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Total No. of Pages : 02

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

REGULATORY ASPECTS OF DRUGS & COSMETICS

Subject Code : MRA201T

M.Code : 79816

Date of Examination : 05-06-2023

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) What is Hatch Waxman Act? Discuss the impact of this act on drug approval.

   b) Highlight the key aspects of SNDA.

2. a) What is IND application? Outline the process for IND approval in USA. Give a detailed account of the data required to be submitted for IND application approval.

   b) Highlight the key aspects of purple book.

3. a) Discuss the post marketing surveillance guidelines according to PMDA.

   b) Comment on the labeling requirements for pharmaceuticals in Japan.

4. a) Discuss the key requirements for registration of drugs in ASEAN countries.

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

5. a) Discuss the regulatory guidelines to import, manufacture and sale in GC countries.

   b) Write a note on WHO requirements for registration of drugs.

6. Write short notes on :

   a) Orphan drugs.

   b) Certificate of suitability in EU.

   c) Legislation for sale of cosmetics in Brazil.

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July-2023

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Total No. of Pages : 01

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

REGULATORY ASPECTS OF MEDICAL DEVICES

Subject Code : MRA-203T

M.Code : 79818

Date of Examination : 02-06-2023

ime : 3 Hrs.

Max. Marks: 75

ISTRUCTIONS TO CANDIDATES :

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

1. Define Medical devices and IVD's. Discuss about the risk-based classification of 15 medical devices and IVD's with examples.

2. Describe the different types of studies for testing of medical devices and IVDs. Discuss about regulations governing medical devices and IVDs.

3. Discuss about clinical investigation plan and Good clinical practices for clinical investigation of medical devices.

4. Discuss in detail about regulatory approval process and premarket notification for 15 medical devices.

5. Discuss about quality system and labeling requirements for medical devices under CFR.

6. Discuss about quality risk management and adverse event reporting of medical devices.

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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 : 30-05-2023

Time : 3 Hrs.

Max. Marks: 75

NSTRUCTIONS TO CANDIDATES :

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

1. What are the regulatory requirements in India for the following? (5+5+5)

   a) Biosimilars

   b) Vaccines

   c) Traditional herbal products

2. a) Compare the regulatory requirements for biosimilars and herbal medicines in USA and the European Union.

   b) When can you apply for IND and NDA? (8+7)

3. What is pharmacovigilance? Why is it required? What are the steps involved? Is this required for herbal medicine? (2+3+6+4)

4. What are the steps for preclinical and clinical evaluation of biologics? What are the requirements for clinical trial application? (8+7)

5. What are the requirements for quality, safety and stability of herbal products in India, USA and EU?

6. What is the procedure for the following : (5+5+5)

   a) Marketing authorization for vaccines

   b) Setting up a blood bank

   c) Labelling requirements for biologics.

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M.Pharmacy (Regulatory Affairs) (Sem–2)
REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS
Subject Code : MRA204-T
M.Code : 79819
Date of Examination : 07-06-2023

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. Describe guidelines on Good Manufacturing Practices of Nutraceuticals.

2. a) Distinguish between Nutraceuticals, Functional Foods and Dietary Supplements. Elaborate your answer with examples.

   b) Discuss the current trends and future scope of Nutraceuticals market.

3. a) Describe FSSAI regulations applicable on manufacture and sale of Nutraceutical products in India.

   b) Define Recommended Dietary Allowance. Write a note on 'RDA in India'.

4. Write in detail on Dietary Supplement Health and Education Act. Discuss labelling requirements for Dietary Supplements.

5. Write down functions of EFSA. Describe EU directives and regulations for manufacture and sale of Nutraceuticals.

6. **Write short notes on :**

   a) European Regulations on Novel Food

   b) NSF Certfication

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

REGULATORY ASPECTS OF MEDICAL DEVICES

Subject Code : MRA-203T

M.Code : 79818

Date of Examination : 08-07-22

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. Define :
   a. Medical devices
   b. IVDs
   c. ISO
   d. Global Medical Device Nomenclature
   e. UDI
   f. Validation
   g. Diagnostics
   h. Clinical evaluation
2. Classify medical devices? Enumerate principle and life cycle of medical devices.
3. Explain :
   a. Clinical investigation of medical devices as per USA guidelines
   b. Quality system regulation of medical devices in general

4. a. Enumerate regulatory approval process for medical devices as per European Union guidelines.
   b. Highlight in vitro diagnostics as per European Union guidelines.
5. a. What are 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. Labelling requirements (as per USA guidelines).
   b. Post marketing surveillance of MD (as per USA guidelines).

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

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

Subject Code : MRA-204T

M.Code : 79819

Date of Examination : 12-07-22

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. Answer very briefly :

a) What are medical foods? Give two examples. (2)

b) What are essential amino acids? Give examples. (2)

c) What are dietary supplements? What is their use? (2)

d) Mention the label requirements for dietary supplements. (2)

e) Mention the role and recommended daily intake of zinc and potassium. (2)

f) Mention the natural dietary sources of iron and calcium. (2)

g) Mention the diseases / disorders due to dietary deficiency of Calcium, Vit C and Iron. (3)

2. a) What is EFSA? Give an overview of its functions. (7.5)

b) Give an account of the dietary reference values set by EFSA for carbohydrates, sugar and dietary fibre. (7.5)

3. a) Distinguish between functional foods and medical foods, giving suitable examples. Briefly explain the importance of nutraceutical market. (7.5)

b) What is NSF International and its purpose? Enlist the information to be submitted for NSF registration of dietary supplements. (7.5)

4. a) Highlight the WHO guidelines for iron and folic acid supplementation in pregnant women. (7.5)

b) Summarize the essential nutrition actions suggested by WHO to prevent malnutrition. (7.5)

5. a) What is FSSAI and what are its functions? Give an overview of its organizational structure. (7.5)

b) Highlight the FSSAI regulations on prohibited advertisements and unfair trade practices. (7.5)

6. Write **short notes** on :

a) EU directives related to presence of allergens and intolerant ingredients on food labels. (5)

b) RDA in India for calcium and iron. (5)

c) Novel food ingredients. (5)

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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 : 06-07-22

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. What are the guidelines in India for the following?
   a) Clinical trials of Biosimilars. (5)
   b) Marketing of Vaccines. (5)
   c) Quality testing of herbal products. (5)
2. a) What are the regulatory guidelines for biologics and herbal medicines in USA and the European Union? (8)
   b) What are the steps involved in development of biologics? (7)
3. What is the importance of Pharmacovigilance? What are the steps involved for herbal medicine and vaccines? (7+8)
4. a) What are the requirements for clinical trial application? (8)
   b) Write a note on blood and blood products regulation (7)
5. Compare the requirements for quality, efficacy, safety and stability testing of herbal products in India, USA and EU? (15)
6. Write note on :
   a) Marketing authorization for biologies. (5)
   b) Difference between Generic Drugs, Branded Drugs and Biosimilars. (5)
   c) Labelling requirements for Biosimilars. (5)

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

REGULATORY ASPECTS OF DRUGS & COSMETICS

Subject Code : MRA-201T

M.Code : 79816

Date of Examination : 04-07-22

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) What is Hatch Waxman Act? Discuss the impact of this Act on drug approval. (10)

   (B) Highlight the key aspects of SNDA. (5)

2. (A) Discuss the requirements for Investigational Medicinal Product Dossier approval. (10)

   (B) Write briefly about packaging and labelling requirements in EU. (5)

3. (A) What is PMDA? Write about the master file system for drug substances in Japan. (10)

   (B) Write briefly about post marketing surveillance in Japan. (5)

4. (A) Discuss the WHO requirements for product registration in South Africa. (10)

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

5. (A) Discuss the key requirements for registration of drugsin ASEAN countries. (10)

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

6. Write short notes on :

   (A) Documentation requirements for drug approval in UAE. (5)

   (B) Certificate of suitability in EU (5)

   (C) Legislation for sale of cosmetics in GCC countries. (5)

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

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

Subject Code : MRA-204T

M.Code : 79819

Date of Examination : 12-07-22

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. **Answer very briefly :**

   a) What are medical foods? Give two examples. (2)

   b) What are essential amino acids? Give examples. (2)

   c) What are dietary supplements? What is their use? (2)

   d) Mention the label requirements for dietary supplements. (2)

   e) Mention the role and recommended daily intake of zinc and potassium. (2)

   f) Mention the natural dietary sources of iron and calcium. (2)

   g) Mention the diseases / disorders due to dietary deficiency of Calcium, Vit C and Iron. (3)

2. a) What is EFSA? Give an overview of its functions. (7.5)

   b) Give an account of the dietary reference values set by EFSA for carbohydrates, sugar and dietary fibre. (7.5)

3. a) Distinguish between functional foods and medical foods, giving suitable examples. Briefly explain the importance of nutraceutical market. (7.5)

   b) What is NSF International and its purpose? Enlist the information to be submitted for NSF registration of dietary supplements. (7.5)

4. a) Highlight the WHO guidelines for iron and folic acid supplementation in pregnant women. (7.5)

   b) Summarize the essential nutrition actions suggested by WHO to prevent malnutrition. (7.5)

5. a) What is FSSAI and what are its functions? Give an overview of its organizational structure. (7.5)

   b) Highlight the FSSAI regulations on prohibited advertisements and unfair trade practices. (7.5)

6. Write **short notes** on :

   a) EU directives related to presence of allergens and intolerant ingredients on food labels. (5)

   b) RDA in India for calcium and iron. (5)

   c) Novel food ingredients. (5)

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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 : 06-07-22

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. What are the guidelines in India for the following?
   a) Clinical trials of Biosimilars. (5)
   b) Marketing of Vaccines. (5)
   c) Quality testing of herbal products. (5)
2. a) What are the regulatory guidelines for biologics and herbal medicines in USA and the European Union? (8)
   b) What are the steps involved in development of biologics? (7)
3. What is the importance of Pharmacovigilance? What are the steps involved for herbal medicine and vaccines? (7+8)
4. a) What are the requirements for clinical trial application? (8)
   b) Write a note on blood and blood products regulation (7)
5. Compare the requirements for quality, efficacy, safety and stability testing of herbal products in India, USA and EU? (15)
6. Write note on :
   a) Marketing authorization for biologies. (5)
   b) Difference between Generic Drugs, Branded Drugs and Biosimilars. (5)
   c) Labelling requirements for Biosimilars. (5)

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