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

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

REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS

Subject Code : MRA/202T

M.Code : 79817

Date of Examination : 11-05-2024

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) Describe the key data requirements for preclinical studies. Discuss the types of data needed, such as pharmacological, toxicological, and pharmacokinetic data.

   b) Explain their significance in evaluating the safety and efficacy of a new drug or treatment.

2. a) Differentiate between generic drugs and biosimilars in terms of their manufacturing process, approval pathway, and therapeutic equivalence.

   b) Discuss the key regulatory requirements and guidelines that govern the development, approval, and marketing of generic drugs and biosimilars.

3. a) Explain the concept of a Plasma Master File (PMF) and its significance in the regulatory approval process of biologies in European Union.

   b) Discuss the role of the PMF in providing confidential, detailed information about the quality and safety of plasma used in the manufacturing of biologies.

4. a) Discuss the regulatory framework for vaccine approval and distribution in India.

   b) Describe the key regulatory bodies involved in the oversight of vaccines, such as the Central Drugs Standard Control Organization (CDSCO) and the National Regulatory Authority (NRA).

   c) Explain the stages of vaccine development, clinical trials, and the approval process in India, highlighting the importance of safety, efficacy, and quality control measures.

5. Describe the legislative framework governing the manufacturing, sale, and distribution of herbal products in India. Discuss the key regulatory bodies responsible for overseeing herbal products, such as the Ministry of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy), and the Central Drugs Standard Control Organization.

6. Explain the process of clinical evaluation for pharmaceutical products in the United States. Discuss the key stages of clinical trials, including Phase I to Phase III trials, and the regulatory requirements set by the U.S. Food and Drug Administration (FDA) for evaluating safety and efficacy.

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Total No. of Pages : 01

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 : 15-05-2024

Time : 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

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

1. Discuss about various stages of lifecycle of Medical Devices and classify Medical Devices.

2. Discuss about IMDRF, its objectives, organizational structure, functions and its regulatory guidelines.

3. Discuss about classification and approval process of *in vitro* diagnostics in detail.

4. Discuss in detail about post marketing surveillance and unique device identification of Medical Devices.

5. Discuss about IMDRF study groups and guidance documents in detail.

6. Discuss about premarket approval and investigational device exemption for Medical Devices.

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Total No. of Pages : 01

Total No. of Questions : 06

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

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

Subject Code : MRA-204T

M.Code :79819

Date of Examination : 18-05-2024

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

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

1. (a) Describe WHO guidelines on Nutrition.

   (b) Discuss the role of NSF standards for producing Nutraceuticals and Dietary supplements.

2. (a) Give historical background of Nutraceutical regulations.

   (b) What are Dietary Supplements and Medical Food?

3. (a) Describe FSSAI regulations applicable on import of Nutraceutical products in India.

   (b) Give organization of FSSAI and write down its functions.

4. Describe US regulations applicable on manufacture and, sale of Nutraceuticals and Dietary Supplements.

5. Give organization of European Food Safety Authority. Describe EU directives and regulations for manufacture and sale of Nutraceuticals

6. **Write short notes on :**

   (a) Recommended Dietary Allowances in Europe

   (b) US FDA Food Safety Modernization Act.

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Total No. of Pages : 01

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

REGULATORY ASPECTS OF DRUGS & COSMETICS

Subject Code : MRA201T

M.Code : 79816

Date of Examination : 08-05-2024

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1.Attempt any FIVE questions out of EIGHT questions.

2.Each question carries FIFTEEN marks.

1. a) Discuss the WHO requirements for product registration in South Africa. (10)

   b) Discuss the regulations concerning transgenic plants. (5)

2. a) What is Certificate of Pharmaceutical Product? Mention its applicability in India. (10)

   b) Comment on CoPP for African countries. (5)

3. a) What is Active Substance Master File? Discuss the contents of ASMF. (10)

   b) Outline the marketing authorization procedure in according to EMA. (5)

4. a) Differentiate between IND, NDA, SNDA and AND A. Discuss the key regulatory guidelines for each. (10)

   b) Comment on the main features of Orange Book. (5)

5. a) Discuss the key requirements for registration of drugs in ASEAN countries. (10)

   b) Briefly write about the pre-requisites for marketing authorization in CIS countries. (5)

6. **Write short notes on :** (5×3)

   a) Documentation requirements for drug approval in UAE.

   b) Packaging and labelling requirements in EU.

   c) Legislation for sale of cosmetics in GCC countries.

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