28/6/22 M

Roll Number ---------- (Total Number of Questions 13) (Total number of Printed Pages 01)

Programme	B. Pharmacy
Semester	6th
Subject	Biopharmaceutics and Pharmacokinetics
Subject Code	BP604T
Paper ID	77989
Time	3Hours
Maximum Marks	75

Instructions to Candidates:*No supplementary/continuation sheet will be issued to the candidates. Answer the questions precisely.*
Section A consists of Ten parts of 2 marks each (Objective Type); Attempt **ALL.*
***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*
****Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section A (10 X2 = 20)

1. Give very short answers to the followings (2 marks each):

i.	Differentiate Pharmacokinetics and Pharmacodynamics.
ii.	Define bioavailability.
iii.	What do you mean by plasma protein binding? Write its effect on metabolism of drug.
iv.	What do you mean by compartment model?
v.	Differentiate IV bolus and IV injection.
vi.	Define half-life of drug. How it affect the bioavailability?
vii.	What do you mean by extra –vascular route? Give any two examples.
viii.	Define Biopharmaceutics.
ix.	Define Bioequivalence.
x.	What do you mean by IVIVC?

Section B (2 X 10 = 20)

2.	Define drug absorption. Discuss in detail various factors affecting drug absorption.
3.	What are the various methods to enhance dissolution and bioavailability of poorly soluble drugs?
4.	Discuss in detail Bioequivalence studies. What are various methods to assess the bioequivalence?

Section C (7 X 5 = 35)

5.	Discuss in detail one compartment model.
6.	Discuss in detail factors affecting plasma protein binding of drugs.
7.	Give a note on factor affecting renal excretion of drug.
8.	Write a note on *in-vitro* dissolution methods.
9.	Discuss in detail various metabolic pathways for the renal excretion of drugs.
10.	What is the clinical significance of protein binding of drugs?
11.	Discuss in detail the mechanism of drug absorption through GIT.
12.	Give a detail note on non-renal route of drug excretion.
13.	Differentiate absolute v/s relative bioavailability. Give a note on method to measure absolute and relative bioavailability.

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210123

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**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A **(10X2=20)**

1.	Give very short answers to the followings:
i.	Define bio pharmaceutics.
ii.	Define Bioequivalence.
iii.	What do you mean by non-renal route of drug excretion?
iv.	What do you mean by open compartment model?
v.	Differentiate drug dissolution and solubility.
vi.	Define apparent volume of distribution of drug.
vii.	What do you mean by BCS classification of drugs?
viii.	Define bioavailability.
ix.	What do you mean by extra-vascular administration?
x.	What do you mean by steady state drug levels.

Section- B **(2X10=20)**

2.	Enumerate different pharmacokinetics parameters. Discuss in detail various methods for the estimation of pharmacokinetic parameters.
3.	Discuss in detail methods for the calculation of loading and maintenance dose and it's clinical significance.
4.	Discuss in detail Bioequivalence studies. What are various method to assess the bioequivalence?

Section- C **(7X5=35)**

5.	Discuss in detail kinetics of multiple dosing.
6.	Elaborate different factors which affect the non-linearity.
7.	What is the significance of estimating pharmacokinetics? Discuss in brief it's clinical significance.
8.	What are different methods to enhance bioavailability of poorly soluble drugs?
9.	Discuss in detail kinetics of plasma protein binding.
10.	Give a detail note on *invitro- invivo* correlation.
11.	Give a detail note on factor affecting drug distribution.
12.	Give a note on two compartment open model.
13.	Give a note on renal clearance and renal excretion of drug.

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290523

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**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A (10X2=20)

1.	Give very short answers to the followings:
i.	Give examples of non per oral extra-vascular routes.
ii.	Define biotransformation.
iii.	What is sink condition?
iv.	Give the formula for determining Vd from plasma concentration.
v.	Define bioequivalence.
vi.	Explain principle of Plateau or Steady State.
vii.	Define MRT and give its equation.
viii.	Define dosing frequency.
ix.	What is difference between linear and non linear pharmacokinetics?
x.	What is zero order reaction?

Section- B (2X10=20)

2.	Discuss in detail one-compartment open model for a drug administered as IV Infusion. Give the schematic representation, graphs and equations for the same.
3.	Explain in detail various study designs for performing bioequivalence Studies.
4.	Discuss in detail various factors affecting drug absorption from GIT.

Section- C (7X5=35)

5.	List out the reasons for non-linearity in pharmacokinetic study.
6.	Give the plasma concentration time plot for multiple oral administration of drug.
7.	Explain statistical moment theory.
8.	Explain Michaelis - Menten equation in determining non-linearity.
9.	Explain phase I reactions.
10.	What is pH partition theory?
11.	Write the importance of compartment modeling in pharmacokinrtic study.
12.	Write about plasma protein binding of drugs.
13.	Define loading dose and maintenance dose.

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231123
(Evening)

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***Section B consists of three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*

****Section C consists of nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section A **(10 X2 = 20)**

1.	Define the following:
i.	Sink condition.
ii.	Extraction ratio.
iii.	Bioequivalence.
iv.	Capacity limited kinetics.
v.	Loading dose.
vi.	Phase-I metabolic reactions.
vii.	Volume of distribution.
viii.	The Area under the curve.
ix.	Relative Bioavailability.
x.	Facilitated diffusion.

Section B **(2 X 10 = 20)**

2.	Define Absorption. Discuss in detail the various factors affecting drug absorption.
3.	What do you understand by the pharmacokinetic model? Discuss in detail a one-compartment open model for a drug administered as IV infusion.
4.	Define bioequivalence. How bioequivalence study can be performed by cross- over Design?

Section C **(7 X 5 = 35)**

5.	Explain pH partition theory.
6.	What is biotransformation? Explain its importance.
7.	Explain the various factors leading to non-linearity.
8.	Name any four methods for enhancing bioavailability of the drugs.
9.	Explain about the binding of drugs to HAS (Human Serum Albumin)
10.	Explain the BCS classification of drugs.
11.	Explain phase I reactions
12.	Give the plasma concentration- time – plot for multiple oral administration of drug.
13.	Give details of IVIVC.

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***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*

****Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A **(10 X2 = 20)**

1.	Give a very short answers to the followings:
i.	Define the terms biopharmaceutics and bioavailability.
ii.	What is gastric emptying time?
iii.	What do you mean by mean residence time?
iv.	Clarify the process of endocytosis.
v.	Illustrate the concept of total body clearance.
vi.	What is a dose regimen?
vii.	Write down the objective of bioavailability studies.
viii.	Express Fick's first law equation for passive diffusion.
ix.	What is the flip-flop phenomenon?
x.	Define the term elimination half-life.

Section- B **(2 X 10 = 20)**

2.	Explain in detail the two-compartment open model for intravenous bolus administration.
3.	Describe the Wagner-Nelson method and the Loo-Riegelman method.
4.	What is bioequivalence? What are the criteria for declaring two products bioequivalent, and what are the regulatory considerations regarding bioequivalence studies in India?

Section- C **(7 X 5 = 35)**

5.	Describe the Michaelis-Menten equation.
6.	Differentiate between absolute bioavailability and relative bioavailability.
7.	Enumerate various pharmaceutical factors influencing drug absorption.
8.	Explain apparent volume of distribution and distribution coefficient.
9.	Write a note on clearance. What are its units?
10.	Write down the methods for measurement of bioavailability.
11.	Comment on factors affecting drug distribution in the body.
12.	What is the Sigma Minus method?
13.	Explain briefly non-compartmental modeling.

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27 11 24

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Section A consists of Ten parts of 2 marks each (Very Short Answer); Attempt **ALL.*

***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*

**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

Section- A (10X2=20)

1.	Give very short answers to the followings:
i.	Give examples of non per oral extra-vascular routes.
ii.	Define biotransformation.
iii.	What is sink condition?
iv.	Give the formula for determining Vd from plasma concentration.
v.	Define bioequivalence.
vi.	Explain principle of plateau or steady state.
vii.	Define MRT and give its equation.
viii.	Define dosing frequency.
ix.	What is the difference between linear and non linear pharmacokinetics?
x.	What is zero order reaction?

Section- B (2X10=20)

2.	Discuss in detail one-compartment open model for a drug administered as IV infusion. Give the schematic representation, graphs and equations for the same.
3.	Explain in detail various study designs for performing bioequivalence studies.
4.	Discuss in detail various factors affecting drug absorption from GIT.

Section- C (7X5=35)

5.	List out the reasons for non-linearity in pharmacokinetic study.
6.	Give the plasma concentration time plot for multiple oral administration of drug.
7.	Explain statistical moment theory.
8.	Explain Michaelis - Menten equation in determining non-linearity.
9.	Explain phase I reactions.
10.	What is pH partition theory?
11.	Write the importance of compartment modeling in pharmacokinetic study.
12.	Write about plasma protein binding of drugs.
13.	Define loading dose and maintenance dose.

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(Evening)
180125

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Subject Code	BP604T
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Maximum Marks	75

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Section- A *consists of* ***ten questions****, each carrying* ***2 marks*** *(Very Short Answer Type);* ***Attempt all.***
Section- B** consists of* ***three questions*, each carrying* ***10 marks*** *(Long Answer Type);* ***Attempt any two.***
****Section- C** consists of* ***nine questions****, each carrying* ***5 marks*** *(Short Answer Type);* ***Attempt any seven.***

Section- A **(10X2=20)**

1.	Give very short answers to the followings:
i.	Enumerate the factors that affect drug absorption.
ii.	What is the apparent volume of distribution of a drug?
iii.	Define clearance. What are its units?
iv.	Differentiate between absolute and relative bioavailability.
v.	Classify the various types of pharmacokinetic models.
vi.	Illustrate a one-compartment open model for intravenous (IV) infusion.
vii.	Define steady-state drug concentration.
viii.	Mention the methods used to enhance the dissolution rate of poorly soluble drugs.
ix.	Define nonlinear pharmacokinetics.
x.	State the Michaelis-Menten equation.

Section- B **(2X10=20)**

2.	Discuss the various mechanisms of drug absorption through the gastrointestinal tract (GIT).
3.	What are the different pharmacokinetic methods used to measure bioavailability?
4.	Explain in detail the two-compartment intravenous (IV) bolus with Include a schematic representation, relevant graphs, and the associated equations.

Section- C **(7X5=35)**

5.	Write a short note on the Wagner-Nelson method.
6.	List the factors causing non-linearity in pharmacokinetics.
7.	What factors affect the renal excretion of drugs?
8.	Which pharmacokinetic processes cause non-linearity? Give examples.
9.	What is AUC? Explain the trapezoidal rule for its calculation.
10.	How is the loading dose calculated? State its role in maintenance dosing.
11.	Why is there an initial rapid and terminal slow decline in drug levels in the central compartment?
12.	How is dosage adjusted in hepatic failure?
13.	Define the following: Clearance, Total body clearance, Hepatic clearance, and Renal clearance.

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16 12 25

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***Section- B consists of Three questions carrying 10 marks each (Long Answer); attempt any TWO.*
**** Section -C consists of Nine questions carrying 5 marks each (Short Answer); attempt any SEVEN.*

Section- A **(10X2=20)**

1.	Give very short answers to the followings:
i.	Define mixed order kinetics.
ii.	What is gastric emptying time?
iii.	Define T_{max} and C_{max} and its units.
iv.	Define bioequivalence.
v.	What is dosage regimen?
vi.	Define bioequivalence studies.
vii.	Define catenary model.
viii.	What is zero order reaction?
ix.	Define biotransformation.
x.	What is polymorphism?

Section- B **(2X10=20)**

2.	Write a note on absorption and various mechanisms of drug absorption.
3.	Define bioavailability. Write its objectives. Explain different methods for measurement of bioavailability.
4.	Discuss in detail one compartment open model iv infusion. Give graphs and equations for same.

Section- C **(7X5=35)**

5.	Write advantages and limitations of multiple dose Study.
6.	Write about pH partition theory and its limitations.
7.	Explain sigma minus method.
8.	Describe non compartment analysis.
9.	Explain factors causing non linearity.
10.	Define loading dose and maintenance Dose. Give the formula for the same.
11.	Define metabolism. Explain phase I and phase II reactions.
12.	Write a note on non renal route of excretion.
13.	Explain bioequivalence studies.

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