Ref.No.: Ex/MPH202T/2024

M. PHARM FIRST YEAR SECOND SEMESTER EXAMINATION - 2024
COURSE NAME: ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
COURSE CODE: MPH202T

Time: 3hour **Full Marks: 75**

Answer **question No. 1** and **any one** from the rest of **Group-A** and **question No. 4** and **any two** from the rest of **Group-B**

Group: A

1. (a) Write Lipinski's rule of five approaches. Why it is important? (3)
   (b) For the measurement of bioavailability from urine sample, which criteria should follow by the drug? (2)
   (c) Write IVIVC Level-A? (2)
   (d) Draw plasma-drug profile curve, level and calculate AUC mathematically (4)
   (e) Define Fick's law of diffusion. How we can relate permeability with diffusion? (4)
   (f) How solubility of a salt form of a drug is increased? (2)
   (g) Define dissociation constant. How could you predict the ionization of drug from it? (3)
2. Describe in details the theory of drug dissolution. (15)
3. Write notes on (a) Dissolution acceptance criteria (b) Brush border membrane vesicles permeability study (c) Vesicular transport and ABC transporter. (5×3=15)
4. How can the solubility of a poorly water soluble drug be increased? (15)

Group: B

5. (a) Determine Ka by Loo-Riegelman method. Write the advantages of this method over other methods for determination of Ka. (4+2 =6)
   (b) Deduce the time-concentration relationship equations for more than one capacity limited elimination process. (3)
   (c) Find out the intravenous infusion rate of a drug administered to a patient who achieved the steady-state plasma concentration of the drug 18 mg/L. The apparent volume of distribution of the dose is 15 L, and the elimination rate is 0.15 h^{-1}. Find out how long the drug requires achieving 85 and 98% of the steady-state plasma concentration in the patient? When the rate of elimination is 0.12 h^{-1}, what should be the rate of infusion then? (6)
6. (a) In a two-compartmental model, when the drug undergoes hepatic first-pass metabolism, show that bioavailability of a drug is invariably more by i.v. route of drug administration.
   (b) A drug that undergoes elimination following nonlinear kinetics has been administered to a patient with two different doses, 500 and 650 mg, in two different situations. The values for Km and V_{max} of the drug in the patient are 120 mg and 75 mg/h. Calculate the half-life of the drug on both occasions in the patient. (9+6=15)
7. (a) In one-compartment open model, determine overall elimination rate constant when the infusion has been stopped before the plasma drug concentration reaches the steady-state level in a patient. (5)
   (b) Explain the terms chemical equivalent, pharmaceutical equivalent, bioequivalent, and therapeutic equivalent. Deduce the equation of Sandberg plot. (2+2=4)
   (c)A bi-exponential series represents the plasma concentration of a drug at time *t* in a two-compartmental model in the form of $cp = Ae^{-\alpha t} + Be^{-\beta t}$, where A = 28 and B =7.5 and α =1.8 and β = 0.32. The dose of the drug is 600 mg. Find K_{21}, K_{12}, K_E and V_c. (6)
8. Write short notes on (**any two**): (5X2 = 10)
   (a) Flip-flop phenomenon
   (b) Peeling method
   (c) Apparent and absolute bioavailability and their relationship with $t_{1/2}$values