THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[BPHARM 0321] MARCH 2021 Sub. Code: 2065

(SEPTEMBER 2020 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION

PCI Regulation SEMESTER – VI

PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Write about the pharmaceutical factors influencing drug absorption.
2. Discuss the method of measuring of bioavailability.
3. Give brief summary on Michaelis - Menton equation.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Write the factors affecting protein drug binding.
2. Explain the clearance.
3. Explain the one compartment model following intravenous injection.
4. Pharmacokinetic model.
5. Explain steady state drug level.
6. Explain two compartment model.
7. Explain factors causing non linearity.
8. Method to enhance the bioavailability of poorly soluble drugs.
9. Bio equivalence studies.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Active diffusion.
2. Process of Biliary excretion of drug
3. Biotransformation
4. Dissolution.
5. Pharmacokinetics.
6. Loading dose.
7. Absorption.
8. Absolute bioavailability.
9. Clearance.
10. Clinical significance of protein binding.

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[BPHARM 0921] **SEPTEMBER 2021** **Sub. Code: 2065**

(SEPTEMBER 2020 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION
PCI Regulation 2017 - SEMESTER - VI
PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS
Q.P. Code : 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 x 10 = 20)**

1. Explain physicochemical factors influencing drug absorption through Gastro Intestinal Tract (GIT).
2. Explain one compartment model following extra vascular administration.
3. Discuss different methods used in bioequivalence studies.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. Explain tissue permeability of drugs in details.
2. Write about clinical significance of protein binding of drugs.
3. Write a detail about the phase II reaction of metabolism.
4. Factors affecting drug metabolism.
5. Factors affecting excretion of drug.
6. Determination of bioavailability.
7. Types of pharmacokinetic model.
8. Two compartment open model.
9. Non linear pharmacokinetics.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Endocytosis.
2. Apparent volume of drug distribution.
3. Renal clearance.
4. First pass metabolism.
5. Intravenous infusion.
6. Multi dose.
7. Metabolism.
8. One compartment open model.
9. Non renal route of drug excretion.
10. Bio pharmaceutics.

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[BPHARM 0122] JANUARY 2022 Sub. Code: 2065
(MARCH 2021 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS
Q.P. Code : 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Discuss the mechanism of drug absorption through Gastro Intestinal Tract (GIT).
2. Give brief summary on kinetics of multiple dosing.
3. Discuss about factors affecting drug metabolism.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Explain apparent volume of drug distribution.
2. Write about kinetic of protein binding.
3. Method enhances the dissolution rate.
4. Plasma and tissue protein binding drug.
5. Non compartment model.
6. *Invitro* and *Invivo* correlation.
7. Factors causing non linearity.
8. Steady state drug level.
9. One compartment open model for intravenous infusion.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Mention the pharmaceutical formulation factors.
2. Factors affecting protein drug binding.
3. Testing of kidney function.
4. Bioequivalence.
5. Bioavailability.
6. Application of pharmacokinetics.
7. Difference between linear and non linear.
8. Elimination.
9. Two compartment model.
10. Total body clearance.

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[BPHARM 0522] MAY 2022 Sub. Code: 2065

(SEPTEMBER 2021 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION

PCI Regulation SEMESTER - VI

PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Explain the pharmaceutical factors influencing the absorption of drug through GIT with examples.
2. Explain the Michaelis - Menton method of estimating parameters.
3. Explain the methods to enhance the dissolution rate and bioavailability of poorly soluble drugs.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Explain the Clinical significance of protein binding of drugs.
2. Explain the Non renal routes of drug excretion of drugs
3. Bioequivalence studies
4. Explain the steady state drug levels and calculation of loading doses.
5. Explain the Factors causing Non-linearity.
6. Explain the elimination rate constant.
7. Explain the physiological models
8. Explain the Non compartment models
9. Methods of assessment of bioavailability

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Tissue Permeability.
2. What is relative bioavailability
3. What is apparent volume of distribution
4. Renal clearance
5. Any two phase II reactions
6. In-vitro-in-vivo correlations
7. AUC
8. Steady state concentration
9. MRT
10. Maintenance dose

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[BPHARM 1022] OCTOBER 2022 Sub. Code: 2065
(MARCH 2022 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS
Q.P. Code : 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Discuss the elements of protocol for bioequivalence studies.
2. Estimate the Pharmacokinetics parameters of the drug using Sigma minus method adopting one compartment open model for a bolus Intravenous Injection.
3. Explain the patient related factors influencing the absorption of drugs through GIT with examples.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Clinical significance of protein binding of drugs.
2. Factors causing Non-linearity.
3. Michaelis-menton method of estimating parameters.
4. Phase I metabolism.
5. Non compartment models.
6. Method of residuals.
7. Loading and maintenance doses.
8. Absolute and relative bioavailability.
9. Non renal routes of drug excretion of drugs.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Active transport.
2. Renal clearance.
3. MRT.
4. Michaelis-menton equation.
5. Physiological Barriers.
6. Non linear pharmacokinetics.
7. Drug disposition.
8. Therapeutic window.
9. Biological half life (t½).
10. Volume of distribution (vd).

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0323] MARCH 2023 Sub. Code: 2065
(SEPTEMBER 2022 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Explain the role of physiological barriers to drug distribution.
2. Describe the kinetics of dose dependent model with the help of an equation.
3. Detail the principle mechanism of transportation of drug molecule across various membranes.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Draw a plasma drug concentration Vs time profile and mention all possible kinetic parameters.
2. Explain the concept of clearance.
3. Kinetics of protein binding.
4. Tissue binding of drug.
5. Theories of drug dissolution.
6. First pass metabolism.
7. Apparent volume of distribution.
8. Outline in brief about various of pharmacokinetic models.
9. Note on tubular reabsorption.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Endocytosis.
2. Bioequivalence.
3. C_{max} and $T_{max.}$
4. Capacity limited kinetics.
5. Absolute bioavailability.
6. BCS classification.
7. Recite a simple block diagram of one and two compartment model.
8. Tissue binding and its effect.
9. Equate the rate of excretion.
10. Recall Phase I and II reactions.

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0823] AUGUST 2023 Sub. Code: 2065
(MARCH 2023 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Discuss about of binding of drug to blood component.
2. Write a detailed description on Measurement of bioavailability.
3. Elaborate in detail about renal excretion of drug.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Draw a graph stating all pharmacokinetic parameters of plasma drug concentration Vs time profile.
2. Discuss in detail about *invitro* dissolution models.
3. Outline the steady state level of drug on repeated dose administration.
4. Discuss about two compartment model.
5. Describe the objective and approaches of *invitro invivo* correlation.
6. Absorption of drug by non per oral extra vascular route.
7. Pre-systemic metabolism.
8. Discuss in brief about Non compartmental analysis.
9. Types of pharmacokinetic models.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Perfusion rate.
2. Define prodrug with one example.
3. Clinical significance of protein binding.
4. Test to detect non-linearity.
5. Clinical pharmacokinetics.
6. Name the non-renal route of excretions.
7. Loading and Maintenance dose.
8. Competitive binding with example.
9. Drug interaction.
10. Name the principle process in urinary excretion of drugs.

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 1223] DECEMBER 2023 Sub. Code: 2065
(SEPTEMBER 2023 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Write in detail about dosage form characteristics and pharmaceutical ingredients influencing in GI absorption of a drug.
2. One compartment open model IV bolus administration.
3. Elaborate in detail about the approaches to improve the bioavailability of BCS class II drugs.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Draw a plasma drug concentration Vs time profile of an single oral administration stating all pharmacokinetic parameter.
2. Mamillary model.
3. Outline the sources of non-linearity in connection to ADME.
4. Discuss the Bio equivalence study protocol.
5. State the absorption of drug by any two non per oral extra vascular route.
6. Factors affecting renal clearance.
7. Binding of drug to human serum albumin.
8. Non compartmental analysis.
9. Importance of pharmacokinetic model.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Bioavailability.
2. Catenary model.
3. Loading Dose.
4. Open compartment Vs Closed compartment apparatus.
5. Relative bioavailability.
6. Name the type of dosage form used to test in Type I and Type II dissolution apparatus.
7. GFR.
8. Significance of protein binding.
9. Passive transport.
10. Total clearance.

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0524] **MAY 2024** **Sub. Code: 2065**

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 x 10 = 20)**

1. Discuss about the physiochemical properties of drug influencing the drug absorption.
2. Explain the biliary excretion and discuss the factors involved in biliary excretion.
3. Discuss one compartment open model for I.V infusion.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. What is gastric emptying rates and how it affect drug absorption?
2. How the principle of protein binding can be used for drug targeting?
3. Explain non renal route of drug excretion of drug.
4. Biotransformation.
5. Explain various cross over design in bioequivalence.
6. What are the different methods used to calculate the AUC?
7. Determination of Km and Vmax at steady state concentration.
8. Two compartment model for I.V infusion.
9. Write about in vitro dissolution models.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Vesicular transport.
2. Effective surface area.
3. Define clearance.
4. What are the drugs binding in HSA?
5. Lag time.
6. Chemical equivalence.
7. Biological half life.
8. Why non linear kinetics is called dose depended kinetics?
9. Pharmacodynamic drug interaction.
10. What is Extra vascular administration?

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 1024] OCTOBER 2024 Sub. Code: 2065
(SEPTEMBER 2024 EXAM SESSION)

B. PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. What are the various phases of drug transfer from GI absorption site into systemic circulation?
2. Discuss the factors influencing protein binding of drugs.
3. Define clearance and what are the various routes of drug excretion?

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Explain the theories of drug dissolution.
2. Name the various binding sites on human serum albumin.
3. What are the specialized barriers to distribution of drugs.
4. Classify the chemical pathways of drug metabolism.
5. List the factors influencing renal excretion of drugs.
6. What are the various types of bioequivalence?
7. Elimination half life.
8. Explain the factor causes of non- linearity.
9. Absolute and relative bioavailability.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Down hill transport.
2. Apparent volume of distribution.
3. Ficks first law of diffusion.
4. Excretion.
5. Gastric emptying.
6. Loding dose.
7. Toxic level.
8. Drug disposition.
9. Extraction ratio.
10. Fluctuation.

****

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[B.PHARM 0325] **MARCH 2025** **Sub. Code: 2065**

B. PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 – SEMESTER VI
PAPER IV – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 562065

Time: Three hours **Maximum: 75 Marks**

I. Elaborate on: Answer any TWO questions. **(2 x 10 = 20)**

1. Explain the pharmaceutical factors influencing the absorption of drug through GIT with examples.
2. Elaborate in detail about renal excretion of drug.
3. Describe in detail about the approaches to improve the bioavailability of BCS class II drugs.

II. Write notes on: Answer any SEVEN questions. **(7 x 5 = 35)**

1. Types of pharmacokinetic models.
2. Volume of Distribution.
3. Clinical significance of protein binding of drugs.
4. One compartment model for I.V. bolus.
5. Factors contributing to drug interactions.
6. Loading and maintenance doses.
7. Explain the Non-compartment models.
8. Explain the elimination rate constant.
9. Bio-equivalence studies.

III. Short answers on: Answer ALL questions. **(10 x 2 = 20)**

1. Define Biopharmaceutics.
2. Perfusion rate.
3. Passive diffusion.
4. Placental barrier.
5. Name the organs involved in drug metabolism.
6. Define in vitro in vivo correlation (IVIVC).
7. Compartment models.
8. Applications of Pharmacokinetics.
9. Endocytosis.
10. What is open model?

****