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## MANIPAL UNIVERSITY

SECOND YEAR PHARM D (POST BACCALAUREATE)/FIFTH YEAR PHARM D.  
DEGREE EXAMINATION – MAY 2014

SUBJECT: PD 5.1: CLINICAL RESEARCH

Tuesday, May 06, 2014

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

✍ Answer ALL the questions.

✍ Long Essays:

1A. Explain the principles of ICH-GCP guidelines.

1B. Explain Phase 0 and Phase 1 clinical Trials.

(5+5 = 10 marks)

2. Explain the content and process of Protocol writing as per ICH E6 guidelines.

(10 marks)

3. What are the various approaches to drug discovery? Explain drug development process with an insight on approximate duration, cost and regulatory requirements to launch a New Drug in the market.

(3+7 = 10 marks)

✍ Short Essays:

4A. Explain IND application process with the help of an algorithm with appropriate form numbers and details of data to be provided to the FDA.

4B. Explain the role and responsibilities of IRB/IEC.

4C. Outline the methodology of Ames's Genotoxicity Test.

4D. Discuss the challenges in the implementation of Clinical trial guidelines.

4E. List out the differences between ICH E6 and Schedule Y guidelines.

4F. Explain Pharmacovigilance program of India (PvPI).

(5 marks×6 = 30 marks)

✍ Short Answers:

5A. Give four main differences between conventional dosage forms and Novel Drug delivery systems.

5B. Define ADE with a suitable example.

5C. List all the project team personnel involved in data management.

5D. Write a note on lead optimization during drug development process.

5E. Write a note on biological drug characterization in preclinical screening.

(2 marks×5 = 10 marks)



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**SECOND YEAR PHARM D (POST BACCALAUREATE)/FIFTH YEAR PHARM D.  
DEGREE EXAMINATION – MAY 2014**

**SUBJECT: PD 5.2: PHARMACOEPIDEMOLOGY AND PHARMACOECONOMICS**

Thursday, May 08, 2014

Max. Marks: 70

Time: 10:00 – 13:00 Hrs.

☞ **Answer ALL the questions.**

☞ **Long Essays:**

- 1A. Explain various strategies for improving medication adherence.
- 1B. Explain attributable risk and relative risk with suitable examples. (5+5 = 10 marks)
  
2. Define & explain the steps involved in establishing a drug utilization review (DUR) program in a hospital setup. (10 marks)
  
3. Enlist various automated data base systems. Explain any two in detail. (10 marks)

☞ **Short Essays:**

- 4A. Define and Explain aims and applications of Pharmacoepidemiology.
- 4B. Explain spontaneous reporting system with its application.
- 4C. Explain various clinical & methodological problems in vaccine safety Studies
- 4D. Define Pharmacoeconomics and explain cost- benefit analysis with suitable examples.
- 4E. Explain cohort studies with suitable examples.
- 4F. Discuss the important considerations while performing a meta-analysis? (5 marks×6 = 30 marks)

☞ **Short Answers:**

- 5A. Explain prescribe daily doses with suitable examples.
- 5B. Enlist various applications of Pharmacoeconomics research.
- 5C. Explain indirect medical cost with suitable examples.
- 5D. Write a short note on surveys of drug use.
- 5E. Enlist various methods used for outcome analysis. (2 marks×5 = 10 marks)



## MANIPAL UNIVERSITY

SECOND YEAR PHARM D (POST BACCALAUREATE)/FIFTH YEAR PHARM D.  
DEGREE EXAMINATION – MAY 2014

SUBJECT: PD 5.3: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTICS DRUG MONITORING

Saturday, May 10, 2014

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

✍ Answer ALL the questions.

✍ Long Essays:

1. Explain various types of pharmacokinetic interactions with examples.
2. Explain the indications for Therapeutic Drug Monitoring and explain TDM of gentamycin, digoxin and cyclosporin.
- 3A. Explain the procedure for dosage adjustment in renal failure.
- 3B. Explain the principles for dosage adjustment in hepatic failure.

(10 marks×3 = 30 marks)

✍ Short Essays:

- 4A. Explain the Non-linear Mixed Effect Model Approach of population pharmacokinetics.
- 4B. Explain the patient selection criteria for IV to oral conversion.
- 4C. Describe the pharmacokinetic factors which govern dosage adjustment in elderly.
- 4D. Describe the process of assigning probability for a diagnosis using Bayesian approach.
- 4E. Describe nomograms and their applications in designing dosage regimen.
- 4F. Explain the factors affecting dialyzability of a drug.

(5 marks×6 = 30 marks)

✍ Short Answers:

- 5A. Which ethnic group has higher proportion of poor metabolizers for N-Acetyl transferase?
- 5B. Mention the formula to calculate creatinine clearance in obese patients.
- 5C. Mention any four drugs metabolized by CYP2D6.
- 5D. Define population pharmacokinetics.
- 5E. Mention the therapeutic range of lithium and lamotrigine.

(2 marks×5 = 10 marks)

