Nutraceutical and Functional Food Regulations in the United States and Around the World , by Debasis Bagchi , Academic Press, Elsevier, 2008
- 3 Food Regulation: Law, Science, Policy, and Practice , Food Regulation: Law, Science, Policy, and Practice , by Neal D. Fortin , Wiley, 2008

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	Understand	Apply	Analyze	Evaluate	Higher order Thinking / Creative
10.00	20.00	25.00	25.00	10.00	10.00

Supplementary Resources:

- 1 <http://www.who.int/publications/guidelines/nutrition/en/>.
- 2 [http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU\(2015\)536324_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf).