

B.Pharm III Year II Semester (R19) Supplementary Examinations January/February 2023
BIOPHARMACEUTICS & PHARMACOKINETICS

Time: 3 hours

Max. Marks: 75

PART – A

(Compulsory Question)

- 1 Answer the following: (10 X 02 = 20 Marks)
- | | |
|--|----|
| (a) How drugs are classified according to BCS? | 2M |
| (b) What is the effect of food on absorption of drugs? | 2M |
| (c) Differentiate between absolute and relative bioavailability. | 2M |
| (d) Why phase II reaction is called true detoxification reactions? | 2M |
| (e) What are the assumptions of one compartment model? | 2M |
| (f) Mention the methods for calculating of AUC. | 2M |
| (g) Define dosing frequency. | 2M |
| (h) Define loading and maintenance dose. | 2M |
| (i) What is K_m and V_{max} . | 2M |
| (j) What is the difference between linear and non-linear PK? | 2M |

PART – B

(Answer any two questions: 02 X 10 = 20 Marks)

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|--|----|
| 2 (a) Explain the various mechanisms of drug absorption. | 6M |
| (b) Explain pH partition theory. | 4M |
| 3 (a) Discuss the various considerations for bioequivalence studies. | 5M |
| (b) List out the various factors affecting excretion and discuss any two. | 5M |
| 4 (a) Discuss in detail one-compartment open model for a drug administered as IV infusion. | 5M |
| (b) Explain various pharmacokinetic parameters after oral administration of drug. | 5M |

PART – C

(Answer any seven questions: 07 X 05 = 35 Marks)

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|---|----|
| 5 (a) Describe the importance of volume of distribution in detail. | 2M |
| (b) Explain drug transport. Describe carrier mediated transport. | 3M |
| 6 Explain various methods used for enhancement of bioavailability. | 5M |
| 7 (a) Explain Wagner nelson method for estimation of absorption of rate constant in detail. | 3M |
| (b) Write a short note on hepatic clearance. | 2M |
| 8 (a) Give relation between loading dose and maintenance dose. | 2M |
| (b) Explain principle of plateau or steady state. | 3M |
| 9 Explain Michaelis –Menten equation in determining non-linearity. | 5M |
| 10 (a) Explain the effect of GI components on the gastric emptying rate. | 3M |
| (b) Write the pore transport process. | 2M |
| 11 (a) How bioequivalence study can be performed by Latin Square Cross Over Design? | 3M |
| (b) How do you determine renal clearance of drugs? | 2M |
| 12 How do you determine KE using rate of excretion method from urine data? | 5M |
| 13 (a) What are the limitations of one compartment model? | 2M |
| (b) Explain the various factors leading to non-linearity. | 3M |

B.Pharm III Year II Semester (R19) Regular Examinations July/August 2022
BIOPHARMACEUTICS & PHARMACOKINETICS

Time: 3 hours

Max. Marks: 75

PART – A
 (Compulsory Question)

- 1 Answer the following: (10 X 02 = 20 Marks)
- | | |
|--|----|
| (a) Write the importance of particle size in drug absorption. | 2M |
| (b) Name the various barriers for drug distribution. | 2M |
| (c) Define clearance. Give the expression relating clearance to half life. | 2M |
| (d) What is first pass or presystemic metabolism? | 2M |
| (e) Define biological half life. | 2M |
| (f) What are the limitations of one compartment model? | 2M |
| (g) Give relation between loading dose and maintenance dose. | 2M |
| (h) What is multi compartment model? | 2M |
| (i) Write the significance of Michaelis-Menten equation. | 2M |
| (j) List out the reasons for non-linearity in PK studies. | 2M |

PART – B

(Answer any two questions: 02 X 10 = 20 Marks)

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|---|---|-----|
| 2 | (a) Discuss in detail the various physico-chemical factors affecting drug absorption. | 7M |
| | (b) Define volume of administration and how do you determine Vd? | 3M |
| 3 | Define biotransformation. Explain with examples phase I and phase II reactions. | 10M |
| 4 | (a) Discuss in detail one-compartment open model for a drug administered as IV Bolus. | 5M |
| | (b) What are pharmacokinetic models? Explain in detail non-compartmental approach. | 5M |

PART – C

(Answer any seven questions: 07 X 05 = 35 Marks)

- | | | |
|----|---|----|
| 5 | Write in detail about protein binding and its significance. | 5M |
| 6 | (a) List out the various factors affecting biotransformation and discuss any two. | 3M |
| | (b) Define bioequivalence. Mention various types of equivalence. | 2M |
| 7 | Explain Loo-Riegelman method for calculation of absorption rate constant. | 5M |
| 8 | (a) Discuss in detail two-compartment open model for a drug administered as IV Bolus. | 3M |
| | (b) Write the applications of pharmacokinetic models. | 2M |
| 9 | Write in detail about Estimation of Km and Vmax in determining non-linearity. | 5M |
| 10 | Discuss the absorption of drugs from non-oral extra vascular routes. | 5M |
| 11 | (a) Explain how bioavailability is measured using plasma data. | 3M |
| | (b) Give an example for Mono exponential equation. | 2M |
| 12 | (a) How do you determine KE using sigma minus method from urine data? | 3M |
| | (b) Write a short note on hepatic metabolism of drugs. | 2M |
| 13 | (a) Give the plasma concentration time – plot for multiple dosing of an IV bolus. | 3M |
| | (b) Explain statistical moment's theory. | 2M |

B.Pharm III Year II Semester (R15) Supplementary Examinations January/February 2023
BIOPHARMACEUTICS & PHARMACOKINETICS

Time: 3 hours

Max. Marks: 70

PART – A
(Compulsory Question)

- 1 Answer the following: (10 X 02 = 20 Marks)
- (a) What do you understand by sink condition?
 - (b) Drug protein binding increases renal excretion of drugs. True/false explain.
 - (c) Define clearance. How clearance is calculated?
 - (d) Brief the term biotransformation and detoxification.
 - (e) Define therapeutic window.
 - (f) Define absolute bioavailability.
 - (g) What is elimination half-life?
 - (h) Write the equation used for urinary excretion rate and sigma-minus method following oral administration of a drug.
 - (i) Write Michaelis-Menten equation and explain the terms.
 - (j) What is non-linear pharmacokinetics?

PART – B
(Answer all the questions: 05 X 10 = 50 Marks)

- 2 Describe the role of physiologic barriers for distribution of drugs in the body.
- OR**
- 3 Discuss the various theories of drug dissolution.
- 4 Mention about factors influencing metabolism of drugs.
- OR**
- 5 Write about Phase-I reactions with examples.
- 6 Describe about BIBD in bioequivalence studies.
- OR**
- 7 Explain in detail about bioequivalence study design.
- 8 Explain the procedure involved in Wagner and Nelson method.
- OR**
- 9 Explain about urinary excretion studies.
- 10 Explain in detail about statistical moment theory.
- OR**
- 11 What do you understand about nonlinear pharmacokinetics? Give explanation about cause of nonlinearity.

B.Pharm III Year II Semester (R15) Supplementary Examinations March 2022
BIOPHARMACEUTICS & PHARMACOKINETICS

Time: 3 hours

Max. Marks: 70

PART – A
 (Compulsory Question)

- 1 Answer the following: (10 X 02 = 20 Marks)
- Drug protein binding increases renal excretion of drugs. True/false explain.
 - Drug distribution is a passive diffusion process explain.
 - List two applications of biotransformation reaction in the body.
 - Draw the flow diagram showing enterohepatic cycling of drugs.
 - Define 'reference' and 'test' product in bioequivalence study.
 - What do you mean by washout period?
 - Provide a pictorial representation of two compartment open model IV administration.
 - Define the term apparent volume of distribution.
 - Describe how steady state plasma concentration can be used to determine the nonlinearity in pharmacokinetics.
 - Write Michaelis Menten equation and explain each term in the equation.

PART – B
 (Answer all the questions: 05 X 10 = 50 Marks)

- Discuss the various theories of drug dissolution.
 - Differentiate passive and active transport mechanism.

OR
- Describe the kinetics of drug protein binding.
- Describe phase II biotransformation reaction with one example for each.
- OR**
- Write the factors influencing the renal excretion of drugs.
- What are the various methods for measurement of bioavailability?
- OR**
- Explain in detail about bioequivalence study design.
- Find out the various pharmacokinetic parameters following one-compartment IV bolus administration.
- OR**
- Write a shot note on Sigma minus method.
 - Differentiate between linear and non-linear pharmacokinetics.
- Describe the importance of non-linear pharmacokinetics with suitable examples. What is its implication?
- OR**
- Describe the estimation of K_m and V_{max} assuming one compartment model and a single capacity limited process.

B.Pharm III Year II Semester (R15) Supplementary Examinations July/August 2022
BIOPHARMACEUTICS & PHARMACOKINETICS

Time: 3 hours

Max. Marks: 70

PART – A
(Compulsory Question)

1 Answer the following: (10 X 02 = 20 Marks)

Write short notes on:

- (a) Active transport.
- (b) Protein binding.
- (c) First pass effect.
- (d) Glomerular filtration.
- (e) Absolute and Relative bioavailability.
- (f) Therapeutic equivalent.
- (g) Significance of AUC.
- (h) Concept of compartmental model.
- (i) Time dependent pharmacokinetics.
- (j) Capacity limited elimination.

PART – B
(Answer all the questions: 05 X 10 = 50 Marks)

2 Describe different formulation factors influencing drug absorption.

OR

3 Explain different physiological barriers to the diffusion of drugs.

4 (a) Explain conjugation reactions in drug metabolism with examples.

(b) Explain the concept of clearance. How will you calculate hepatic clearance of drug?

OR

5 (a) Explain the phenomena enzyme induction and enzyme inhibition.

(b) What are different factors influencing excretion of drugs?

6 (a) Write a note on Latin square design used for assessment of bioavailability.

(b) Write short notes on IVIV correlation.

OR

7 Describe briefly different methods used or assessment of bioavailability.

8 How do you calculate pharmacokinetic parameters from urine data?

OR

9 Draw a typical concentration time curve following iv bolus administration and how will you calculate different pharmacokinetic parameters from the same.

10 Explain different factors responsible for non linear pharmacokinetics and their significance.

OR

11 Explain the significance of Michaelis Menten equation and determination of V_{max} and K_m .
