MPH 104 T

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Total No. of Questions : 14]

M. PHARMACY DEGREE EXAMINATIONS, JULY - 2022

First Semester

PHARMACEUTICS

REGULATORY AFFAIR

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

SECTION - A

Answer any FIVE Questions. **5x5 = 25 M**

1. Write a note on Drug Master File.
2. Outline the regulatory requirements for obtaining ANDA for generic drugs.
3. Briefly discuss the regulations for combination products and medical devices.
4. Write a brief outline on ICH-S Guidelines.
5. Give an account on Investigator Brochure.
6. Mention the role of pharmacovigilance safety monitoring in clinical trials.
7. Write a short note on Informed consent process.

SECTION - B

Answer any FIVE Questions. **5x10 = 50 M**

8. Discuss in detail the Hatch Waxman Act and its ammendments.
9. Explain the regulatory requirements for obtaining NDA for biologics and novel therapies.
10. Write a detailed note on Common Technical Document.
11. Enumerate the regulatory requirements of European Union (EU) and TGA.
12. Discuss the process involved in global submission of IND in non-clinical drug development.
13. Write an account on development of clinical trial protocol.
14. Give a brief account on
    a) HIPAA.
    b) Code of Federal regulations.

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M. PHARMACY (SUPPLE) DEGREE EXAMINATIONS, JANUARY - 2022

First Semester

PHARMACEUTICS

REGULATORY AFFAIR

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

SECTION - A

Answer any FIVE Questions. 5x5 = 25 M

1. Give an account on Master formula record.
2. Briefly outline the NDA submission process for API.
3. Write the regulatory requirements of TGA.
4. Briefly explain the importance of safety monitoring in clinical trials.
5. Outline the ICH - E guidelines.
6. Write a short note on outsourcing BA and BE to CRO.
7. Describe Investigation of medicinal products dossier.

SECTION - B

Answer any FIVE Questions. 5x10 = 50 M

8. Give a detailed note on Post Marketing Surveillance.
9. Write a note on Hatch Waxman act and ammendments.
10. Describe the regulatory requirements for approval of generic drugs.
11. Give an account on CTD and differentiate it from eCTD.
12. Write a note on
    a) Global submission of ANDA.
    b) Investigator brochure.
13. Discuss the constitution and functions of Institutional Review Board.
14. Write a detailed note on HIPAA.

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Total No. of Questions :14]

M.PHARMACY (Regular) DEGREE EXAMINATIONS, FEB/MAR-2020

First Semester

M.PHARMACY

PHARMACEUTICS

REGULATORY AFFAIRS

Time: Three Hours Maximum marks:75

SECTION-A

Answer any FIVE Questions 5X5=25M

1. Give the differences between master formula record and batch manufacturing record.
2. Write about Hatch-Waxman act and its significance.
3. Give the advantages of eCTD over CTD.
4. Give the differences between phase I and phase II clinical trials.
5. Write the functions of Institutional Review Board.
6. What is pharmacovigilance and how it is used for the safety of patients?
7. Write about the need for post marketing surveillance.

SECTION-B

Answer any FIVE Questions 5X10=50M

8. Explain the current good manufacturing practices specifically for parenterals.
9. Explain the process of filing for ANDA.
10. Explain the regulations relating to medical devices approval in India.
11. Explain the stages of non-clinical drug development.
12. Write about HIPAA and its role in conducting clinical trials.

P.T.O

13. Explain the salient features of MHRA functioning.

14. Write notes on the following

a) Informed consent

b) Investigator brochure

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Total No. of Questions :14]

M.PHARMACY (Supply) DEGREE EXAMINATIONS, AUGUST-2019

First Semester

PHARMACEUTICS

REGULATORY AFFAIR

Time: Three Hours **Maximum marks:75**

SECTION-A

Answer any FIVE Questions 5X5=25M

1. Write a short note on Hatch-Waxman act.
2. What is Drug Master File, and give its importance.
3. Outline the regulations for Medical devices.
4. Give a brief outline on ICH-M Guidelines.
5. Write a short emphasis on investigation of medicinal product dossier.
6. Write the composition of Institutional Ethics committee.
7. Mention the steps involved in global submission of ANDA as per USFDA guidelines.

SECTION-B

Answer any FIVE Questions 5X10=50M

8. Write a note on
   a) Master Formula Record
   b) Code of Federal Regulation.
9. Describe the process involved and regulatory requirements for biologics and Novel therapies obtaining NDA.
10. Write a note on common Technical Documnent (CTD).
11. Enumerate ICH-Q Guidelines.

P.T.O

12. Give a detailed note on global submission of IND.

13. Write a note on development of clinical trial protocol.

14. Write an account on

    a) HIPAA and its requirement to clinical study process

    b) Regulatory requirements of TGA