(PHD50110)

Pharm. D DEGREE EXAMINATION, APRIL 2018.

(Regular)

(Examination at the end of Fifth Year of 6 Years Course)

Paper I — CLINICAL RESEARCH

(Regulation 2010-11)

Time : Three hours Maximum : 70 marks

Answer any FIVE questions.

1. Define Clinical Trials. Discuss in detail various phases involved in drug development process.

2. What is ANDA? What are the drugs that come under ANDA? What is meant by generic drugs?

3. What is Institutional human ethical committee? Give the composition. Qualification required for the members. Explain the functions of the committee?

4. Describe in detail the various approaches to drug discovery.

5. Write a note on the following :
   (a) Design of a protocol
   (b) Informed consent form.

6. Explain the protocols and method of reporting ADR under Pharmacovigilance.

7. Discuss the roles and responsibilities of auditors in clinical research.

8. Describe the guidelines of Central drug standard control organization.

(PHD50210)

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Paper II — PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

(Regulation 2010-2011)

Time : Three hours Maximum : 70 marks

Answer any FIVE questions.

1. Explain about the following.
   (a) Cost-minimization with an example
   (b) Spontaneous reporting system.
2. Write about Ad Hoc data sources available for Pharmacoepidemiological studies.
3. Briefly explain about the significance of Hospital Pharmacoepidemiology.
4. Discuss the various types of Pharmacoeconomic evaluations.
5. Write a note on the following.
   (a) Methods of measurement of medication adherence
   (b) Aims and applications of Pharmacoepidemiology.
6. Write about the following.
   (a) Prescription event monitoring
   (b) Measurement of risk.
7. Write about the following.
   (a) Merits and demerits of automated systems
   (b) Role of Pharmacist in Drug Utilization Evaluation.
8. Write a note on the following.
   (a) Various cost factors involved in pharmacoeconomic evaluations
   (b) Cost-benefit and cost-utility analysis.

(PHD50310)

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Paper III — CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING

(Regulation 2010-11)

Time : Three hours Maximum : 70 marks

Answer any FIVE questions.

1. Write the general approach for dosage adjustment in Hepatic diseases?

2. Explain the following

   (a) Extracorporeal removal of drugs

   (b) Pharmacokinetic drug interactions.

3. Discuss in detail the methods adopted in the analysis of population pharmacokinetic data?

4. Describe the following

   (a) Genetic polymorphism in drug metabolism

   (b) Dosing in obese patients.

5. Explain the determination of dose and dosing interval?

6. Explain the drug dosing in elderly and paediatric patients?

7. Describe the inhibition and induction of drug metabolism with example?

8. Explain in detail the drug dosage regimen for individual dosage?