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M.Pharmacy (Regulatory Affairs) (Sem.–1)

REGULATIONS & LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICE, BIOLOGICALS & HERBALS, FOOD & NUTRACEUTICALS IN INDIA & INTELLECTUAL PROPERTY RIGHTS

Subject Code : MRA-104T

M.Code : 79183

Date of Examination : 20-12-2024

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) Discuss briefly the provisions contained in the Drugs and Magic Remedies Act. (7.5)

   b) Write a note on the responsibilities of CDSCO. (7.5)

2. a) Discuss briefly the regulatory guidelines for herbal products. (7.5)

   b) Write a note on the procedure for obtaining drug retail license in a State in India. (7.5)

3. a) Write a note on the regulations governing manufacture of nutraceuticals in India. (7.5)

   b) What is bioequivalence? Highlight the key features of a bioequivalence protocol. (7.5)

4. a) Highlight the ethical issues related to human participants in clinical trials. (7.5)

   b) What is CPCSEA? Enumerate its constitution and functions. (7.5)

5. a) Highlight the tests to be conducted for evaluating carcinogenicity in animals. (7.5)

   b) Write a note on Trademarks. (7.5)

6. What is a Dossier? Discuss the format and contents of a dossier for regulatory filing. (15)

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M.Pharmacy (Regulatory Affairs) (Sem.-1)

GOOD REGULATORY PRACTICES

Subject Code : MRA-101T

M.Code : 79180

Date of Examination : 23-12-2024

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES:

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

1. Write a detailed note on WHO cGMP guidelines GAMP - 5.

2. Discuss in detail about Clinical Performance Study Design Types for IVD medical devices.

3. Discuss in detail about GLP inspection and quality audit process and tools.

4. Discuss in detail about SOP's of software usage for GALP.

5. Discuss in detail about quality by design and six sigma concept.

6. Define ICH and discuss the ICH guidelines to establish quality, safety and efficacy of drug substances and products.

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M.Pharmacy (Regulatory Affairs) (Sem.–1)

CLINICAL RESEARCH REGULATIONS

Subject Code : MRA-103T

M.Code : 79182

Date of Examination : 18-12-2024

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 concept and significance of post-marketing surveillance studies.

   b) Classify various types of observational and experimental studies and the study designs.

2. a) Describe the ethical issues related to use of placebo in clinical trials.

   b) Describe the constitution and functions of Institutional Ethics Committee.

3. **Briefly describe the following :**

   a) Clinical research regulations in India.

   b) US FDA Good clinical practice guidelines.

4. Describe the principles and practices of Indian GCP guidelines.

5. a) Describe the USA FDA guidance on financial disclosure by clinical investigators.

   b) Describe the EMA guidance on pharmacovigilance for medicinal products for human use.

6. **Write a short note on the following:**

   a) EU Annual safety report

   b) Data safety monitoring board

   c) Phase 0 studies.

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M.Pharmacy (Regulatory Affairs) (Sem.–1)

DOCUMENTATION & REGULATORY WRITING

Subject Code : MRA 102T

M.Code : 79181

Date of Examination : 16-12-2024

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. **Write in brief or define :**

   a) Certificate of analysis

   b) ESG

   c) EIR

   d) DMF

   e) ISO 13485

2. a) What is product development report? (3)

   b) Discuss the significance of PDR. (7)

   c) Describe the process of post approval labelling changes. (5)

3. a) Outline the content and organization of a dossier. (8)

   b) Summarize the process and need in inspection of drug distribution channels. (7)

4. Describe the root cause analysis of a deviation. Describe corrective and preventive action process. (15)

5. a) Describe the non eCTD electronic submission. Discuss the difference between eCTD and CTD. (10)

   b) Discuss quality aspects of National Good distribution practices. (5)

6. What are audits? Explain the process of preparation and conduct of audit. (15)

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