

# UKA TARSADIA UNIVERSITY

M. Pharm. (Pharmacology) (3<sup>rd</sup> Semester)

**Subject:** 040050302 - Clinical Pharmacology and Pharmacy Practice

**Time :** 2.30 pm to 5.30 pm

**Duration:** 3 Hours

**Date :** 15/05/2014

**Max. Marks:** 70.

## **Instructions:**

1. Attempt all questions.
2. Write each section in a separate answer book.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks allocated to that question.
5. Draw diagrams/figures whenever necessary.

## **Section 1**

**Q-1 a)** Define Therapeutic drug monitoring. Explain various factors affecting TDM. **(5)**

**OR**

**a)** Define ANDA. Discuss AND Application for generic drugs **(5)**

**b)** Discuss: (i) Volume of distribution (ii) Loading and Maintenance doses **(6)**

**Q-2 a)** Explain role and responsibilities of principal investigator as per ICH GCP Guidelines **(6)**

**OR**

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

**b)** Explain the significance of genetic polymorphism to drug response **(6)**

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

**a)** How does the dosage regimen need to be modified when the renal clearance of a drug changes?

**b)** Discuss the objective of different phases involved in clinical trial

**c)** Write a note on Institutional Review Board.

## **Section 2**

**Q-4 a)** Describe advantages and disadvantages of cohort and case control study. **(5)**

**OR**

**a)** Write note on biosimilars **(5)**

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

**Q-5 a)** Explain importance of clinical laboratory test and patient case history in drug therapy monitoring **(6)**

**OR**

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

**b)** Classify pharmacoeconomic evaluation studies and explain any two of them 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 a note on pharmacovigilance
- c)** Write note on food-drug interactions with some appropriate examples