Exam Seat No:_____ **Enrollment No:_____**

C.U.SHAH UNIVERSITY
WADHWAN CITY
University (Winter) Examination -2013

Course Name :M.Pharm Sem-I **Subject Name: -Biopharmaceutics, Pharmacokinetics & Methods in Drug Evaluation**
Duration :- 3:00 Hours
Date : 13/1/2014 **Marks : 70**

Instructions:-
(1) Attempt all Questions of both sections in same answer book / Supplementary.
(2) Use of Programmable calculator & any other electronic instrument is prohibited.
(3) Instructions written on main answer Book are strictly to be obeyed.
(4) Draw neat diagrams & figures (If necessary) at right places.
(5) Assume suitable & Perfect data if needed.

SECTION-I

Q.1

1. Define the terms: bioavailability and bioavailability fraction. Also write their significances (3)
2. Why do we prefer multiple dose study over single dose study? (2)
3. Who does prefer for bioavailability studies? Healthy subject or patient? Why? (2)

Q.2

1. What is Biological half life? How can it be calculated? (5)
2. Which parameters are primary pharmacokinetic parameter? (5)
3. What is Volume of Distribution? How can it be calculated? (4)

OR

1. What is Renal Clearance? How it is related with $t_{1/2}$? (5)
2. Describe the any one method of establishing IVIVC. (5)
3. How are half life and Clearance related to each other? (4)

Q.3

1. Describe the Biological-, Pharmaceutical- and Analytical-aspects of Caco-2 cells. (7)
2. What is plasma protein binding? Enlist the methods to determine it factor affecting it and effect on therapeutic efficacy. (7)

OR

1. What are the characteristics of drugs showing greatest potential to create bioavailability related problems? Mention the objectives of bioavailability studies? Write a note on single dose versus multiple dose studies. (7)
2. Define various types of equivalence. How does Latin square cross over design work? State advantages and drawbacks of this method. What is significance of statistical interpretation of bioequivalence data? (7)

SECTION-II

Q.4

1.What is therapeutic equivalence as per FDA? (2)
2. Define sub acute toxicity. (2)
3.Define:Biowaivers (2)
4. Enumerate the causes of non- linear (1)

Q.5

1. Give advantages and disadvantages of urine data analysis over blood data analysis. (5)
2. What is AUC? How can it be measured? (5)
3. Describe the any one in-vivo model of antihypertensive. (4)

OR

1. What is plasma protein binding? Enlist the methods to determine its factors affecting it and effect on therapeutic efficacy. (5)
2. Define absorption and Absolute bioavaibility. Explain the schematic diagram of sequential absorption of oral drug. (5)
3. What is the significance of measuring plasma drug concentration? (4)

Q.6

1. Explain One Compartment Open Model – Extravascular administration (for first order kinetics) with equations. (7)
2. Explain Wagner-Nelson Method for estimation of Ka. (7)

OR

1. Describe Two compartment models with detail. (7)
2. Explain ICH guidelines (E6R1) (7)

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