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SB-1171

Fourth Year B. Pharm. Examination

March/April – 2011

PH-401 : Pharmaceutics - V

(Biopharmaceutics, Pharmacokinetic & Dosage Form Design)

Time : **3** Hours] [Total Marks : **70**

Instructions :

(1)

નીચે દર્શાવેલ ☛ નિશાનીવાળી વિગતો ઉત્તરવહી પર અવશ્ય લખવી.
Fillup strictly the details of ☛ signs on your answer book.

Name of the Examination :

☛ **Fourth Year B. Pharm.**

Name of the Subject :

☛ **Pharmaceutics - 5**

☛ Subject Code No. : **1 1 7 1** ☛ Section No. (1, 2,.....) : **1&2**

Seat No. :

Student's Signature

(2) There are two sections each of 35 marks.

(3) Each section having three questions.

(4) Answer and submit both the sections separately.

SECTION - I

1 Attempt any **five** from the following : **10**

(a) Write the characteristic of passive diffusion.

(b) Why is the placental barrier not effective as BBB ?

(c) Why HSA considered a versatile protein for drug distribution ?

(d) Phase II reactions are called as true detoxification reaction. Explain.

(e) What is sink condition and how is it maintained and why it is needed ?

(f) List the various pharmaceutical and pharmacokinetic application of prodrug.

(g) What factors determine the pulmonary excretion of drug ?

2 Attempt any **four** from the following : **16**

(a) Explain BBB (Blood brain barrier)

(b) Discuss drug metabolizing enzyme.

(c) Following data is obtained for 4 formulation of a drug in patients of average weight 50 kg.

Drug Product	Dose (mg/kg)	AUC (mcg.hr/l)
I.V. solution	1.2	450
Oral solution	4.0	822
Oral capsule	4.0	736
Oral S.R tablet	8.0	1040

(i) What is the absolute bioavailability from capsule and S.R. tablet ?

(ii) What is the relative bioavailability of capsule and S.R. tablet against oral solution ?

(iii) Which solid formulation shows better bioavailability?

(iv) Are the two solid formulation shows bioequivalent ?

(d) A new antibiotic drug was given in a single intravenous bolus of 4 mg/kg to five healthy male adults ranging in age from 23 to 38 years (average weight 75 kg). The pharmacokinetics of the plasma drug concentration-time curve for this drug fits a one-compartment model. The equation of the curve that best fits the data is

$C_p = 78\ e^{-0.46t}$

Determine the following (Asuming units of μ g/ml for C_p and hr for t)

(i) What is the $t_{1/2}$?

(ii) What is the V_D ?

(iii) What is the plasma level of the drug after 4 hours ?

(iv) How much drug is left in the body after 4 hours ?

(e) Explain cross over study and Balance incomplete block design.

(f) What are the two methods of calculating K_E from urinary excretion data ? Compare their merits and demerits.

3 Attempt any **three** from the following : **9**

(a) Define dose ratio. Why is it always smaller for extra vascularly administered drug in comparison to intravenously administered drug ?

(b) Discuss diffusion controlled release system.

(c) Define preformulation and write about solubility studies.

(d) Write the limitation and significance of P^H partition hypothesis.

(e) Estimate the creatinine clearnace of a 30 year old, 70 kg man with serum creatinine value 2.0 mg%. What is renal function value of such a patient ?

SECTION - II

4 Attempt any eleven from the following : **11**

(a) Define extraction ratio.

(b) Enlist all official apparatus of dissolution.

(c) Why buffered tablet are more soluble than salt form of aspirin ?

(d) Name the three approaches by which a polar drug can be targeted to brain.

(e) Define intrinsic solubility.

(f) Define fluctuation and accumulation index.

(g) Delayed intestinal transit time is some time desirable. Why ?

(h) Define prospective validation.

(i) What is stress testing ?

(j) Comment - Micronization of hydrophobic drug is not advisable.

(k) Define MRT.

(l) Why are reservoir devices susceptible to dose dumping ?

(m) What is dose dependent kinetics and write the name of tests by which it can detect ?

(n) Comment - Can a drug have two or more than V_d ?

(o) Define IVIVC.

5 Attempt any **three** from the following : **12**

(a) Write the name of non renal methods of drug excretions and discuss in detail biliary excretion.

(b) Discuss in detail process variable of tables.

(c) Write in brief the effects of urine P^H, drug PKa and lipid solubility on re-absorption of drug.

(d) Discuss BCS (Biopharmaceutical Classification System).

(e) How a dosage regimen will design. Explain every step in detail.

6 Attempt anay two from the following : **12**

(a) Calculate the absorption rate constant using wagner-nelson method of following given data. Ke = .086 hr^{-1}.

Time (hr)	0	1	2	3	5	7	9	12	18	24	36	48
Drug Concentration (μ g/ml)	0	1.88	3.05	3.74	4.21	4.08	3.70	3.02	1.86	1.12	0.40	0.14

(b) Explain all methods to increase bioavailability in detail.

(c) Atenolol is to be administered orally to a 50 kg patient suffering from hypertension. The typical parmeter of the drug on population basis are :

F	V_d	CL_T	Therapeutics range
0.4	1.23 l/kg	118.4 ml/min	0.2 - 1.3 mcg/ml

Design a dosage regimen to attain and maintain the plasma concentration within the therapeutics range. Assume rapid absorption.