Roll No. | | | | | | | | | | | Total No. of Pages: 02

Total No. of Questions: 06

M.Pharmacy (Regulatory Affairs) (Sem.-02)
REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS
Subject Code: MRA204-T
M.Code :79819
Date of Examination: 21-05-2026

Time: 3 Hrs. **Max. Marks : 75**

INSTRUCTIONS TO CANDIDATES:
1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. (a) What are medical foods, functional foods and nutraceuticals? Giving examples explain their role in health care.

   (b) Give an overview of the WHO guidelines on nutrition.

2. (a) Write briefly about GMP 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) Summarize the prohibition orders served under FSSAI Act.

4. (a) Summarize the USFDA Food Safety and Modernization Act regulations with respect to dietary supplements and ingredients.

   (b) Write a note on the RDA for calcium and iron in the US.

5. (a) Mention the EFSA suggested dietary reference values for long chain omega-3 fatty acids and dietary fibre.

   (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 USA.

   (b) EU regulations for sale of nutraceuticals.

   (c) Labelling requirement for carbonated soft drinks according to US regulations.

May - 2026

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Roll No. | | | | | | | | | | | Total No. of Pages : 02

Total No. of Questions : 06

M.Pharmacy (Regulatory Affairs) (Sem–2)

REGULATORY ASPECTS OF MEDICAL DEVICES

Subject Code : MRA203T

M.Code : 79818

Date of Examination : 18-05-2025

Time : 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. **Explain:**

   a) Medical devices

   b) PMA

   c) IDE

   d) UDI

   e) STED

2. How medical devices differ from pharmaceuticals? Explain the principle and life cycle of medical devices.

3. (a) Ethics of clinical investigation plan for medical devices.

   (b) Quality risk management of medical devices.

   (c) Validation and verification of medical devices.

4. (a) Explain regulatory approval process for medical devices as per USA guidelines.

   (b) Highlight labeling requirements and quality system requirements as per USA guidelines.

5. (a) Explain the regulatory registration procedures as per China and Japan guidelines.

   (b) Explain the clinical evaluation and investigation as per ASEAN guidelines.

6. Write short note on:

   (a) Active implantable medical device (as per European Union guidelines).

   (b) In vitro diagnostics.

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Total No. of Questions : 06

M.Pharmacy (Regulatory Affairs) (Sem–2)

REGULATORY ASPECTS OF DRUGS & COSMETICS

Subject Code : MRA201T

M.Code : 79816

Date of Examination : 11-05-2026

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. Explain the structure and organization of EMA and EDQM? What are important components of IMPD? Comment on Active Substance Master Files system in EU?
2. Explain the regulatory approval process for Investigational New Drug (IND), New Drug Application (NDA) and Abbreviated New Drug Application (ANDA)?
3. Discuss Centralized procedure, Decentralized procedure, Mutual recognition procedure and national marketing authorization procedures in EU?
4. What are regulations for import, manufacture, distribution and sale of cosmetics in Japan? Write a note on organization of PMDA?
5. Highlight the significance of ASEAN, APEC, EAC, GCC, PANDRH, and SADC across the globe?
6. What are regulatory requirements for registration of drugs and post approval requirements in ASEAN region?

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Total No. of Questions: 06

M. Pharmacy (Regulatory Affairs) (Sem.–2)

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS

Subject Code : MRA-202T

M.Code: 79817

Date of Examination: 14-05-2026

Time: 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES:

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. Discuss the regulatory requirements for development of similar biologics in India.
2. Explain preclinical and clinical development considerations of biologics in USA.
3. Describe regulatory considerations for advertising, labelling and packing of biologicals in EU.
4. (a) Explain the procedure for registration of vaccines in India.

   (b) What are the objectives of ISBT and IHN?
5. What are the regulatory bodies governing herbal products in India, USA and European Union? What are the regulatory requirements for quality and safety assessment of herbal products in India?
6. Write short note on:

   (a) Plasma master file

   (b) GMP for similar biologics

   (c) Different biological products

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