MRA 101 T

(Total No. of Questions : 14] [Total No.of Pages : 01)

M. PHARMACY DEGREE EXAMINATIONS, JUNE- 2023

First Semester

(PHARMACEUTICAL REGULATORY AFFAIRS)

GOOD REGULATORY PRACTICES

Time : **Three Hours** Maximum : **75** Marks

****

SECTION - A

Answer any FIVE Questions. 5x5 = 25 M

1. Write a short note on Global Harmonization Task Force (GHTF) guidance documents.
2. Discuss the future of GLP regulations.
3. Explain the principles of GALP.
4. Describe the GDP regulations for premises and equipment.
5. Write a note on validation master plan.
6. What do you mean by Total Quality Management.
7. Write a brief note on cGMP guidelines related to Medical devices.

SECTION - B

Answer any FIVE Questions. 5x10 = 50 M

8. Write a brief note on production and process controls and packaging and labeling control as per US cGMP.
9. Give an account on goals of laboratory quality audit and audit tools.
10. Discuss the principles and legal GDP requirements.
11. Write a detailed note on general checklist of 21 CFR Part 11.
12. Discuss about ICH guidelines for safety about drug substances and products.
13. Explain six sigma concept in Quality management.
14. Discuss about relevant ISO and Quality Council of India (QCI) standards for Good laboratory practices.

MRA 102 T

(No. of Questions: 14] **[No. of Pages: 01)**

M.PHARMACY (Regular) DEGREE EXAMINATIONS, JUNE- 2023

First Semester

PHARMACEUTICAL REGULATORY AFFAIRS

DOCUMENTATION AND REGULATORY WRITING

Time : 3 hours **Maximum : 75 Marks**

****

Answer Any FIVE Questions **(5 x 5 =25M)**

1. Describe about different approaches used in root cause analysis.
2. What is Nees? Explain its objectives and significance.
3. What is Product recall? Explain recall procedure for drug product.
4. Discuss about preparation for Pre- approval inspection of FDA.
5. Compare European and US drug master file preparation.
6. Explain certificate of analysis with examples.
7. Write a note on a) CBE -30
   b) Regulatory agencies for Brazil and Australia.

Answer Any FIVE Questions **(5 x 10 =50M)**

8. Discuss in detail overview and modules of eCTD.
9. Write in detail about SUPAC IR guideline to Industry for Solid oral dosage forms with respect to site change.
10. Write a note on EPDB and Product development plan.
11. Discuss in detail auditing / Inspection of manufacturing facilities by regulatory agencies.
12. a) Discuss about Quality system requirements for national good manufacturing practices.
    b) Add a note on Establishment inspection reports (EIR).
13. a) Write a note on GHTF study groups & guidance document.
    b) Add a note on auditing strategies.
14. a) Discuss about print pack specifications.
    b) Write about site master file and drug master files (DMF).

MRA 103 T

(No. of Questions: 14] **[No. of Pages: 01)**

M.PHARMACY (Regular) DEGREE EXAMINATIONS, JUNE- 2023

First Semester

PHARMACEUTICAL REGULATORY AFFAIRS

CLINICAL RESEARCH REGULATIONS

Time : 3 hours **Maximum : 75 Marks**

****

Answer Any FIVE Questions (5 x 5 =25M)

1. Write a note on Phase II studies of clinical trials.
2. Explain the role of placebo in clinical trials.
3. Briefly outline the FDA guidance for Industry – acceptance of Foreign clinical trials.
4. Write a note on guidelines for clinical investigation of medicinal products in the pediatric population.
5. Write a note on ISO standards for clinical investigation of medical devices for human subjects.
6. Give a brief account on CFR 21 part 822: Post market surveillance.
7. Mention the role and responsibilities of Institutional Review Board.

Answer Any FIVE Questions (5 x 10 =50M)

8. Discuss the key concepts of Medical Device clinical Evaluation.
9. Write a note on declaration of Helsinki and Thalidomide study.
10. Outline the clinical research regulations in European Union (EMA).
11. Discuss in detail E4 and E7 guidelines of ICH.
12. Write an account on IND application (CFR 21 Part 312) and application for FDA approval to market a New drug (CFR 21 part 314).
13. Discuss the EU guidelines on pharmacovigilance for medicinal products for human use.
14. Give an overview on Drug safety monitoring board.

MRA 104 T

(No. of Questions: 14] [No. of Pages: 01)

M.PHARMACY (Regular) DEGREE EXAMINATIONS, JUNE- 2023

First Semester

PHARMACEUTICAL REGULATORY AFFAIRS

REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICAL & HERBALS AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

Time : 3 hours **Maximum : 75 Marks**

****

Answer Any FIVE Questions **(5 x 5 =25M)**

1. Write the salient features of Prevention of cruelty to animals act.
2. Enumerate the responsibilities of state licensing authority.
3. Give a brief overview on BIS specification's for cosmetics.
4. Write the BCS classification of drugs.
5. Define Intellectual Property Rights and write a note on Industrial designs.
6. Write a short note on Natural Pharmaceutical Pricing Authority (NPPA).
7. Briefly outline ICMR DBT guidelines for stem cell research.

Answer Any FIVE Questions **(5 x 10 =50M)**

8. Discuss the objectives of drugs and cosmetics act 1940 and rules 1945 and add a special emphasis on schedule 'H' and schedule 'P'.
9. Write the organization and responsibilities of CDSCO (Central Drug Standard control Organization).
10. Give a brief outline on ISO standards for Food and Nutraceuticals.
11. Discuss the CPCSEA guidelines for animal procurement and personal hygiene.
12. Write different types of Intellectual property rights and explain Trademark and copyright.
13. Discuss the regulatory requirements for Bioequivalence study.
14. Give an account on objectives of pharmacy act 1948 and add a note on registration of pharmacists.