

MANIPAL UNIVERSITY**SECOND YEAR PHARM D (POST BACCALAUREATE)/FIFTH YEAR PHARM D.
DEGREE EXAMINATION – MAY 2013****SUBJECT: PD 5.1: CLINICAL RESEARCH**

Friday, May 24, 2013

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

Long Essay questions:

1. Explain the scope and purpose of ICH-GCP guidelines and outline its principles.
(4+6 = 10 marks)
2. Explain composition of ethics committee as per ICMR ethical guideline/schedule-Y. Comment on decision making process at ethics committee.
(6+4 = 10 marks)
3. What is NDA? Explain the contents and process of NDA.
(2+8 = 10 marks)

Short Essay questions:

- 4A. Explain the steps involved in preclinical drug development with illustrations.
- 4B. Discuss the details of 'effect in humans' and 'non clinical studies' incorporated in Investigator's Brochure.
- 4C. Explain the informed consent process and comment on compensation for participating in a trial.
- 4D. Describe the procedure for carcinogenicity test.
- 4E. Describe the 'background information' and 'trial design' of a clinical trial protocol.
- 4F. Discuss premature termination/suspension of a clinical trial according to ICH-GCP.
(5×6 = 30 marks)

Short Answer questions:

- 5A. Define sponsor and investigator as per ICH-GCP guidelines.
- 5B. Outline the procedure acute toxicity studies.
- 5C. Enlist the methods of post marketing surveillance.
- 5D. Outline the responsibilities of auditors in clinical trials.
- 5E. List the records to be maintained with IRB/IEC
(2×5 = 10 marks)



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DEGREE EXAMINATION – MAY 2013****SUBJECT: PD 5.2: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS**

Monday, May 27, 2013

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

☞ Long Essay questions:

- 1A. Explain the major predictor of poor adherence to medication.
1B. Explain time-risk relationship in Pharmacoepidemiological studies with suitable examples.
(5+5 = 10 marks)
- 2A. Explain the contents of an Ideal Automated Data System.
2B. Explain Medical Record Automated Database system with its application.
(5+5 = 10 marks)
3. Define Pharmacoconomics and explain various steps employed for conducting Pharmacoconomics evaluations.
(10 marks)

4. Short Essay questions:

- 4A. Define Pharmacoepidemiology and explain Scope of Pharmacoepidemiology in drug regulation.
4B. Define and explain information flow in Record Linkage System (RLS).
4C. Explain various clinical and methodological problems of drug-induced birth defect studies.
4D. Explain cost- utility analysis with suitable examples.
4E. Explain various function of WHO Global Drug Surveillance.
4F. Explain cross – sectional studies with suitable examples.
(5×6 = 30 marks)

5. Short Answer questions:

- 5A. Explain Defined Daily Doses (DDD) with suitable examples.
5B. Write a short note on Health Related Quality of Life.
5C. Write a short note on Case Reports.
5D. Write advantages and disadvantages of prescription event monitoring.
5E. Define 'Signal' and explain its role in adverse drug reaction monitoring.
(2×5 = 10 marks)



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DEGREE EXAMINATION – MAY 2013

SUBJECT: PD 5.3: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTICS DRUG MONITORING

Wednesday, May 29, 2013

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

Long Essay questions:

1. Explain the genetic polymorphism of G6PD and N-Acetyltransferase and its effect on drug metabolism.

(10 marks)

2. Explain methods for analysis of population pharmacokinetic data.

(10 marks)

3. Explain the following types of drug-drug interactions with examples:

3A. Absorption interactions

3B. Distribution interactions

3C. Elimination interactions

(10 marks)

Short Essay questions:

4A. Describe the process of conversion from Intravenous dosage to oral dosing.

4B. Explain the mechanisms of enzyme inhibition in drug metabolism.

4C. Describe general considerations for dosage adjustment in children.

4D. Mention the objectives and procedures for carrying out TDM.

4E. Explain Bayesian theory with an example.

4F. Explain the factors affecting dialyzability of a drug.

(5×6 = 30 marks)

Short questions:

5A. Enumerate four enzyme inhibitors.

5B. Mention the formula to calculate dosing body weight in obese patients.

5C. Define direct link model for pharmacokinetic and pharmacodynamic correlation.

5D. Mention the therapeutic range of any two anti-epileptic drugs.

5E. Mention the alleles for the gene of N-Acetyltransferase.

(2×5 = 10 marks)

