ADICHUNCHANAGIRI UNIVERSITY

M.Pharmacy II Semester Examination – December 2021

TIME: 3 HOURS **MAX.MARKS: 75 MARKS**

Sub: Regulatory Aspects of Drugs and Cosmetics

Q P Code: - 54201

INSTRUCTIONS: 1. Your answer should be specific to the questions asked.
2. Write legibly.
3. Write the same question numbers as they appear in this question paper.
4. Draw neat labelled diagrams wherever necessary.

Long essay (answer **any three**) **3X10=30**

1 Describe the Hatch Waxman Act in the United States. Discuss the Hatch Waxman Act's consequences and legislative amendments.

2 Describe the marketing authorization procedures in the European Union, including timelines.

3 Explain the WHO Prequalification programme in detail. Add a comment about the regulatory procedures for drug registration in Brazil.

4 Pre-requisite regulatory criteria for medication marketing permission and post-approval procedures in any two CIS nations

Short essays (answer **any nine**) **9X5=45**

5 Discuss the Drug Master File (DMF) system in USA

6 Describe the steps involved in obtaining CoPP in South Africa.

7 What are the countries that make up the SADC? Name the countries' regulatory authorities.

8 Explain the South Korean regulatory standards for drug registration.

9 Explain Japan cosmetics manufacturing and import rules

10 What are the various countries that make up the ASEAN Market? Make a note about ACTD.

11 Describe the content and approval process of IMPD

12 Explain the pharmaceutical market in GCC Countries

13 Explain active substance master file in EU

14 Write a note on APEC

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M.Pharmacy II Semester Examination – December 2021

TIME: 3 HOURS **MAX.MARKS: 75 MARKS**

Sub: Regulatory Aspects of Herbals and Biologicals

Q P Code: - 54202

INSTRUCTIONS: 1. Your answer should be specific to the questions asked.
2. Write legibly.
3. Write the same question numbers as they appear in this question paper.
4. Draw neat labelled diagrams wherever necessary.

Long essay (answer **any three**) **3X10=30**

1 Principles for development of similar biologics. Write a short note on GMP for biologics

2 Write the difference between biological and biosimilars. Approval process for biologics in India

3 Write in details of scientific guidelines for bio similarity assessment as per EMA directives

4 Explain the regulations that govern the vaccine development by as per US FDA

Short essays (answer **any nine**) **9X5=45**

5 Write a note on TSE/BSE evaluation.

6 Write the clinical development considerations in USA

7 Safety and advertising requirements for biological in EU

8 Packaging guidelines for Biosimilars in USA

9 Explain ISBT

10 Pharmacovigilance for vaccines in India

11 Legislative guidelines for herbal medicine in EU

12 Write the Indian Regulatory guidelines for herbal medicine

13 US FDA regulatory guidelines for herbal quality

14 Safety regulatory guidelines for herbal medicines in India.

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M.Pharmacy II Semester Examination – December 2021

TIME: 3 HOURS **MAX.MARKS: 75 MARKS**

Sub: Regulatory Aspects of Medical Devices

Q P Code: - 54203

INSTRUCTIONS: 1. Your answer should be specific to the questions asked.
2. Write legibly.
3. Write the same question numbers as they appear in this question paper.
4. Draw neat labelled diagrams wherever necessary.

Long essay (answer **any three**) **3X10=30**

1 Write a brief note on IMDRF and its functions. Explain STED

2 Explain Clinical research in medical devices. Write a note on Clinical Investigation Plan.

3 Approval process for in vitro diagnostics. Add a note on labelling requirements

4 Explain the regulatory approval process as per medical device directives. Classify *in vitro* diagnostics

Short essays (answer **any nine**) **9X5=45**

5 Write a note on Product Life Cycle of Medical Devices

6 Global medical device nomenclature (GMDN)

7 Explain Clinical Investigational Plan

8 Validation and verification of medical devices

9 Write a note on IDE

10 Classification and regulatory approval process for medical devices in EU

11 Implantable medical device directive

12 Write about 21 CFR part 820

13 Clinical Investigation requirements for medical devices Japan

14 Describe the quality system requirements for medical devices in WHO

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M.Pharmacy II Semester Examination – December 2021

TIME: 3 HOURS **MAX.MARKS: 75 MARKS**

Sub: Regulatory Aspects of Food and Nutraceuticals

Q P Code: - 54204

INSTRUCTIONS: 1. Your answer should be specific to the questions asked.
2. Write legibly.
3. Write the same question numbers as they appear in this question paper.
4. Draw neat labelled diagrams wherever necessary.

Long essay (answer **any three**) **3X10=30**

1 What is US FDA Food Safety Modernization Act? What are the Labelling Requirements and Label Claims for Dietary Supplements in USA?

2 Discuss the organization and function of FSSAI and explain the regulation for import of Nutraceuticals?

3 Explain the regulations for manufacture and sale of nutraceuticals and dietary supplements in US?

4 Explain the regulations for Import, Manufacture and Sale of Nutraceutical products in India?

Short essays (answer **any nine**) **9X5=45**

5 Briefly explain European regulation on novel foods and food ingredients?

6 Discuss regulatory requirements for manufacture of nutraceuticals in Europe?

7 What are the recommended dietary allowances in Europe?

8 Write the history of Food and Nutraceutical regulation

9 Recommended Dietary Allowances (RDA) in US?

10 Briefly comment on Dietary supplement Health and Education Act.

11 Explain the registration procedure for nutraceuticals in India

12 Write on Nutrition labelling in Europe

13 Describe the organization and functions of FSSAI?

14 Describe the scope and opportunities in Nutraceuticals Market?

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