03-12-14 (R9)

Total No. of printed pages = 7

PY 134104

Roll No. of candidate | | | | | | | | | | |

2014

M. Pharm 1st Semester End-Term Examination

BIOPHARMACEUTICS AND PHARMACOKINETICS

Full Marks – 100 Pass Marks – 35 Time – Three hours

The figures in the margin indicate full marks for the questions.

1. (a) Which of the following is a rate limitting step in absorption of hydrophobic drug ? 1×10=10

   (i) disintegration

   (ii) dissolution

   (iii) permeation across

   (iv) biological membrane

   (b) Bioavailability is defined as rate and extent of drug ..... .

   (c) Passive diffusion is expressed by ..... law of diffusion.

[Turn over

(d) Which of the following are true ?

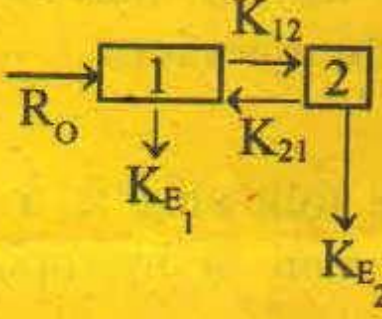
(i) $V_d \propto K_E$ (ii) $V_d \propto \frac{1}{K_E}$

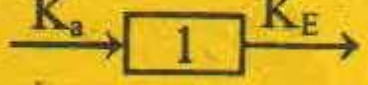
(iii) $V_d = K_E$ (iii) $V_d \neq K_E$

(e) Which of the following are true for IV infussion model ?

(i) 

(ii) 

(iii) 

(iv) 

(f) In non-linear kinetics..... is an example of cause drug excretion.

(g) How will you evaluate child dose ? Give one formula.

(h) In a patient suffering from renal disease ..... of drug will decrease.

(i) K_a and K_E both can be determined by

(i) Wagner-Nelson method

(ii) Method of residuals.

(j) Which of the following is a property of central component ?

(a) High blood pressure rate

(b) Low vascularity.

2. Answer any *ten* questions : 2×10=20

(i) List out the different causes of non-linearity.

(ii) What do you mean by lag time in drug absorption ?

(iii) Explain in brief per oral drug absorption.

(iv) What is intrinsic clearance ?

(v) What is bioavailability factor ?

(vi) Write a short note on physiological pharmacokinetic model.

(vii) What are the limitations of multiple dose regimen ?

(viii) What are pharmaceutical and therapeutic equivalence ?

(ix) Explain the effect on solubility in drug absorption.

(x) Explain Latin square design.

(xi) What is drug-drug interaction mediated through absorption ?

(xii) Briefly discuss the effect of residence time and transit time of food on dry absorption.

3. Answer any *ten* questions : 3×10=30

(i) Explain the dose adjustment in renal impairment.

(ii) Explain the concept of multicompartment modeling.

(iii) Derive K_E and $t_{1/2}$ for I.V infusion. (One compartment)

(iv) Describe drug disposition and clearance ratio.

(v) Write a note on significance of protein binding and volume of distribution.

(vi) Explain non-linear pharmacokinetics and its effect on protein binding.

(vii) What are the different biological barriers to drug absorption ? Explain.

(viii) Determine K_m and V_{max} for a non-linear reaction.

(ix) Explain mixed drug elemination.

(x) Briefly highlight the kinetics of drug interaction.

(xi) Write notes on the different dissolution testing apparatus as per USP.

(xii) Write in brief about

(a) medianism of clearance

(b) C_{max} and t_{max}.

4. Answer any *five* questions : 4×5=20

(i) Discuss the effect of alcohol and food on drug action.

(ii) Define bioavailability of a new drug product. What are the different pharmacokinetic parameters for determination of bioavailability and explain them.

(iii) Derive absorption rate constant by Wagner Nelson method.

(iv) Give a brief account of :

(a) Hepatic clearance

(b) AUC

(v) Explain flip-flop model.

(vi) What is V_d ? Explain its significance. Discuss its relationship with clearance and K_E.

(vii) How can dissolution of drug product be improved ?

5. Answer any *four* questions : 5×4=20

(i) What are the objectives and approaches in developing invivo-invitro correlation ?

2+3=5

(ii) Explain the detailed procedure of bioequivalence study of a rarely formulated tablet.

(iii) What are the different considerations for compartmental modeling ? Explain.

(iv) Derive the different pharmacokinetic parameters applicable to one compartment I.V bolus administration.

(v) Explain direct, linear and orbit graph method of dosing.