

MANIPAL UNIVERSITY**SECOND YEAR PHARM D (POST BACCALAUREATE) DEGREE EXAMINATION – MAY 2012****SUBJECT: PD 5.1: CLINICAL RESEARCH**

Thursday, May 24, 2012

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

✍ Long Essay Questions:

1. Describe the composition, roles and responsibilities of IRB/IEC as per ICH-GCP guidelines.
(4+6 = 10 marks)
2. Outline the scope of schedule Y. Explain the structure and content of clinical study report as per Schedule Y.
(4+6 = 10 marks)
3. Discuss the need of Abbreviated New Drug Application process. How does it differ from NDA?
(5+5 = 10 marks)

4. Short Essay Questions:

- 4A. Explain the role of clinical investigator in clinical trials.
- 4B. Define Audit and audit trail as per ICH-GCP guidelines. Outline the responsibility of quality assurance unit.
- 4C. Outline the content and format of IND application.
- 4D. Describe the procedure for Ames test.
- 4E. Differentiate between ADR, AE, and SAE with suitable examples. Give the timelines of reporting SAE to sponsor and IRB/IEC.
- 4F. Explain the objectives and features of Phase I to IV clinical trials.
(5×6 = 30 marks)

5. Short Answer Questions:

- 5A. Outline the delegation of responsibility and management of investigational products in a clinical trial.
- 5B. Mention the contents of CRF and ICF.
- 5C. Outline the method for teratogenicity testing.
- 5D. Enlist the advantages and disadvantages of enteric coated tablets.
- 5E. Who are vulnerable subjects? Give examples.
(2×5 = 10 marks)



MANIPAL UNIVERSITY**SECOND YEAR PHARM D (POST BACCALAUREATE) DEGREE EXAMINATION – MAY 2012****SUBJECT: PD 5.2: PHARMACOEPIDEMOLOGY AND PHARMACOECONOMICS**

Saturday, May 26, 2012

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

Long Essay Questions:

1. Explain development and evaluation of Patient Reported Outcome (PRO) instrument.
2. Discuss theoretical aspects of various Pharmacoepidemiological methods.
3. Describe cost- minimization analysis and cost – effectiveness analysis with their application giving suitable examples.

(10×3 = 30 marks)

Short Essay Questions:

- 4A. Explain Medical record data base system with its applications.
- 4B. Explain attributable risk and relative risk with suitable examples.
- 4C. Explain cohort studies with suitable examples.
- 4D. Outline the strengths and limitations of spontaneous ADR reporting.
- 4E. Explain the various methodological problems to be addressed by Pharmacoepidemiologic research.
- 4F. Discuss aims and applications of Pharmacoeconomics.

(5×6 = 30 marks)

Short Answer Questions:

- 5A. Define prescribed daily doses with suitable example.
- 5B. Explain the role of data mining in ADR reporting.
- 5C. Enlist various methods used for outcome analysis.
- 5D. Write a short note on PSUR
- 5E. Explain indirect medical cost with suitable examples.

(2×5 = 10 marks)



MANIPAL UNIVERSITY**SECOND YEAR PHARM D (POST BACCALAUREATE) DEGREE EXAMINATION – MAY 2012****SUBJECT: PD 5.3: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTICS DRUG MONITORING**

Tuesday, May 29, 2012

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

✍ Long Essay Questions:

1. Explain various types of pharmacokinetic interactions with examples.
(10 marks)
2. Explain the indications for Therapeutic Drug Monitoring and explain TDM of digoxin, theophylline and phenytoin.
(4+6 = 10 marks)
3. Explain any four methods for analysis of population pharmacokinetic data.
(10 marks)

4. Short Essay Questions:

- 4A. Outline the pharmacokinetic considerations in renal failure.
- 4B. Explain the conversion of Intravenous dosage to oral administration.
- 4C. Describe the genetic polymorphism in CYP 2D6 and 3A4 and its clinical significance.
- 4D. Explain the significance of age and weight of a patient in dosage adjustment.
- 4E. Explain Bayesian theory.
- 4F. Explain the mechanisms of enzyme induction.
(5×6 = 30 marks)

5. Short Questions:

- 5A. Enumerate four drugs that are cleared by hemodialysis.
- 5B. Define Direct Model of pharmacokinetic and pharmacodynamic correlation.
- 5C. Mention any one formula for dosage adjustment in paediatrics.
- 5D. Mention the formulae to calculate loading and maintenance doses.
- 5E. What is adaptive method for dosage adjustment?
(2×5 = 10 marks)

