

**(PHD50110)**

Pharm. D DEGREE EXAMINATION,  
APRIL 2017

(Special 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.

1. Explain the roles and responsibilities of the following?
  - (a) Clinical research associate
  - (b) Regulatory authority
2. Define investigational new drug application and describes the component and categories of investigational new drug application?
3. Explain about the data management and its components in clinical research.
4. Describe in detail the various pharmacological and toxicological approaches to drug discovery.

5. Write a note on the following?
  - (a) Post marketing surveillance and its methods.
  - (b) Source documents in clinical trial.
6. Write about the following?
  - (a) Drug characterization
  - (b) Ethical issues in clinical research
7. Define serious adverse event in clinical trial and responsibilities of investigators in reporting?
8. Write a note on the following?
  - (a) Randomization
  - (b) Vulnerable subjects

**(PHD50210)**

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Paper II — PHARMACOEPIDEMIOLOGY AND  
PHARMACOECONOMICS

(Regulation 2010-11)

Time : Three hours

Maximum : 70 marks

Answer any FIVE questions.

1. Explain about the following :
  - (a) Applications of Pharmacoeconomics
  - (b) Attributable risk and relative risk.
2. Explain the Pharmacoepidemiological methods used to study drug induced birth defects?
3. How do you express the outcome of drug use in pharmacoepidemiologic studies? Add a note on meta-analysis?
4. Describe in detail about the studies of vaccine safety?

5. Write a note on the following :

- (a) Methods of measurement of medication adherence
- (b) Origin and evolution of Pharmacoepidemiology.

6. Write about the following :

- (a) Phases of DUE.
- (b) Units of drug use.

7. Write about the following :

- (a) Cross-sectional studies and cohort studies.
- (b) Record linkage system and case reports.

8. Write a note on the following :

- (a) Cost effectiveness analysis with an example.
- (b) Odds ratio and Incidence.

**(PHD50310)**

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Paper III — CLINICAL PHARMACOKINETICS AND  
PHARMACOTHERAPEUTIC DRUG MONITORING

(Regulation 2010-2011)

Time : Three hours

Maximum : 70 marks

Answer any FIVE questions.

1. Describe the dose adjustment in renal disease with respect to total body clearance and elimination rate constant.
2. Explain the following
  - (a) Adaptive method for dosing
  - (b) Application of clinical pharmacokinetics.
3. Discuss in detail the methods adopted in the analysis of population pharmacokinetic data?
4. Describe the following
  - (a) Conversion from intravenous to oral dosing
  - (b) Inhibition of biliary excretion.

5. Enumerate the pharmacokinetic drug interactions with examples.
6. What is therapeutic drug monitoring? Explain the steps involved in the TDM. Add note on therapeutic drug monitoring of Digoxin.
7. Explain the Bayesian theory and add notes on adaptive method for drug dosing.
8. Explain the polymorphism in Cytochrome isoenzymes.