KATHMANDU UNIVERSITY
End Semester Examination
January/February 2024

Marks Scored:

Level : B.Pharm.
Year : II

28 JAN 2024

Course : PHAR 223
Semester : II

Exam Roll No. :

Time: 30 mins.

F. M. : 20

Registration No.:

Date :

SECTION "A"
[20Q. × 1 = 20 marks]

Encircle the most appropriate answer

1. If the absorption rate of the Aspirin drug is Slow but shows complete absorption, then we can obtain:
   a. short T_{max}, high C_{max}, high AUC
   b. short T_{max}, low C_{max}, low AUC
   c. long T_{max}, high C_{max}, high AUC
   d. long T_{max}, low C_{max}, low AUC

2. Two or more drug products are identical in strength, quality, purity, content uniformity and disintegration and dissolution characteristics, but may differ in containing different excipients.
   a. Bioequivalent products
   b. Generic equivalent products
   c. Therapeutic equivalent products
   d. Pharmaceutic equivalent products

3. Which condition usually increases the rate of drug dissolution from a tablet?
   a. Increase in particle size of the drug
   b. Decrease in surface area of the drug
   c. Use of ionized form of the drug
   d. Use of sugar coating around the tablet

4. During the process of dissolution, the precipitation of minute particles takes place in case of following dosage form:
   a. Solution b. Suspension c. Both a and b d. None

5. According to Biopharmaceutical classification System, the rate limiting step for class II type of drug is:
   a. Dissolution b. Permeability c. Both a and b d. None

6. Which of the following is characteristic of the oral route?
   a. Absorption depends on GI tract secretion and motor function
   b. Fast onset of effect
   c. A drug reaches the blood bypassing the liver
   d. The sterilization of medicinal forms is obligatory

7. When the solvent molecules are entrapped in the crystalline structure of the polymorph, it is called as:
   a. Pseudo-polymorphism
   b. Amorphism
   c. Crystallinity
   d. All of the above

8. Which of the following is the essence of the Biopharmaceutical Classification System?
   a. It gives guidance in the design of new preparations on the basis of the degree of ionization of the active agent
   b. It gives guidance on the revelation of the in vitro-in vivo relationship on the basis of the solubility and permeability of the active agent
   c. It gives guidance in the design of preparations with modified drug release preparation
   d. It gives guidance on the physico-chemical properties of the active agent and pharmaceutical excipients applied in the preparation

9. Which of the following statements relating to the drug-meal interactions is **FALSE**?
   a. Meal can influence the functions of enzymes of the drug metabolism
   b. The retention time of a preparation decreases in the GI tract due to the acceleration of the peristalsis
   c. Absorption decreases due to meals with a high fibre content
   d. When the secretion of bile increases, the solubility and absorption of lipophilic drugs usually decline

10. Which of the following statements relating to multiple doses is **CORRECT**?
   a. The first dose of all multiple doses is a higher loading dose, followed by smaller sustaining doses
   b. The functions of enzymes of the liver are taken into account when multiple doses are determined in cases of decreased elimination
   c. There is no significant change in the development of the therapeutic effect in the event of a missed dose during repeated doses
   d. Patient compliance can be increased by lengthening the time interval between repeated doses

11. Movement of drug from gastro intestinal (GI) tract to blood is known as .....
   a. Absorption b. Distribution c. Metabolism d. Excretion

12. ..... route of administration does not by pass first pass metabolism.
   a. Transdermal b. Nasal c. Buccal d. Post oral

13. In process following first order kinetics, drug half life is 5 hours,elimination rate constant, Ke is .....
   a. 0.1386 b. 0.693 c. 0.2 d. d. 0.215

14. Elimination rate constant (Ke) of a drug is 0.3465/h. Volume of drug distribution (Vd) is 140 litre. Calculate clearance of the drug is ..... L/h
   a. 0.002475 b. 48.5 c. 404d. d. 0.002475

15. Metabolism and excretion are combinedly known as .....
   a. Clearance b. Disposition c. Elimination d. Pharmacodynamics

16. Extent of absorption is expressed by .....
   a. Absorption rate constant (Ka) b. Area under the curve (AUC)
   c. Volume of distribution (Vd) d. Peak Plasma drug concentration (Cmax)

17. Volume of distribution (Vd) is important to calculate .....
    a. Maintenance dose
    b. Absorption rate constant (Ka)
    c. Loading dose
    d. Peak Plasma drug concentration (Cmax)

18. Clearance is important to calculate .....
    a. Maintenance dose
    b. Absorption rate constant (Ka)
    c. Loading dose
    d. Peak Plasma drug concentration (Cmax)

19. Rate of absorption is expressed by .....
    a. Absorption rate constant (Ka)
    b. Area under the curve (AUC)
    c. Volume of distribution (Vd)
    d. Peak Plasma drug concentration (Cmax)

20. The rate and extent of drug that reaches the systemic circulation is known as .....
    a. Bioavailability
    b. Biopharmaceutics
    c. Pharmacokinetics
    d. Pharmacodynamics

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Semester : II
F.M. : 55

Indicate by checking (√) of each question you have answered in the cover page of main answer book.

SECTION "B"
[5Q. × 3 = 15 marks]

Attempt *ANY FIVE* questions.

1. Explain cross-over design with its merits and demerits.
2. How does the salt formation approach improve the drug solubility?
3. Give examples of Non-linearity in ADME processes.
4. How can you estimate Cpmax and Cpmin for multiple oral dose regimen?
5. Define Clearance, Apparent volume of distribution and Absolute Bioavailability with their units.
6. Mention the characteristics of ideal plasma drug concentration- time profile.
7. A dose of 100 mg was administered to healthy volunteer. Seven blood samples were collected at 0.5, 1, 2, 4, 6, 8, 10 hours. Plasma was separated from each blood sample and analyzed for drug concentration. The collected data are shown in the table below:

Hour	0	0.5	1	2	4	6	8	10	a
Cp(mg/L)		2.64	2.09	1.57	0.87	0.45	0.25	0.13	

Calculate each AUC segment including the last segment.

SECTION "C"
[5Q. × 5 = 25 marks]

Attempt *ANY FIVE* questions.

8. How do the excipients used in tablet formulation affect the bioavailability of drug?
9. Define Km and Vmax in Non-linear Pharmacokinetics. How can we calculate them?
10. Explain the effect of pH and pKa of the drug on drug absorption.
11. State the principle for multiple dose pharmacokinetics. A patient (weight-70 kg) is to receive a drug by multiple IV bolus doses. For optimal treatment drug concentration should be kept between Cpmax 10 mg/L and Cpmin 1 mg/L. This drug has an apparent volume of distribution of 1 L/kg and an elimination rate constant of 0.1 hr^{-1}. Calculate the loading dose and maintenance dose regimen.

12. A IV bolus dose of 500 mg was administered to a healthy volunteer. Seven blood samples were collected at 1, 2, 3, 4, 6, 10, and 12 hours. Plasma was separated from each blood sample and analyzed for drug concentration. The collected data are shown in the table below:

Time (hr)	1	2	3	4	6	10	12
Cp (mg/L)	18.91	14.11	10.41	7.81	4.05	1.19	0.66

Calculate kel, Vd, t1/2 and Clearance.

13. Calculate the drug concentration 0.5 hours after a continuous IV infusion of 6 mg/hr has been administered to a patient. Assume a one compartment pharmacokinetic model. The Vd and total body clearance values for this drug are 44.2 L and 6.9 L/hr respectively.

14. A drug was administered by IV infusion of 12.5 mg/hr for 45 min to healthy volunteer. Seven blood samples were collected at 2, 3, 4, 6, 8, 10, and 12 hours after the start of the infusion. Plasma was separated from each blood sample and analyzed for drug concentration. The collected data are shown in the table below:

Time (hr)	2	3	4	6	8	10	12
Cp (mg/L)	0.673	0.443	0.288	0.124	0.054	0.023	0.01

Calculate kel, $t_{1/2}$, Vd, and Cl.

SECTION "D"
[2Q. × 7.5 =15 marks]

Attempt *ANY TWO* questions.

15. Explain on Bioavailability and Bioequivalence (BA&BE) study? Mention the evaluation criteria for BA&BE study. Give your opinion on application of Biowaiver and In-vitro In-vivo correlation (IVIVC) concepts on BA&BE study.

16. Explain the influence of food, transit time, and enzymes in GI tract on the drug absorption. Elaborate on the significance of formulation strategies such as prodrugs, nanotechnology, and modified release in enhancing or controlling drug absorption.

17. An IV Bolus dose of 250 mg was administered to a healthy volunteer. Blood samples were collected and plasma was separated from each blood sample and analyzed for drug concentration. The collected data are shown in the table below:

Time (hr)	0.25	0.5	0.75	1	1.25	1.5	2	4	6	9	12
Cp (mg/L)	1.51	1.01	0.83	0.75	0.71	0.69	0.66	0.54	0.45	0.34	0.26

Estimate A, B, α and β. Does the ratio of α to β satisfy the requirement of the method of residuals?