KATHMANDU UNIVERSITY
End Semester Examination
May/June, 2022

Marks Scored:

Level : B.Pharm.
Year : III
Course : PHAR 315
Semester : II

Exam Roll No. :
Time: 30 mins.
F. M. : 20

Registration No.:
Date : 12-June-022

SECTION "A"
[20Q. × 1 = 20 marks]

Encircle the most appropriate answer.

1. _____ is the characteristic of dissolution controlled release.
   a. Release drug in entire length of GIT
   b. Prolong their residence in GIT and release
   c. Release only at specific site
   d. Very slow dissolution rate

2. Larger particle size leads to _____ dissolution.
   a. Slower
   b. Faster
   c. Moderate
   d. Normal

3. The study of manufacturing factors and physicochemical influencing rate and extent of drug absorption from the site of administration of a medicine is called _____ .
   a. Pharmaceutics
   b. Biopharmaceutics
   c. Pharmacokinetics
   d. Clinicopharmacology

4. _____ is the physicochemical property of drug substance.
   a. Drug solubility
   b. Dissolution time
   c. Disintegration time
   d. Tablet Hardness

5. In the sequence of events of drug absorption of orally administered solid dosage form _____ comes first.
   a. Disintegration
   b. Disaggregation
   c. Dissolution
   d. Absorption

6. _____ form of drug formulation has disintegration time.
   a. Injections
   b. Syrups
   c. Capsules and Tablets
   d. Diagonal of the box

7. _____ is not a form of excipients.
   a. Paracetamol
   b. Disintegrants
   c. Binders
   d. Lubricants

8. _____ form of the drug has the highest bioavailability
   a. Suspension
   b. Solutions
   c. Tablets
   d. Emulsions

9. _____ gives extent of drug absorption.
   a. Area under the curve(AUC)
   b. Apparent volume of distribution (Vd)
   c. Maximum concentration time (Tmax)
   d. Clearance(Cl)

10. _____is important to calculate maintenance dose.
    a. Area under the curve(AUC)
    b. Apparent volume of distribution (Vd)
    c. Maximum concentration time (Tmax)
    d. Clearance(Cl)

11. _____is important to calculate Loading dose.
    a. Area under the curve(AUC)
    b. Apparent volume of distribution (Vd)
    c. Maximum concentration time (Tmax)
    d. Clearance(Cl)

12. If the drug is instantly distributed throughout the body, the drug is following _____ compartment model.
    a. 1 b. 2 c. 3 d. 4

13. Non-linear Pharmacokinetics parameters are determined using _____ plot.
    a. Lineweaver Burk
    b. Plasma drug concentration vs. time
    c. AUC vs. Time
    d. Cumulative % drug release vs. Time

14. The most common type of genetic variation among people is _____.
    a. Single Nucleotide Polymorphisms (SNPs)
    b. Deletion
    c. Insertion
    d. Duplication

15. A drug has 4 hours half-life _____ hr^{-1} is the elimination rate constant.
    a. 0.17 b. 0.24 c. 0.09 d. 0.14

16. A drug has half-life of 4 hours and the patient has Vd of 100 litres, ... L/hr will be the clearance of the drug in that patient.
    a. 17.3 b. 107 c. 0.015 d. 400

17. _____is bioequivalence.
    a. Comparison between 3-year-old drugs to the same new drug
    b. Comparison between drugs to another drug
    c. Comparison between a drug's specific characteristics to a defined set of standards
    d. Comparison between two or 3 characteristics of a drug to the same characteristics of a different drug

18. Therapeutic Drug Monitoring (TDM) is not done for _____.
    a. Narrow therapeutic window
    b. High patient variability in pharmacokinetics
    c. Potential for dose related severe adverse effects
    d. Unknown relationship between dose and blood/serum/plasma concentrations

19. Disposition means _____.
    a. Distribution, Metabolism and Excretion
    b. Absorption, Metabolism and Excretion
    c. Absorption, Distribution and Metabolism
    d. Absorption, Distribution and Excretion

20. Elimination means _____.
    a. Absorption and Distribution
    b. Absorption and Metabolism
    c. Distribution and Metabolism
    d. Metabolism and Excretion

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Semester : II
F.M. : 55

Note: Check (√) the number of each question you have answered in the front page of main answer book (of Sections B, C and D).

SECTION "B"
[5Q. × 3 = 15 marks]

Answer *ANY FIVE* questions.

1. How do Biopharmaceutical factors affect drug design?

2. Write down a schematic diagram of two compartment models for oral single dose and write down differential equation for the diagram.

3. Mention categorically the factors that affects bioavailability.

4. Draw the ideal plasma drug concentration profiles of IV bolus, IV infusion and oral dosage form and label it.

5. What is the difference between tailored made medicine and individualized medicine? Explain why the second one is more challenging to implement though effective.

6. How do you decide two products are bioequivalent or not?

7. What are the indications in which TDM is not preferred?

SECTION "C"
[5Q. × 5 = 25 marks]

Answer *ANY FIVE* questions.

8. What are the indications that drive you for Therapeutic Drug Monitoring (TDM)?

9. 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 analysed for drug concentration. The collected data are shown in the table below.

Time (hr)	0	0.5	1	2	4	6	8	10	α
Conc(mg/L)		3.12	2.75	1.85	1.06	0.51	0.3	0.16	

10. A dose of **300 mg** was administered to a healthy volunteer via IV bolus. Seven blood samples were collected at 1, 2, 3, 4, 6, 10, and 12 hours. Plasma was separated from each blood sample and analysed for drug concentration. The collected data are shown in the table below.

Time (hr)	1	2	3	4	6	10	12
Cp (mg/L)	29.63	22.46	16.83	13.36	7.96	2.81	1.59

Estimate kel, V, $t_{1/2}$ and Clearance.

11. A drug was administered by IV infusion of **12.5 mg/hr** for 15 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 analysed for drug concentration. The collected data are shown in the table below.

Time (hr)	2	3	4	6	8	10	12
Cp (mg/L)	0.165	0.137	0.112	0.076	0.051	0.035	0.023

Estimate kel, t1/2, V, and Cl.

12. Assuming a one compartment linear pharmacokinetic model, with kel = 0.14 hr^{-1}; ka = 1.1 hr^{-1}; F = 0.95; and V = 21.8 L, calculate the plasma concentration at 0.5, 1, 1.5, 2, 4, 6, 9, and 12 hours after a 250 mg oral dose.

13. A potent drug has been given by multiple IV bolus dose of 250 mg every 12 hours. Assume a one compartment linear model applies to this drug in this concentration range. The half-life and V for this drug in this patient are 5.4 hr and 39.5 L, respectively. Calculate the expected Cpmax and Cpmin values at steady state.

14. A drug was given by multiple oral doses of 150 mg every 12 hr. Assume a one compartment linear model applies to this drug in this concentration range. For this dosage form and patient, the bioavailability is 0.91 and the absorption rate constant is 1.97 hr^{-1}. The kel and V for this drug in this patient (63.1 kg) are 0.196 hr^{-1} and 0.72 L/kg, respectively. Calculate the average drug concentration.

SECTION "D"

[2Q. × 7.5 = 15 marks]

Answer *ANY TWO* questions.

15. A drug has been given by multiple oral dose of 150 mg every 3 hours. Assume a one compartment linear model applies to this drug in this concentration range. The half-life and V for this drug in this patient (69.9 kg) are 2.9 hr and 0.66 L/kg, respectively. For this dosage form and patient, the bioavailability is 0.34 and the absorption rate constant is 2.01 hr^{-1}. Assume that e-ka • τ approaches 0. Calculate the expected $Cp_{average}$, Cp_{min} value and a 'very' approximate Cp_{max} value at steady state.

16. A **100 mg** oral dose of a drug was administered to a healthy volunteer. Blood samples were collected and plasma was separated from each blood sample and analysed for drug concentration. The collected data are shown in the table below.

Time (hr)	0.2	0.3	0.5	0.7	0.8	1	2	4	6	8
Cp (mg/L)	0.6216	0.8378	1.156	1.336	1.388	1.436	1.177	0.5536	0.2398	0.1042

Estimate kel, ka and V/F. Does the ratio of ka to kel satisfy the requirement of the method of residuals?

17. What are the purposes of purpose of bioavailability and bioequivalence studies? Explain the methods for assessing bioavailability and bioequivalence.