Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/M.Pharm/SEM-1/MPT-116/2012-13

2012

BIOPHARMACEUTICALS AND PHARMACOKINETICS

Time Allotted : 3 Hours *Full Marks* : 70

The figures in the margin indicate full marks.

Candidates are required to give their answers in their own words as far as practicable.

GROUP – A

(Multiple Choice Type Questions)

1. Choose the correct alternatives for any *ten* of the following : 10 × 1 = 10

   i) Drug disposition kinetics refers to the rate process of

      a) absorption

      b) distribution

      c) elimination

      d) both distribution and elimination.

   ii) The substance use for the measurement of glomerular filtration rate is

      a) inulin

      b) para aminohippuric acid

      c) glucose

      d) mannitol.

iii) Enhancement of half life of penicillin by probenacid is due to interaction during

a) Absorption b) Distribution

c) Metabolism d) Excretion.

iv) The 'flip flop' phenomenon occurs when

a) Ka/Ke < 0.3 b) Ka/Ke > 0.3

c) Ka/Ke > 3.0 d) none of these.

v) Wagner-Nelson holds true for

a) one compartment model

b) two compartment model

c) non-compartment model

d) all of these.

vi) The creatinine clearence of a normal person is

a) 70 ml b) 90 ml

c) 120 ml d) 150 ml.

vii) Warfarin & phenylbutazone used to bind with which of the following class of protein

a) Lipoprotein b) Albumin

c) Globulins d) Hemoglobin.

viii) The expression for relative bioanailability is

a) $\frac{AUC_{test} \times Dose_{ref}}{Dose_{test} \times AUC_{ref}}$ b) $\frac{AUC_{ref} \times Dose_{test}}{Dose_{ref} \times AUC_{test}}$

c) $\frac{AUC_{test} \times Dose_{iv}}{Dose_{test} \times AUC_{iv}}$ d) none of these.

ix) In the placental barrier the fetal membrane is made of

a) Glial cell

b) Choroidal cell

c) Trophoblast and endothelium

d) Trophoblast and exothelium.

x) Evans blue is a marker for

a) total body water

b) plasma volume

c) extra cellular fluid volume

d) cerebrospinal fluid volume.

xi) If a drug has half-life of 4h in a 60 kg patient and V_d is 5.5L/Kg, the total systemic clearance of drug is

a) 872 ml/min b) 900 ml/min

c) 1243 ml/min d) 953 ml/min.

xii) Commonly, $r/[D]$ vs. 'r' plot is known as

a) orbit plot b) scatchard plot

c) double reciprocal d) mullen plot.

GROUP – B
(Short Answer Type Questions)

Answer any *three* of the following. 3 × 5 = 15

2. Show that the zero-order kinetic constant is concentration dependent whereas first order kinetic constant is independent of concentration.
3. Explain the assumptions of classical compartment modeling.
4. Enumerate the physiological significance of protein binding.
5. Explain different levels of in-vivo and in-vitro correlations (IVIVC) for a pharmaceutical dosage form.
6. Define BA and BE. How the bioequivalence data of drug products is interpreted statistically ?

GROUP – C
(Long Answer Type Questions)

Answer any *three* of the following. 3 × 15 = 45

7. a) What is steady state concentration ? Discuss the factors which influence steady state concentration ?
   b) Derive expression for the calculation of C_{ss} in one compartment open model IV infusion. 2 + 4 + 9

8. Define and classify compartments ? Mention the advantages and disadvantages of classical compartmental modeling. Derive the disposition equation of a drug following one compartment open model IV bolus administration. 2 + 4 + 9

9. a) Define apparent volume of distribution. Why is it called "apparent" ?
   b) Derive the relationship between Vapp and protein binding. Explain the significance of the relationship.
   c) Discuss briefly the factors influencing bioavailability. (1 + 1 + (5 + 2) + 6

10. What is meant by non-liner pharmacokinetics ? What causes non-linear pharmacokinetic behaviour of drugs ? Mathematically, show that Michaelis-Mention kinetics may describe a zero-order and/or a first-order process.

    Theophylline was administered to a patient at dosing rates of 600 mg/day and 1.2g/day and the respective steady state concentration were found to be 9.8 mg/L and 28.6mg/L. Find V_{max} and K_m . Determine the dosing rate to achieve a C_{ss} of 15mg/L. 2 + 3 + 5 + 5

11. Explain renal clearance of drugs and its method of determination ? Establish a mathematical relationship between hepatic blood flow (Q_H), intrinsic clearance (CL_{int}), hepatic clearance (CL_H) and fraction of plasma protein-unbound drug (fu). 5 + 10