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M.Pharm (Sem.–1)

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

Subject Code : MRA104T

M.Code : 79183

Date of Examination : 15-12-2023

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. a) How the prices of biological and herbals are fixed or revised by Government under DPCO?

   b) Discuss all the provisions which NPPA notifies for medical devices as drugs under DPCO2013 for quality control & price monitoring.

2. a) Discuss the powers of Central Government to permit/control and regulate the sale of Narcotic and Psychotropic substances.

   b) Write the Education regulation prescribed in Pharmacy Act.

3. a) What are BA and BE studies? Discuss the regulatory requirements of bioequivalence studies.

   b) Discuss about BCS classification of drugs

4. a) Discuss about Pharmacy Act 1948.

   b) Discuss about ICMR - DBT guidelines for stem cell research.

5. Discuss in detail the ICH guidelines for testing of stability of Pharmaceuticals.

6. Define IPR. Discuss in detail about patent, trademark and copyright.

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Total No. of Pages : 01

Total No. of Questions : 06

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

CLINICAL RESEARCH REGULATIONS

Subject Code : MRA103T

M.Code : 79182

Date of Examination : 13-12-2023

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 and explain significance of various phases of clinical trials.

   b) Describe the concept of clinical evaluation of medical devices.

2. a) Describe various ethical issues of clinical research in children.

   b) Describe the role and responsibilities of investigator in ethical conduct of clinical research.

3. **Briefly describe the following :**

   a) Clinical Research regulations in European Union.

   b) Application for approval of a generic drug product.

4. Describe the basic clinical and ethical guidelines for biomedical research as per ICMR.

5. a) Describe the US FDA guidance on IND application,

   b) Describe the EMA guidance on Preparation of Annual Safety Report.

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

   a) Informed consent documentation

   b) Issues on choice of control group in clinical trials

   c) EU MDD with respect to clinical research.

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Total No. of Pages : 1

Total No. of Questions : 06

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

DOCUMENTATION AND REGULATORY WRITING

Subject Code : MRA 102 T

M.Code : 79181

Date of Examination : 11-12-2023

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) Give objectives of Drug Master File (DMF). (5)

   b) Compare US and European Drug master file preparation. (10)

2. a) Discuss in detail Certificate of Analysis (CoA) with its purpose and scope. (4)

   b) Write a note on Product Development Report. (3)

   c) What do mean by BMR. Explain various steps involved to complete BMR. (8)

3. a) Write a note on Product Development Plan. (3)

   b) What do you mean by Batch Reconciliation? Explain its objective and task performed during batch reconciliation. (6)

   c) What do you mean by CTD? Discuss modules of CTD. (6)

4. a) Define audits. Enlists types of audits, explain in brief Audit policy. (9)

   b) Write a short note on Company Auditor. (6)

5. a) Discuss in detail submission process in SUGAM system of CDSCO. (8)

   b) Discuss in detail about preparation for pre-approval inspections of FDA. (7)

6. a) Explain SUPAC guideline to Industry for Immediate Release Solid Oral Dosage Forms with respect to site change. (9)

   b) Define recall. Explain recall procedure for drug product. (6)

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Total No. of Questions : 06

Total No. of Pages : 1

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

GOOD REGULATORY PRACTICES

Subject Code : MRA-101T

M.Code : 79180

Date of Examination : 08-12-2023

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. Write a detailed note on US cGMP part 210 and part 211.

2. Discuss in detail about stages involved in the assessment of clinical evidence for IVD medical devices.

3. Discuss in detail about the provisions contained under USFDA GLP Regulations Subpart E - Testing Facilities Operation.

4. Discuss in detail about principles of GALP and its requirements.

5. Discuss in detail about GDP legal requirements worldwide.

6. Write in detail about types of validation and validation master plan.

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