

IV PHARM D/PHARM D P.B- I
BIOPHARMACEUTICS AND PHARMACOKINETICS
QUESTION BANK

UNIT I – BIOPHARMACEUTICS: ABSORPTION, DISTRIBUTION, ELIMINATION

10 MARKS

1. Define Absorption. Discuss in detail the various biological factors affecting drug absorption.
2. Discuss in detail the various physico-chemical factors affecting drug absorption.
3. Discuss in detail the various physiological factors affecting drug absorption.
4. Discuss in detail the various pharmaceutical factors affecting drug absorption.
5. Explain the various mechanisms of drug absorption.
6. Define drug distribution. Describe the factors affecting distribution.
7. Write in detail about protein binding and its significance.
8. Define biotransformation. Explain with examples phase I and phase II reactions.
9. What is clearance? Give the formula for the same. Explain organ clearance and hepatic extraction ratio.
10. Explain the process of renal elimination.
11. How do you calculate the pharmacokinetic parameters for a drug undergoing metabolism from the urine data? Give the relevant graphs.
12. How do you calculate the pharmacokinetic parameters for a drug (no metabolism) from the urine data? Give the relevant graphs.
13. Draw a typical plasma concentration time profile curve following oral, IV bolus and IV infusion and explain the pharmacokinetic parameters that can be determined from the same.
14. Compare and contrast passive diffusion versus active transport. Add a note on facilitated transport.
15. What do you understand by pH-partition theory? Give its importance and its limitations.

5 Marks

Absorption

1. Explain the differences between passive diffusion and active transport.
2. Explain passive diffusion of drugs and the principle behind it.
3. Explain pH partition theory.
4. Explain In vitro methods for determining absorption of drugs.
5. Explain In vivo methods for determining absorption.
6. Explain the pore transport process.
7. Explain the influence of gastric emptying and intestinal transit time on absorption of drugs.
8. Explain the structure of cell membrane with a neat labelled diagram.
9. Explain the effect of GI components on the gastric emptying rate.
10. What do you understand by gastric emptying and discuss factors affecting the same.
11. What factors affect the absorption of drugs when administered as tablets and capsules.

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12. Explain the “Everted Sac Modification” technique for measuring the absorption.
13. Explain BCS classification of drugs.
14. Name the parameters considered in pH-partition theory. Mention the limitations of pH-partition theory.

DISTRIBUTION

15. Write about the significance of protein binding.
16. Explain the kinetics of protein binding.
17. Explain about binding of drugs to HAS (Human Serum Albumin).
18. Write about plasma protein binding of drugs.
19. Define volume of administration and give its significance.
20. Define volume of administration and how do you determine V_d ?
21. How is drug distributed to CNS through blood brain barrier ?
22. Explain drug distribution to foetus through placental barrier.
23. Explain intra cellular and extra cellular binding of drugs.

ELIMINATION

24. Explain renal clearance of drugs.
25. How do you determine renal clearance of drugs ?
26. Explain hepatic extraction ratio and its importance.
27. Explain various non-renal routes of excretion.
28. Explain hepatic clearance.
29. Explain glucuronic acid conjugation.
30. Explain phase I reactions.
31. What is biotransformation and explain its importance.
32. Explain the hepatic metabolism of drugs.
33. Explain the pre systemic metabolism of drugs.
34. List out the various factors affecting biotransformation and discuss any two.
35. List out the various factors affecting excretion and discuss any two.

2 marks

1. Write briefly about Active transport
2. Draw the Structure of Cell membrane
3. What is Facilitated diffusion?
4. What is Pinocytosis and phagocytosis?
5. What is Endocytosis?
6. Write modified Noyes Whitney’s equation.
7. What is polymorphism.
8. Name rate limiting steps in drug absorption.
9. What is the effect of food on absorption of drugs?
10. How particle sizes affect the drug absorption?
11. How do solvates and hydrates affect drug absorption?

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12. Give two examples of drugs which are unstable in the GIT.
13. List out the methods to study absorption of drugs.
14. How drugs are classified according to BCS?
15. List the orally administered dosage form in order of their increasing absorption.
16. Define drug distribution.
17. Define protein binding.
18. What are distribution characteristics of protein bound drug?
19. Mention the significance of protein binding.
20. Mention the significance of tissue binding.
21. Define biotransformation.
22. What are xenobiotic?
23. What is clearance? Give the formula for same
24. What is enterohepatic cycle?
25. Define apparent volume of distribution.
26. What do you understand by inhibition and induction?
27. Name the various barriers for drug distribution.
28. List out the non renal routes of drug excretion.
29. Hepatic clearance. Mention its significance.
30. What is Total body clearance.
31. What is renal clearance? How do you calculate it?
32. Define extraction ratio.
33. Write the formula to calculate hepatic extraction ratio.
34. Define clearance? Give the expression relating clearance to half life.
35. Why phase II reaction is called true detoxication reactions?
36. What the consequences are phase I reaction?
37. List out phase II biotransformation reactions.
38. What is first pass or presystemic metabolism?
39. What is glucuronidation?
40. Give the relation between clearance and volume of distribution.
41. Define apparent volume of distribution.
42. What is sink condition?
43. Give the formula for determining V_d from plasma concentration (C).

UNIT II – INTRODUCTION TO PHARMACOKINETICS, ONE COMPARTMENT MODEL, TWO COMPARTMENT MODEL

10 MARKS

1. What do you understand by pharmacokinetic model ? Classify the pharmacokinetic models, give their salient features, advantages and disadvantages.
2. Discuss in detail one-compartment open model for a drug administered as IV Bolus. Give the schematic representation, graphs and equations for the same.

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3. Discuss in detail one-compartment open model for a drug administered as IV infusion. Give the schematic representation, graphs and equations for the same
4. Discuss in detail two-compartment open model for a drug administered as IV Bolus. Give the schematic representation, graphs and equations for the same.
5. What is a compartment? Classify the compartment models. Give the schematic representation of the same.

5 MARKS

1. Write a note on Catenary and mammillary modeling.
2. Write the importance of Compartment modeling in pharmacokinetic study.
3. With a neat labeled diagram explain the drug levels in blood after oral administration.
4. Explain various pharmacokinetic parameters after oral administration of drug.
5. Write the applications of pharmacokinetic models.
6. Explain how steady state level of the drug is achieved through I.V infusion.
7. Give schematic representation of two and three compartment models with brief explanation.
8. Explain the assumptions of one-compartment open model
9. Write about the advantages and disadvantages of compartment modeling.
10. Compare blood level curves between I.V and oral routes with a graph.
11. Give the monoexponential and biexponential equations for drugs administered as IV bolus and explain the terms.
12. How do you determine K_E using rate of excretion method from urine data.
13. How do you determine K_E using sigma minus method from urine data.

5 MARKS

Non-Linear Pharmacokinetics

1. Explain the various factors leading to non-linearity.
2. Explain Michaelis –Menten equation in determining non-linearity.
3. How do you estimate K_m and V_{max} .

5 MARKS

Bioavailability and Bio-equivalence

1. Define bioavailability. Mention the objectives of bioavailability studies.
2. Define bioequivalence. Explain various types of equivalence.
3. Explain about the subject selection criterion in bioavailability studies.
4. Discuss the various study designs in for performing bioavailability.
5. Explain two way cross over design.
6. Discuss the various considerations for bioequivalence studies.
7. Explain any two methods to calculate AUC.
8. Explain how bioavailability is measured using plasma data.

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9. Explain how bioavailability is measured using urinary data.
10. List out the various methods of assessment of bioavailability and explain any two.
11. What are the various methods of enhancement of bioavailability.

2 marks

1. Define pharmacokinetics.
2. In compartment modelling why does excretion takes place from central compartment
3. What are the limitations of one compartment model
4. Define elimination rate constant?
5. Describe the influence of K_e on C_{max} , T_{max} and AUC.
6. Mention the methods for calculating of AUC.
7. Define biological half life.
8. Enumerate the applications of pharmacokinetics.
9. What is first order and second order reaction?
10. What is Zero order reaction?
11. Write equation for zero and first order half life.
12. What do mean by therapeutic index?
13. Give an example for Mono exponential equation.
14. Give an example for Bi exponential equation.
15. Draw the blood level profiles for oral and intravenous route of administration.
16. Enlist different pharmacokinetic parameters.
17. Define C_{max} and T_{max} .
18. Classify Pharmacokinetic models.
19. What is multi compartment model?
20. Give the schematic representation of one compartment open model-oral.
21. Give the schematic representation of one compartment open model-IV.
22. Give the schematic representation of two compartment open model-oral.
23. Give the schematic representation of two compartment open model-IV.
24. Give the schematic representation of three compartments model-oral.
25. Give the schematic representation of three compartments model-IV.
26. What are the assumptions of one compartment model?
27. Give the formula AUC_{0-t} & $AUC_{0-\infty}$.

BIO-AVAILABILITY AND BIOEQUIVALENCE

1. Define bio-availability and bio-equivalence.
2. Differentiate between absolute and relative bioavailability.
3. Give the significance of bio-equivalence.
4. List out the methods to calculate AUC.
5. Give an example for Latin square cross over design for the conduct of bioavailability study.
6. Name any four methods for enhancing bio-availability of drugs.
7. Define therapeutic equivalence and chemical equivalence.

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8. Give the equation to calculate bio-availability from urine data?
9. Name the methods to calculate K_e from urine data.

NON-COMPARTMENTAL ANALYSIS

1. Explain statistical moment's theory.
2. Give the formula for AUMC and MRT.
3. What are the advantages of physiological model?
4. What is the difference between AUC and AUMC?
5. Define MRT and give its equation.
6. Give schematic representation for Physiological –Pharmacokinetic

NON LINEAR PHARMACOKINETICS

1. What is the difference between linear and non-linear PK?
2. List out the reasons for non-linearity in PK studies.
3. Write the tests to determine non-linearity.
4. Give Michaelis-Menton equation. Explain the terms.
5. What is K_m and V_{max} ?

MULTIPLE DOSAGE REGIMEN

1. Define loading and maintenance dose. Give the formula for the same.
2. Give the equations to calculate the steady state maximum, minimum and average drug concentrations.
3. Give the plasma concentration time – plot for multiple dosing of an IV bolus.
4. What do you understand by accumulation index and give the formula.
5. Explain principle of plateau or steady state.
6. What are the factors which influence dosage regimen?
7. Name two parameters used in adjusting dosage regimen.
8. Define dosing frequency.
9. Give relation between loading dose and maintenance dose.
10. Give the plasma concentration time – plot for multiple oral administration.