UKA TARSADIA UNIVERSITY

M.Pharm. (Pharmacology) (3rd Semester)

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

Duration: 3 Hours **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) Answer the following. **[07]**

I) What is Investigator Brochure?
II) Define Pharmacogenetics
III) Define AUC and AUMC
IV) Give formula showing relationship between primary pharmacokinetic parameters
V) Which kinetic parameter affects the estimation of maintenance dose?
VI) Give composition of IRB.
VII) Define clearance

Q-1 (B) Answer the following in brief. (Any 4) **[08]**

I) Define IND. Enlist types of INDs.
II) What is Phase 0 trial?
III) Give difference between ANDA and NDA
IV) What is Clinical hold?
V) Dose ratio is greater than 2 produces sub-therapeutic effect - comment
VI) What are the different types of clinical trials?

Q-2 Answer the following. **[10]**

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

OR

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

B) Define Clinical trial. Give importance of Post marketing Surveillance and Clinical Pharmacological Evaluation

OR

B) Describe the factors affecting drug response in different racial, ethnic and sex groups.

Q-3 Answer the following in detail. (Any 2) **[10]**

A) Writa a note on following documents in a clinical study-
(i) Investigator's brochure (IB)
(ii) Case report form (CRF)

B) Write the influence of hepatic diseases on pharmacokinetics.

C) What is role and responsibilities of sponsor as per ICHGCP guidelines?

Section-2

Q-4 (A) Answer the following. **[07]**

I) Enlist renal function test
II) Define absolute bioavailability
III) What is therapeutic equivalence?
IV) Enumerate different laboratory parameters helps to evaluate pulmonary function
V) Define pharmacovigilance
VI) Name the methods for determining bioavailability of a drug from its dosage form.
VII) Enumerate the objectives of drug therapy monitoring.

Q-4 (B) Answer the following in brief. (Any 4) **[08]**

I) Enumerate the objectives of bioavailability studies.
II) Give the objectives and importance of pharmacoepidemiology
III) Give the significance of creatinine clearance test in Urinary tract obstruction
IV) Explain the objectives for conductance of bioequivalence studies
V) Outline the components of drug therapy review.
VI) Explain how spirometry is helpful in differentiating obstructive and restrictive pulmonary disease.

Q-5 Answer the following. **[10]**

A) Discuss the various factors affecting bioavailability of drug.

OR

A) Describe steps involved in conducting Drug Utilization Review/Evaluation
B) Explain importance of clinical laboratory test and patient case history in drug therapy monitoring

OR

B) What is rational drug use? Explain the factors influencing rational use of drugs

Q-6 Answer the following in detail. (Any 2) **[10]**

A) Describe pharmacokinetic drug interactions giving suitable examples
B) Describe in detail various types of costs and outcomes used in Pharmacoeconomic evaluation.
C) Write note on biosimilars