Total No. of Questions : 7]

P.D 5.1

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V/VI PHARM - D DEGREE EXAMINATIONS, JULY - 2022

Fifth Year

CLINICAL RESEARCH

Time : **Three Hours**

Maximum : **70** Marks

Answer any FIVE Questions. **5x14 = 70 M**

All Questions carry equal marks

1. Discuss Ethical guidelines in Clinical Research.
2. a) Give an account on methods of Post Marketing Surveillance.
   b) Explain the first two phases of clinical trials.
3. Write an overview of regulatory environment in USA and India.
4. Write a note on
   a) Case Report Form in study design.
   b) Informed Consent Form.
5. a) Discuss ICH guidelines in good clinical practice.
   b) Online the submission of Abbreviated New Drug Application.
6. Write a note on
   a) Role and responsibilities of clinical research associate and Auditors in clinical trials.
   b) Composition of IRB.
7. Give a brief account on
   a) Components in Data Management.
   b) Significance of safety monitoring in clinical trials.

P.D 5.1

Total No. of Questions :07]

[Total No. of Pages : 01

V/VI Pharma.D (Regular) DEGREE EXAMINATIONS, MAY-2019

Fifth Year

PHARMA-D

CLINICAL RESEARCH

Time: Three Hours **Maximum marks:70**

Answer any FIVE questions.

All questions carry equal marks. **5X14=70M**

1. Describe the roles and responsibilities of Investigators and Clinical Research associates?
2. Discuss the importance of safety monitoring in clinical trials?
3. Write about the following
   a) Case report form
   b) Preparation of Informed Consent Form.
4. Define Clinical trials. Discuss in detail about the various phases involved in Clinical trial?
5. Discuss in detail the overview of regulatory environment in Europe and USA?
6. Explain the following
   a) Role and responsibility of regulatory authority
   b) Challenges in the implementation of guidelines
7. Describe the following
   a) Ethical guidelines in clinical research
   b) Toxicological approach to drug discovery

P.D 5.1

Total No. of Questions :07]

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V/VI Pharma.D (Regular) DEGREE EXAMINATIONS, April-2018

5th year

Pharma-D

CLINICAL RESEARCH

Time: Three Hours **Maximum marks:70**

Answer any FIVE questions.

All questions carry equal marks. 5X14=70M

1. Explain the different types of studies and the protocols for the studies, to be carried out under the toxicological approach to drug discovery.
2. Explain in detail, how phase I, II and III trials are to be carried out.
3. Explain the legal and technical background of submission of an Abbreviated New Drug Application. What is the data required and how is the application processed?
4. Explain the principles of ethics in clinical research.
5. Explain the responsibilities of (a) Sponsor, (b) Investigators and (c)Clinical research associate; in clinical trials, as per ICH GCP.
6. Explain (a) Informed consent process and (b) Data management.
7. Explain the responsibilities of Institutional Ethics Committee. What are the procedures to be followed by it? How does it monitor safety in clinical trials?

P.D 5.1

Total No. of Questions :07] [Total No. of Pages : 01

V/VI Pharma.D (Regular) DEGREE EXAMINATIONS, JUNE-2017

(Examination at the end of Fifth year)

Paper-I- CLINICAL RESEARCH

Time: Three Hours **Maximum marks:70**

Answer any FIVE questions.

All questions carry equal marks. **5X14=70M**

1. Explain how toxicological studies and drug characterisation studies are to be carried out.
2. Explain how phase III and phase IV clinical trials are to be carried out
3. Write a comparitive report of the regulatory environment in USA, Europe and India with respect to clinical trials.
4. Explain the ethical guidelines given by CDSCO for clinical research.
5. Explain the responsibilities of the principal investigator and the clinical research associate as per ICH Good Clinical Practices.
6. Write a note on the preparation of a protocol for a clinical trial.
7. Explain about
   a) Informed Consent Process and
   b) Severe Adverse Drug Reactions.

P.D 5.1

Total No. of Questions :07] [Total No. of Pages : 01

V/VI Pharm.D (Regular) DEGREE EXAMINATIONS, JULY-2016

(Examination at the end of Fifth year)

Paper I-CLINICAL RESEARCH

Time: Three Hours **Maximum marks:70**

Answer any FIVE questions.
All questions carry equal marks.

1. Explain the different studies to be carried out under pharmacological approach and under drug characterisation.
2. Explain about Phase I and Phase II trials.
3. Explain how a company can apply for an Abbrervated New Drug Application and the requirements for getting it approved.
4. Explain the composition, responsibilities and procedures of Institutional Ethics committee.
5. Explain the role and responsibilities of the sponsor and the principal investigator in clinical trials as per CDSCO guidelines.
6. Explain the contents of the protocol of a clinical trial study.
7. Explain about (a) Post marketing surveillance and (b) Severe adverse reactions.