

Seat No.:-----

Enrolment No.:-----

UKA TARSADIA UNIVERSITY

Maliba Pharmacy College

M. Pharm. Pharmacology 3rd Semester Internal Examination December 2013

040050302 Clinical Pharmacology and Pharmacy Practice

Time: 10:30 a.m. To 1:30 p.m.

Max. Marks: **70**

Date: 12/12/2013

Instructions:

- Attempt all questions.
- Make suitable assumption whenever necessary.
- Figures to the right indicate full marks.

Q-1 a) Enlist the objectives of TDM. Explain the algorithm for interpretation of TDM results for drugs used as prophylactic therapy. **(5)**

OR

a) Explain role and responsibilities of principal investigator as per ICH GCP Guidelines **(5)**

b) Explain the factors affecting drug response in different racial, ethnic and sex groups. **(6)**

Q-2 a) Discuss: (i) Volume of distribution (ii) Loading and Maintenance doses **(6)**

OR

a) Explain the pharmacokinetic and pharmacodynamic factors that are responsible for major changes in disposition of drugs in pediatric population as compared to adults. **(6)**

b) Explain the two parameters that are generally adjusted in developing a dosage regimen. **(6)**

Q-3 Answer the following questions. (any two) **(12)**

a) Write the influence of hepatic diseases on pharmacokinetics.

b) What is Phase 0 trial? Give its significance in drug development process.

c) Discuss the objective of different phases involved in clinical trial

Q-4 a) Discuss the methods for determining bioavailability of a drug from its dosage form **(5)**

OR

a) What test should be performed to verify hepatic function and injury? How these test finding can be correlated? **(5)**

b) Discuss the methods for determining bioavailability of a drug from its dosage form **(6)**

Q-5 a) Describe advantages and disadvantages of cohort and case control study. **(6)**

OR

a) Discuss various Hematological parameters with their clinical significance. **(6)**

b) List various Pharmacoeconomics evaluation techniques and describe in detail cost-effective analysis with suitable examples. **(6)**

Q-6 Answer the following questions. (any two) **(12)**

a) Define the concept of essential and rational drug use. Explain the properties and advantages of essential drugs.

b) Write note on biosimilars

c) Describe steps involved in conducting Drug Utilization Review/Evaluation