5th Pharm D II Pharm D - PB

Reg. No.										

MANIPAL UNIVERSITY

SECOND YEAR PHARM D (POST BACCALAUREATE)/FIFTH YEAR PHARM D. DEGREE EXAMINATION – MAY 2015

SUBJECT: PD 5.1: CLINICAL RESEARCH

Monday, May 04, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 70

✍ **Answer ALL the questions.**

✍ **Long Essay Questions:**

1. Discuss the roles and responsibilities of a monitor as per ICH-GCP guidelines. Explain how monitoring differs from auditing.

(5+5 = 10 marks)

2. Discuss the activities of sponsors and institutional review board during the conduct of clinical study. Enlist the trial documents to be filed at investigator's location.

(3+3+4 = 10 marks)

3. Discuss safety monitoring and reporting in clinical trials.

(5+5 = 10 marks)

4. **Short Essay Questions:**

4A. Explain the composition, function and operation of independent ethics committee (IEC).
4B. Explain clinical data management.
4C. Describe the IND application review process.
4D. How short term and long term toxicity are assessed in preclinical testing?
4E. Explain subject selection criteria for a clinical study.
4F. Discuss the challenges in the implementation of clinical trial guidelines.

(5 marks × 6 = 30 marks)

5. **Short Answer Questions:**

5A. List out the advantages of high throughput screening.
5B. Briefly describe the objectives of Phase-II clinical trial.
5C. Briefly discuss the handling of noncompliance and protocol deviations as per ICH-GCP.
5D. Enlist the roles of contract research coordinators in a clinical trial.
5E. Enlist the contents of Helsinki declaration.

(2 marks × 5 = 10 marks)

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SECOND YEAR PHARM D (POST BACCALAUREATE)/FIFTH YEAR PHARM D. DEGREE EXAMINATION – MAY 2015

SUBJECT: PD 5.2: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

Wednesday, May 06, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 70

✍ **Answer ALL the questions.**

✍ **Long Essay Questions:**

1. Discuss cross sectional studies and case control studies with examples.
2. Enumerate various automated data base systems. Explain any two in detail.
3. Define Pharmacoeconomics and explain cost- benefit and cost–utility analysis with suitable examples.

(10 marks × 3 = 30 marks)

4. **Short Essay Questions:**

4A. Explain aims and applications of Pharmacoepidemiology.
4B. Explain time-risk relationship and odds ratio with suitable examples.
4C. Explain the process for prescription event monitoring (PEM).
4D. Differentiate between case cohort and cohort study with suitable examples.
4E. Explain the methodological problems of drug-induced birth defect studies.
4F. Explain role of Pharmacoeconomics in formulary management decision.

(5 marks × 6 = 30 marks)

5. **Short Answer Questions:**

5A. Explain defined daily doses (DDD).
5B. Define drug utilization research.
5C. Define 'Signal' and explain its role in adverse drug reaction monitoring.
5D. Write a short note on Patient Reported Outcomes.
5E. Define and enumerate different types of record linkage systems.

(2 marks × 5 = 10 marks)

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SECOND YEAR PHARM D (POST BACCALAUREATE)/FIFTH YEAR PHARM D. DEGREE EXAMINATION – MAY 2015

SUBJECT: PD 5.3: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTICS DRUG MONITORING

Friday, May 08, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 70

✍ **Answer ALL the questions.**

✍ **Long Essay Questions:**

1. Explain the genetic polymorphism of G6PD and N-Acetyltransferase and its effect on drug metabolism.
2. Explain the indications for Therapeutic Drug Monitoring and explain TDM of gentamycin, digoxin and cyclosporin.
3. Explain direct and indirect link models for pharmacokinetic and pharmacodynamic correlation.

(10 marks × 3 = 30 marks)

4. **Short Essay Questions:**

4A. Describe extracorporeal elimination techniques with their applications.
4B. Mention all the formula used in dosage calculation for pediatrics.
4C. Explain the patient selection criteria for IV to oral conversion.
4D. Describe the pharmacokinetic factors which govern dosage adjustment in elderly.
4E. Explain adaptive dosing or dosing with feedback.
4F. Describe the salient features that differentiates conventional and population pharmacokinetics.

(5 marks × 6 = 30 marks)

5. **Short Questions:**

5A. Mention the formula to calculate BMI and classify overweight and obesity.
5B. Mention two drug interactions due to alteration of protein binding.
5C. Name the mutant alleles of CYP 2D6.
5D. Name the analytical method for quantification of amiodarone.
5E. Mention the uses of dosage nomograms in clinical situations.

(2 marks × 5 = 10 marks)