Cerlogy - 20110410005100

MALIBA PHARMACY COLLEGE

M. Pharmacy Sem-III Examination Nov 2012

Subject code: 040050302

Subject Name: - Clinical Pharmacology and Pharmacy Practice

Date: 08 /11/ 2012 **Time: 1.00 To 4.00 pm**

Total Marks: 70

Instructions:

1. Attempt all questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks allocated to that question.

Q.1

A) Answer the following **07**

1. Enumerate patient group most likely to need TDM.
2. Which kinetic parameter affects the estimation of maintenance dose?
3. Define AUC
4. Enlist the components of Clinical Trial Protocol
5. Give formula showing relationship between primary pharmacokinetic parameters
6. Enumerate the objectives of Phase III involved in clinical trial
7. Define Pharmacogenetics

B) Answer the following (any four) **08**

1. What are the different types of clinical trials?
2. Define clinical trial and explain phase 0
3. Explain the term : Steady state concentration
4. Give the clinical significance of drug clearance
5. Which kinetic parameter is important in determination of a loading dose?
6. Give difference between ANDA and NDA

Q.2 Answer the following **10**

A. Define Therapeutic drug monitoring. Explain various factors affecting TDM.

OR

A. Write essential elements of an ideal Informed Consent Document. Explain inform consent process in brief.

B. Discuss: (i) Volume of distribution (ii) Loading and Maintenance doses

OR

B. Explain the significance of genetic polymorphism to drug response

Q.3 Answer the following (any two) **10**

A) Describe the interrelationship of primary pharmacokinetic parameters and their relevance in determining dosage regimens

B) Explain role and responsibilities of principal investigator as per ICH GCP guidelines

C) Describe the objective of different phases involved in clinical trial

Q.4

A) **Answer the following** **07**

1. Explain ecotoxicology
2. Enlist various lung volumes and lung capacities
3. Define therapeutics orphan
4. Define drug therapy review
5. Define pharmacovigilance
6. Differentiate between absolute bioavailability and relative bioavailability
7. Enlist renal function test

B) Answer the following (any four) **08**

1. Give the significance of BUN test in Urinary tract obstruction
2. Outline the components of drug therapy review
3. What are the drawbacks of using acute pharmacological response as measure of bioavailability?
4. Differentiate between cohort and case control study
5. Distinguish between pharmacoepidemiology and conventional pharmacology.
6. Give importance of Diagonistic tests.

Q.5 Answer the following **10**

A. Explain rational drug therapy. Describe role of pharmacist in overcoming irrational prescribing of drugs

OR

A. What test should be performed to verify hepatic function and injury? How these test finding can be correlated?

B. Discuss the methods for determining bioavailability of a drug from its dosage form

OR

B. Discuss the factors for optimizing the dosage regimen in pediatric patients.

Q.6 Answer the following (any two) **10**

A) Explicate Drug Interactions involving alteration of Enzyme activity.

B) Write general principles for management of poisoning

C) Compare various methods of Pharmacoeconomic evaluations