DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

(Regulations 2008-2009)

(Candidates admitted from 2008-2009 onwards)

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time: Three Hours   **Maximum: 70 marks**

Answer ALL questions

I. Elaborate on: **(2 x 20 = 40)**

1. Elaborate on the pharmacokinetic model and equations in one compartment open model I.V. bolus.

2. a) Define bio-equivalence.
      List the various methods involved in the determination of bio-equivalence.

   b) Elaborate on any one delivery system for estimation of bioequivalence.

II. Write notes on: **(6 x 5 = 30)**

1. Physiological barrier to drug distribution.

2. Causes of non-linearity with example.

3. Mean residence time.

4. Limitations of multi compartmental analysis.

5. Renal impairment and creatinine clearance.

6. A drug has to be administered as a continuous I.V. infusion so as to reach a study state concentration of 0.5mcg/ml. What should be the infusion rate if it is following the one compartment model? (T½=8 hr. and Vα=13L)

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DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time: Three Hours   **Maximum: 100 marks**

Answer ALL questions in the same order.

I. Elaborate on :

	Pages (Max.)	Time (Max.)	Marks (Max.)
1. a) Define Absorption. Explain the various mechanisms of drug absorption.	17	40 min.	20
b) Explain the various models of pharmacokinetic analysis.			
2. a) Elaborate the various methods of improving bioavailability of poorly soluble drugs.	17	40 min.	20
b) Explain Oxidation – reduction cycle.			

II. Write notes on :

	Pages (Max.)	Time (Max.)	Marks (Max.)
1. Explain the BCS system?	4	10 min.	6
2. What are the objectives and approaches in developing in vitro-in vivo correlation?	4	10 min.	6
3. Pharmacodynamic methods for assessing bioavailability.	4	10 min.	6
4. What are the physiological barriers of distribution? Add a note on BBB.	4	10 min.	6
5. Describe briefly about plasma proteins	4	10 min.	6
6. Explain Wagner Nelson method for computing absorption rate constant	4	10 min.	6
7. Apparent volume of distribution and its significance	4	10 min.	6
8. Define dose-dependent kinetics. Give some tests to detect the same in a rate process.	4	10 min.	6
9. Explain the rate of excretion method for the determination of elimination rate constant.	4	10 min.	6
10. A drug was administered by IV infusion at a rate of 20mcg/hr. the volume of distribution and elimination rate constant was found to be 10L and $0.2hr^{-1}$. Calculate steady state concentration achieved by the drug and the loading dose to be administered for achieving steady state concentration.	4	10 min.	6

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PHARM. D / POST BACCALAUREATE DEGREE EXAMINATION

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time: Three Hours **Maximum: 100 marks**

Answer ALL questions in the same order.

I. Elaborate on :

	Pages (Max.)	Time (Max.)	Marks (Max.)
1. Discuss the principle that governs the renal excretion of drugs?	17	40 min.	20
2. Define Nonlinear Pharmacokinetics? What are the causes for the Nonlinearity? Explain Michaelis Menten equation with respect to the estimation of K_m and V_{max}?	17	40 min.	20

II. Write notes on :

	Pages	Time	Marks
1. Write a note on measurement of bioavailability by plasma Level - time study?	4	10 min.	6
2. Discuss Latin square design in bioequivalent study?	4	10 min.	6
3. Derive the equation for two compartment open model intravenous infusion?	4	10 min.	6
4. How to determine the normal renal function in patients?	4	10 min.	6
5. Write a note on statistical moment theory?	4	10 min.	6
6. Calculate the absolute bioavailability of Amoxycillin capsule. The dose of the capsule was 500 mg and the AUC was 50.9 mcghr/L. The dose of IV amoxycillin is 250 mg and the AUC is 34.63 mcghr/L.	4	10 min.	6
7. Write the importance of Wagner Nelson method in pharmacokinetics?	4	10 min.	6
8. Write a note on Non Compartmental Pharmacokinetics	4	10 min.	6
9. What are the formulation factors that affect drug absorption?	4	10 min.	6
10. After oral administration of single dose of 500 mg rifampicin the following urine data were obtained. Calculate the renal excretion rate.	4	10 min.	6

Collection interval	Urine volume (ml)	Urine Concentration (mg/ml)
0-2	119	0.60
2-4	81	0.70
4-8	160	0.50
8-12	220	0.23
12-18	284	0.15
18-24	212	0.10

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DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)
DEGREE EXAMINATION
FOURTH YEAR
PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time: Three Hours   **Maximum: 100 marks**

Answer All questions

I. Elaborate on: **(2 x 20 = 40)**

1. Discuss the principles that governs the renal excretion of drugs?

2. Discuss in detail the physiochemical factors affecting drug absorption?

II. Write notes on: **(10 x 6 = 60)**

1. Write a note on drug – drug interactions in Gastro intestinal tract?

2. Discuss the importance of salivary excretion of drugs?

3. Derive the equation for one compartment open model intravenous infusion?

4. Write the procedure involved in the determination of elimination rate constant using urinary excretion data?

5. Derive the equation for two compartment open model extravascular administration?

6. Write a note on Michaelis menten equation?

7. Discuss in detail regulatory requirements for bioavailability study?

8. The dose of amoxicillin capsule was 500 mg and the AUC was 50.9 mcghr/L.
   The dose of suspension was 500 mg and the AUC is 6 1.93 mcghr/L.
   Calculate the relative bioavailability of capsule to the oral suspension.

9. An ophthalmic solution of mydriatic drug at 5 mg/ml exhibits first order degradation with rate of 0.0005 /day. How much drug will remain after 120 days?

10. Differentiate passive diffusion and active transport?

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DEGREE EXAMINATION

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time: Three Hours   **Maximum: 70 marks**

Answer All questions

I. Elaborate on: **(2 x 20 = 40)**

1. Define drug absorption.
   Discuss the various factors influencing GI absorption of a drug.

2. Discuss the one compartment open model intra venous administration.

II. Write notes on: **(10 x 3 = 30)**

1. Explain in brief about Michaelis menten equation.

2. Explain the Mean residence time.

3. Apparent volume of distribution.

4. Methods to enhance the bioavailability through enhancement of drug solubility.

5. How will you find out K_m and V_{max} from steady state concentration?

6. What are the major parameters studied in the urinary excretion data?

7. What are the factors affecting drug dissolution and dissolution rate?

8. Write the concept and types of clearance.

9. The drug has an elimination half life of 6 hrs. and follows first order kinetics.
   If a single dose of 500 mg is given to an adult male (68 kg) patient by I.V bolus injection, what will be the percentage of dose lost in 24 hrs.?

10. Statistical moment theory.

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DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time: Three Hours   **Maximum: 70 marks**

Answer All questions

I. Elaborate on: **(2 x 20 = 40)**

1. Drug elimination.

2. A 70 kg patient is to be a given a drug by i.v. infusion.
   The drug has a half life of 22 hours, apparent volume of distribution 15.7 litres
   and desired steady state plasma concentration is 0.0002 mcg/ml.
   Assuming one compartment kinetics calculate; time to reach 90% steady state
   concentration, infusion rate to achieve desired steady state concentration, loading
   dose to attain steady state rapidly and concentration of drug in plasma after 48 hours
   from the start of infusion.

II. Write notes on: **(10 x 3 = 30)**

1. Enlist physiological barriers for distribution.

2. Statistical interpretation of bioequivalence data.

3. Endocytosis.

4. Tissue localization.

5. Plasma level time curve.

6. Advantages of Catenary model.

7. Lineweaver-Burke Plot.

8. Persistance factor and loss factor.

9. Approaches for dosage regimen.

10. Dissolution apparatus I.

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DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

(2009-2010 Regulation)

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time: Three Hours　　　　　　　　　　　　　　　　**Maximum: 70 marks**

Answer All questions

I. Elaborate on:　　　　　　　　　　　　　　　　　**(4 x 10 = 40)**

1. Define absorption.
   Explain briefly about different mechanisms of drug absorption.

2. Advantages, Criteria of urinary excretion data.
   How will you find out elimination rate constant from the data?

3. Bioequivalence study protocol.

4. Multiple dosage regimens.

II. Write notes on:　　　　　　　　　　　　　　　　**(6 x 5 = 30)**

1. Partition theory and its modifications.

2. Blood Brain Barrier.

3. Significance of protein binding.

4. Carternary model.

5. Wagner Nelson Method.

6. Theophylline was administered to a patient at a dosing rate of 600 mg/day and 1200 mg/day. Respective steady state concentrations were 9.8 mg/L and 28.6mg/L. Find out K_m and V_{max}. Determine the dosing rate to achieve steady state concentration of 15 mg/L.

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DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

(2009-2010 Regulation)

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time: Three Hours **Maximum: 70 marks**

Answer All questions

I. Elaborate on: **(4 x 10 = 40)**

1. Pharmaceutical factors influencing G.I.T absorption.

2. Nonlinear kinetics – Causes and estimation of K_m and V_{max}.

3. Bioavailability enhancement through solubility / dissolution rate.

4. Pharmacokinetic analysis of mathematical data.

II. Write notes on: **(6 x 5 = 30)**

1. Plasma protein bindings.

2. Apparent Volume of distribution.

3. Factors affecting renal excretion.

4. Statistical Moment Theory.

5. Plateau principle.

6. Estimate the creatinine clearance of a 30 year old 70 kg man with serum creatinine level of 2 mg %. What is the renal function of this patient?

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PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE) DEGREE EXAMINATION

(2009-2010 Regulation)

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 383823

Time: Three Hours   **Maximum: 70 marks**

Answer ALL questions

I. Elaborate on :   **(4 x 10 = 40)**

1. One compartment open IV bolus administration.

2. Define excretion and explain briefly about renal excretion of drugs.

3. Physiological barriers to distribution of drugs.

4. *In Vitro* drug dissolution testing models.

II. Write notes on :   **(6 x 5 = 30)**

1. Approaches for dosage regimen.

2. Biopharmaceutical classification systems.

3. Line-weaver Burk plot.

4. Micro and hybrid constants.

5. Tissue localization of drugs.

6. A drug is administered at a dose of 500 mg IV bolus injection. The drug has elimination rate constant 0.231/hr, volume of distribution is 20 L by following one compartmental kinetics. If Area under the curve is 110 mg hr/L, then calculate mean residence time of the drug.

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[LI 823]   **APRIL 2016**   **Sub. Code: 3823**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FOURTH YEAR
PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time : Three hours   **Maximum : 70 Marks**

I. Elaborate on :   **(4 x 10 = 40)**

1. Explain briefly Michaelis – menton method for estimation of K_m and V_{max}.

2. Define excretion and explain briefly about Renal excretion of drugs.

3. Physiological barriers to distribution of Drugs.

4. Write briefly about Invivo – Invitro correlations and BCS classification.

II. Write notes on :   **(6 x 5 = 30)**

1. Renal impairment and creatinine clearance.
2. Write a note on statistical moment theory.
3. Short notes on bioavailability protocol.
4. Write the concept and types of clearance.
5. Discuss Latin square design in Bioequivalent study.
6. What are the formulation factors that affect drug absorption?

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PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FOURTH YEAR
PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 383823

Time : Three hours   **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Explain briefly mechanism of drug absorption in G.I.T.

2. Discuss the two compartment open model Intra Venous administration.

3. Define Bioavailability. Explain various methods used for determination of Bioavailability.

4. Explain the various models of Pharmacokinetic analysis.

II. Write notes on: **(6 x 5 = 30)**

1. What are the objectives and approaches in developing in vitro-in vivo correlation?

2. Causes of non-linearity with example.

3. Limitations of multi compartmental analysis.

4. Discuss the importance of salivary excretion of drugs.

5. Discuss in detail regulatory requirements for bioavailability study.

6. What are the factors affecting drug dissolution?

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PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FOURTH YEAR
PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 383823

Time : Three hours   Maximum : 70 Marks

I. Elaborate on: (4 x 10 = 40)

1. Define drug absorption. Discuss the physiochemical factors influencing GI absorption of a drug.

2. Explain briefly two compartmental open model extra Vascular Administration.

3. Explain in details about pharmacokinetic and pharmacodynamic parameters.

4. What are the major parameters studied in the urinary excretion data?

II. Write notes on: (6 x 5 = 30)

1. Measurement of bioavailability.
2. Explain the mean residence time.
3. Volume of distribution.
4. Methods to enhance the bioavailability through enhancement of dissolution rate.
5. How can you graphically estimate K_m and V_{max} from steady state concentration?
6. Hepatic clearance and renal clearance.

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PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FOURTH YEAR
PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time : Three hours   **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. What are the dosage form related factors affecting drug absorption?

2. Explain the volume of distribution with its significance.

3. Describe the pharmacokinetics concept involved in repetitive injection in one component open model.

4. Enumerate in detail the bio-availability study protocol.

II. Write notes on: **(6 x 5 = 30)**

1. Add a note on statistical moment theory.

2. How to determine bio-availability through urinary extraction studies?

3. Write about compartment models.

4. Discuss the concept involved in clearance.

5. Differentiate Phase I and Phase II biotransformation reactions.

6. Describe the method of residuals in the determination of absorption rate constant in two compartment open model extra vascular administration.

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

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FOURTH YEAR
PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time : Three hours   Maximum : 70 Marks

I. Elaborate on: (4 x 10 = 40)

1. Outline the physicochemical factors affecting drug absorption.

2. Explain the significance of protein/tissue binding of drugs.

3. Explain Non-linear Pharmacokinetics. Write in estimation of K_m and V_{max}.

4. How to determine pharmacokinetic parameters in one compartment open model intravenous infusion administration?

II. Write notes on: (6 x 5 = 30)

1. Differentiate active transport and passive diffusion.
2. Write the importance of volume of distribution.
3. Describe about salivary excretion.
4. Discuss method of determination and absorption rate constant (Ka).
5. Write the merits and demerits of non compartmental pharmacokinetics.
6. Mention the methodology involved in the determination of bioavailability.

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PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FOURTH YEAR
PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time : Three hours   Maximum : 70 Marks

I. Elaborate on: **(4 x 10 = 40)**

1. Define Pharmacokinetic models and equations of one compartment open model IV Bolus administration.

2. Define drug absorption. Discuss the various factors influencing GI absorption of a drug.

3. Explain the protocol, procedure for bioequivalence study.

4. Discuss the principles that governs the renal excretion of drugs.

II. Write notes on: **(6 x 5 = 30)**

1. Write short note on statistical moment theory

2. Discuss causes of non-linearity with example.

3. Explain significance of Protein binding.

4. Calculate the excretion rate at steady state for a drug given by IV infusion at a rate of 30mg/hr. The C_{ss} is 20mcg/ml. If the rate of Infusion were increased to 40mg/hr, what would be the new steady state concentration C_{ss}? Would the excretion rate for the drug at the new steady state be the same? Assume first order elimination kinetics and a one compartment model.

5. Note on Wagner – Nelson method.

6. Describe Blood Brain Barrier.

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

[LO 823]   **MAY 2019**   Sub. Code: 3823

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FOURTH YEAR
PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 383823

Time : Three hours   Maximum : 70 Marks

I. Elaborate on: (4 x 10 = 40)

1. Define Non Linear Pharmacokinetics. Explain Michaelis-Menten equation with respect to the estimation of K_m and V_{max}.

2. Define Absorption. Explain briefly about different mechanism of drug Absorption.

3. Define Bioavailability. Explain various methods used for determination of Bioavailability.

4. Explain briefly the two compartmental open model extra vascular administration.

II. Write notes on: (6 x 5 = 30)

1. Discuss protocol bioequivalence study.

2. Explain the formulation factors that affect drug Absorption.

3. Apparent volume of distribution and its significance.

4. Explain elimination rate constant and clearance of the drugs.

5. A new drug was given in a single intravenous dose of 200mg to an 80kg adult male patient. After 6 hours the Plasma drug concentration of drug was 1.5mg/100ml of Plasma. Assuming that the apparent V_D is 10% of body weight. compute the total amount of drug in the body fluids after 6 hours. What is the half-life of this drug?

6. Describe open one compartment model IV bolus administration.

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