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Total No. of Pages : 01

Total No. of Questions : 06

**M.Pharmacy(Regulatory Affairs) (2017 Batch) (Sem.-2)**  
**REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS**

Subject Code : MRA-204T

M.Code : 74940

Time : 3 Hrs.

Max. Marks: 75

**INSTRUCTIONS TO CANDIDATES :**

1. Attempt any FIVE questions out of SIX questions.
  2. Each question carries FIFTEEN marks.
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1. a) What are dietary supplements and medical foods? Giving examples critically explain their role in human body.  
b) Give an overview of the NSF certification of foods.
  2. a) Mention the critical considerations about good manufacturing practices for nutraceuticals.  
b) Give an account of the NSF standards for food and dietary supplements.
  3. a) Describe the FSSAI regulations pertaining to import and sale of nutraceutical products in India.  
b) Discuss the regulations for import of nutraceuticals according to FSSAI.
  4. a) Discuss the US FDA dietary supplement health and education act.  
b) Write a note on the RDA for calcium in the US.
  5. a) What is EFSA? Discuss its organization and functions.  
b) Comment on the chemicals other than vitamins and minerals whose addition to food is prohibited according to EFSA.
  6. Write short notes on :
    - a) Labelling requirements for dietary supplements in the EU.
    - b) RDA for dietary fibre in USA.
    - c) Novel food ingredients in EU.

**NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.**

