**Q.P. Code :04397**

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

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. 02
b) Give advantages of Transdermal route of drug administration. 02
c) What is the relation of apparent volume of distribution and clearance? 01
d) Give two characteristics of microsomal enzyme system. 02
e) Why is entero-hepatic circulation important in the conservation of vitamin $B_{12}$? 02
f) What are the challenges in formulating BCS Class II drugs? 02
g) What are the disadvantages of physiological modeling. 02
h) Why is the IV route used to calculate absolute bioavailability. 02

Q.2 a. Explain the various types of active transport mechanisms. 04
b. As per Noye's Whitney equation, state the factors which affect the dissolution of drugs. 04
c. Discuss drug-drug interactions affecting absorption of drugs from GIT. 03

Q.3 a) How does the lubricant and disintegrant affect absorption? 03
b) What are the physico-chemical factors affecting drug distribution? 04
c) What are the causes of non-linearity in drug absorption and drug excretion? 04

OR

Discuss rate of excretion method for determination of $K_E$. 04

Q.4 a. Write a short note on phase I oxidation reactions. 04
b. How does first pass metabolism of a drug affect systemic availability? 03
c. How do distribution and binding characteristics of drug affect renal clearance? 04

Q.5 a. Discuss how the particle size and effective surface area of a drug influences the dissolution rate? 04
b. Explain a dissolution apparatus which maintains sink conditions. 03
c. How do you measure bioavailability by urinary excretion method? 04

OR

Discuss advantages and disadvantages of the various methods of bioequivalence experimental study design. 04

Q.6 a. Describe various pharmacokinetic parameters after I.V bolus dosing. 04

OR

How do you determine absorption rate constant using method of residuals? 04

TURN OVER

Q.6 b. After an intravenous bolus injection of 50 mg of a drug following one compartment kinetics. The plasma concentration time profile is represented by –

$C = 42e^{-0.04t}$

Calculate

a) Elimination half-life and AUC. 01
b) Volume of distribution and clearance. 01
c) Plasma concentration after 5 hours. 01
d) Amount eliminated after 7 hours. 02
e) Time required for elimination of 60% of the dose. 02

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