Time: 3 hours **Marks: 80**

Please check whether you have got the right question paper.

N.B: (1) All questions are **compulsory**.
(2) Figures to the right indicate **full marks**.
(3) **Use of scientific calculator is permitted.**

Q.1		Answer the following:	
	a.	Define: Bioequivalence, Pharmacokinetics	**2**
	b.	Justify "Biomembranes act as a semi permeable barrier"	**2**
	c.	Enlist factors affecting topical administration.	**2**
	d.	Explain the difference between real and apparent volume of distribution.	**2**
	e.	What are mechanisms of direct enzyme inhibition?	**2**
	f.	Write a note on Salivary excretion of drugs.	**2**
	g.	Explain term "Highly permeable" as per BCS classification.	**2**
	h.	Draw a one compartment open model for IV bolus administration.	**2**
	i.	Under what circumstances is the value of Ka computed from method of residuals incorrect?	**2**
	j.	Calculate relative bioavailability of tablet containing drug Y if dose administered is 530mg and [AUC] zero to infinity is 425mg.hr/lit against solution of drug Y if dose administered is 125mg and [AUC] zero to infinity is 222mg.hr/lit.	**2**
Q.2	a.	Enlist the difference between active and passive transport.	**4**
	b.	Explain the effect of particle size of API and diluents on drug absorption.	**4**
	c.	Explain why glucuronidation is the commonest and most important of all phase II reactions.	**4**
Q.3	a.	Describe the physiological factors affecting the distribution of drugs in tissues.	**4**
	b.	What is the effect of protein binding on the apparent volume of distribution?	**4**
	c.	Describe the method of residuals for the calculation of absorption rate constant.	**4**
		OR	
		Explain the equation used for calculation of nonlinear kinetic behavior of drugs.	**4**
Q.4	a.	What are the effects of enzyme induction on drug metabolism? Describe in detail.	**4**
	b.	Write a note on hepatic clearance of drugs.	**4**
	c.	Describe the effect of renal disease state on drug elimination.	**4**

Q.5 a. State the factors affecting dissolution rate of a drug according to the modified Noyes-Whitney's equation. **4**

b. Describe an official method for the estimation of dissolution rate of coated tablets. **4**

c. What are the methods for enhancement of bioavailability of poorly permeable drugs? **4**

OR

Write a note on IVIVC. **4**

Q.6 a. How are the elimination rate constant, elimination half-life and clearance determined after an IV bolus injection? **4**

OR

What is an 'optimal dosage regimen'? For a one-compartment model, state the mathematical expressions for maximum, minimum, and steady-state concentrations of drug in the plasma following multiple IV injections.

Q.6 b.(i) An intravenously administered bolus dose of 25mg of a drug following one compartment kinetics has a half-life of 14hrs. If the plasma concentration at zero time is 25mg/L, calculate

i.) Elimination rate constant and volume of distribution **01**

ii.) AUC(zero to infinity) and total clearance of the drug **01**

iii.) Plasma concentration of the drug after 8 hours **01**

iv.) Amount of drug left in the body after 12 hours **01**

b.(ii) A single oral dose of 75mg of a drug (F=0.6) was given to a 70 kg patient. The plasma concentration-time profile can be described by:

$$C_p = 12(e^{-0.45t} - e^{-1.73t})$$

where, C_p = mg/L, t=hours.

Calculate:

A. Volume of distribution **01**

B. Tmax **01**

C. Cmax **02**