(PHD 50110)

IV PHARM. D DEGREE EXAMINATION, JUNE 2016.

(Regular/Supplementary)

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

Paper I — CLINICAL RESEARCH

(Regulation 2010 – 2011)

Time : Three hours Maximum : 70 marks

Answer any FIVE questions.

All questions carry equal marks.

1. Explain about preclinical toxicological evaluation of drugs in drug discovery process.

2. Discuss about ICH guidelines for good clinical practices.

3. Discuss about the role of CRO in the conduct of clinical research.

4. Discuss in detail about Data management in clinical research.

5. What is Phase IV clinical trial? What is its significance? Discuss about various methods adopted to conduct it.

6. Explain about dosage from design approach in drug discovery.

7. Write about the following :

   (a) Institutional ethics committee

   (b) Phase I and Phase II clinical trials.

8. Discuss about the following :

   (a) safety monitoring in clinical research

   (b) subject profile form.

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(PHD 50210)

IV Pharm. D DEGREE EXAMINATION, JUNE 2016.

(Regular/Supplementary)

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

Paper II — PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

(Regulation 2010-11)

Time : Three hours Maximum : 70 marks

Answer any FIVE questions.

All questions carry equal marks.

1. Explain in detail about the cost-benefit and cost utility evaluations.

2. Describe the various methods of measurement of risk. Add a note on Odds ratio.

3. Explain any two pharmacoepidemiological methods with the case studies.

4. Describe the different types of sources of data used in pharnacoepidemiology studies.

5. Explain in detail about the meta-analysis with suitable examples.

6. Describe in detail about the role of formulary management decisions.

7. Write about the following :
   (a) Cost-minimization.
   (b) Prescription event monitoring.

8. Discuss about the following :
   (a) time-risk relationship.
   (b) cohort studies.

(PHD 50310)

IV Pharm. D DEGREE EXAMINATION, JUNE 2016.

(Regular/Supplementary)

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

Paper I — CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING

(Regulation 2010–11)

Time : Three hours Maximum : 70 marks

Answer any FIVE questions.

All questions carry equal marks.

1. Explain about the calculation of dose and dosing interval in normal and uremic persons.

2. Discuss in detail about pharmacodynamic drug interactions. Add a note on biliary excretion of drugs.

3. What is TDM? Explain about TDM of digoxin and lithium?

4. What are the indicators for extracorporeal removal of drugs? Discuss about peritoneal dialysis?

5. Discuss about renal and hepatic dysfunction influence on pharmacokinetics of drugs.

6. Explain the advantages and disadvantages of population pharmacokinetics? Discuss about adaptive grid method of population pharmacokinetic modellings.

7. What is pharmacogenetics? Discuss about the genetic variations affecting the pharmacodynamics of drugs.

8. Discuss about the following :

   (a) Enzyme induction

   (b) Drug dosing in children.