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RB-1361-62

Final Year B. Pharm. Examination

April / May – 2010

PH-401 : Biopharmaceutics Pharmacokinetics & Dosage Form Design

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

RB-1361

Instructions :

(1)

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

Name of the Examination :

☛ **Final Year B. Pharm.**

Name of the Subject :

☛ **PH-401 : Bio. Pharmacokine. & Dosage Form Design**

☛ Subject Code No. : **1 3 6 1** ☛ Section No. (1, 2,.....) : **1**

Seat No. :

Student's Signature

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

(3) All questions are **compulsory**.

(4) Answer section-I and Section II in **separate** answer books and tie it **separately**.

(5) Numbers to the right indicate marks of the question.

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

(a) Write the steps involved in oxidation of xenobiotics.

(b) Differentiate the passive and facilitated diffusion.

(c) What is the influence of size of counter ion on solubility of salt forms of the drug?

(d) Enumerate different approaches by which a polar drug can be targeted to brain.

(e) Write about the physiochemical properties of drug which affect the distribution of drug.

(f) What is influence of K_a and K_E on C_{max} – t_{max} and AUC?

(g) Explain briefly extraction ratio.

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

(a) What is dose dependent kinetics and what are different ADME processes responsible for this kinetics illustrate with example ?

(b) Which are accepted statistical rules for establishing bioequivalence between formulations and discuss briefly the methods for the measurement of bioavailability?

(c) Explain IVIVC.

(d) The elimination half-life of an antibiotic is 3 hours with an apparent volume of distribution equivalent to 20% of body weight. The usual therapeutic range for this antibiotic is between 5 and 15 μ g/ml average toxicity is observed at serum concentration greater than 20 μ g/ml. Calculate a dosage regimen (multiple IV doses) that will just maintain the serum drug concentration between 5 and 15 μ g/ml.

(e) Discuss briefly various physical and chemical stability testing parameters for different pharmaceutical dosage forms.

(f) Discuss briefly influence of pharmaceutical excipients on drug absorption.

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

(a) A 70 kg patient is given an antibiotic by I.V. infusion. The drug has a half life of 22 hr, apparent volume of distribution 15.7 liter and the desired steady state plasma concentration is 0.00002 mcg/ml. Assuming one compartment kinetics, calculate

(i) The time required to reach 90% of Css.

(ii) The infusion rate to achieve the desired Css.

(iii) The loading dose to attain Css rapidly.

(b) Explain USP type II dissolution apparatus.

(c) Do the renal clearance values reflect the mechanism of clearance? If yes then write the values and their mechanism.

(d) Explain pharmacokinetic applications of prodrug.

(e) What are advantages and disadvantages of transdermal drug delivery system ?

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Name of the Examination :

☛ **Final Year B. Pharm.**

Name of the Subject :

☛ **PH-401 : Bio. Pharmacokine. & Dosage Form Design**

☛ Subject Code No. : **1 3 6 2** ☛ Section No. (1, 2,.....) : **2**

Seat No. :

Student's Signature

(2) There are **two** sections, each of **35** marks.
(3) All questions are **compulsory**.
(4) Answer section-I and Section II in **separate** answer books and tie it **separately**.
(5) Numbers to the right indicate marks of the question.

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

(i) Define retrospective validation.
(ii) What is Biowaiver?
(iii) Write the difference between absolute and relative bioavailability.
(iv) Define shelf life with its equation.
(v) What is intrinsic capacity clearance?
(vi) Why do first order equation requires logarithmic transformation?
(vii) Define in-vitro dissolution test.
(viii) Comment - Healthy subjects are preferred over patients as volunteers for bioavailability studies.
(ix) Why are drugs referred to as xenobiotics?
(x) Define renal clearance ratio.
(xi) What is principle of superposition?
(xii) Write Noyes Whitney equation.
(xiii) What is absorption window?
(xiv) Why zero order release system is considered ideal controlled delivery?
(xv) Classify oral controlled release formulation.

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

(a) Explain the significance of protein binding.
(b) A single oral dose (100 mg) of an antibiotic was given to an adult male patient (43 year. 72 kg), the pharmacokinetic of the drug fits to a one compartment model. The equation that best fit the pharmacokinetics of the drug is $C = 45 (e^{-0.17t} - e^{-1.5t})$

Calculate

(i) t_{max}

(ii) C_{max}

(iii) $t_{1/2}$ of the drug

Assume concentration in μ g/ml and rate constant in hr^{-1}.

(c) The half life of propranolol in a 60 kg patient is 4 hr and V_d is 5.5 liter/kg. Determine

(i) Total systemic clearance of drug

(ii) What will be renal clearance if fraction excreted unchanged 1 urine is 0.047?

(iii) Comment on mechanism of renal excretion of drug.

(d) Explain BCS.

(e) Explain various ways to determine shelf life of a pharmaceutical product.

6 Attempt any **two** questions from the following : **12**

(a) Plasma samples were after an oral bolus dose of 10 mg of a new drug as follows :

Time (hr)	0.25	0.50	0.75	1.00	2.00	4.00	6.00	10.00	14.00	20.00
Concentration μg / ml	2.85	5.43	7.75	9.84	16.20	22.15	23.01	19.09	13.90	7.97

Calculate :

(i) Elimination constant of drug

(ii) Determine Ka by feathering method.

(b) Neomycin is to be administered to a 70 kg patient at rate of 2mg/kg every 12 hr by multiplying i.m. injection. The drug has a half life of 2.2 hour and V_d of 0.2 *l*/kg

(i) Determine Css max, Css min and Css avg.

(ii) If $t_{1/2}$ increases to 5 hours in renal insufficiency, what should be the new dose?

(iii) If drug is to be injected once every 24 hours in renal insufficiency what should be the new dose?

(iv) If same drug is to be administered in an elderly patient of 85 years and 55 kg body weight, determine the dose.

(c) Discuss in detail the factor affecting dissolution rate of drug.
