Reg. No.										

MANIPAL UNIVERSITY

SECOND YEAR PHARM D (POST BACCALAUREATE) DEGREE EXAMINATION – JULY 2010

SUBJECT: PD 5.1: CLINICAL RESEARCH

Friday, July 16, 2010

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

✍ **Answer ALL questions.**

✍ **Long Essay Questions.**

1A. Explain the principles of ICH GCP guidelines.

1B. Define informed consent and explain the informed consent process for enrolling patients into a clinical study.

1C. Discuss safety monitoring in clinical trials.

(10×3 = 30 marks)

✍ **Short Essay Questions.**

2A. Explain the composition, function and operation of independent ethics committee (IEC).

2B. Discuss in detail about lead Optimization stage of drug development.

2C. Describe the IND application process.

2D. Explain the subacute and chronic toxicity studies of preclinical drug development program.

2E. Describe the components of a clinical trial protocol.

2F. Discuss the challenges in the implementation of clinical trial guidelines.

(5×6 = 30 marks)

✍ **Short Answer Questions.**

3A. List the advantages of high throughput screening.

3B. List the parameters in the chemical characterization of a new drug.

3C. Outline the method for teratogenicity testing.

3D. List the roles of contract research coordinators in clinical trial.

3E. List the contents of Helsinki declaration.

(2×5 = 10 marks)

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SECOND YEAR PHARM D (POST BACCALAUREATE) DEGREE EXAMINATION – JULY 2010

SUBJECT: PD 5.2: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

Monday, July 19, 2010

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

✍ **Answer ALL questions.**

✍ **Long Essay Questions.**

1A. Classify different types of study designs used in pharmacoepidemiological research. Explain any two in detail.

1B. Enumerate various automated data base systems. Explain any two in detail.

1C. Explain various steps employed for conducting pharmacoeconomic evaluations.

(10×3 = 30 marks)

✍ **Short Essay Questions.**

2A. Enumerate various barriers to medication adherence.

2B. Define and explain aims and applications of Pharmacoepidemiology.

2C. Explain role and responsibility of National Pharmacovigilance Program (NPP).

2D. Describe the flow of information in a record linkage system.

2E. Explain the methodological problems in of drug-induced birth defect studies.

2F. Explain cost-utility analysis with suitable examples.

(5×6 = 30 marks)

✍ **Short Answer Questions.**

3A. Explain Prescribed Daily Doses (PDD) with suitable examples.

3B. Define attributable risk with a suitable example.

3C. Define Drug Utilization Review (DUR).

3D. Define Prescription Event Monitoring (PEM).

3E. Define prevalence with suitable examples.

(2×5 = 10 marks)

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MANIPAL UNIVERSITY

SECOND YEAR PHARM D (POST BACCALAUREATE) DEGREE EXAMINATION – JULY 2010

SUBJECT: PD 5.3: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING

Wednesday, July 21, 2010

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

✍ **Answer ALL questions.**

✍ **Long Essay Questions.**

1A. Explain the genetic polymorphism in cytochrome P450 isozymes in drug metabolism.

1B. Explain methods for analysis of population of pharmacokinetic data.

1C. Explain various types of pharmacokinetic interactions with examples.

(10×3 = 30 marks)

✍ **Short Essay Questions.**

2A. Explain the process of conversion to oral dosing from Intravenous dosage.

2B. Describe nomograms and their applications in designing dosage regimen.

2C. Explain the factors affecting dialyzability of a drug.

2D. Explain the mechanisms of enzyme induction.

2E. Explain adaptive dosing or dosing with feedback.

2F. Mention the significance of age and weight of the patients in dosage adjustment.

(5×6 = 30 marks)

✍ **Short Answer Questions.**

3A. What is competitive inhibition of enzymes?

3B. Mention the formula to calculate Ideal Body Weight.

3C. Enumerate four drugs cleared by hemodialysis.

3D. Define direct link model for pharmacokinetic and pharmacodynamic correlation.

3E. Mention the therapeutic range of any two anti-epileptic drugs.

(2×5 = 10 marks)

Reg. No.										

MANIPAL UNIVERSITY

SECOND YEAR PHARM D (POST BACCALAUREATE) DEGREE EXAMINATION – JULY 2010

SUBJECT: PD 5.3: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING

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