September 2009

[KV 823] **Sub. Code: 3823**

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. Essay Questions : **(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 Short Notes : **(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 creatinin 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? ($T_{½}$=8 hr and V_{α}=13L)

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October 2011

[KZ 823] **Sub. Code: 3823**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 383823

Time : 3 hours **Maximum : 100 marks**
(180 Min)

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 :			
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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[LB 823] **OCTOBER 2012** **Sub. Code: 3823**

PHARM. D / POST BACCALAUREATE DEGREE EXAMS

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 383823

Time : 3 hours **Maximum : 100 marks**

(180 Min)

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	20
2. Define Nonlinear Pharmacokinetics? What are the causes for the Nonlinearity? Explain Michaelis Menten equation with respect to the estimation of Km and Vmax?	17	40	20

II. Write notes on :

1. Write a note on measurement of bioavailability by plasma Level - time study?	4	10	6
2. Discuss Latin square design in bioequivalent study?	4	10	6
3. Derive the equation for two compartment open model intravenous infusion?	4	10	6
4. How to determine the normal renal function in patients?	4	10	6
5. Write a note on statistical moment theory?	4	10	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	6
7. Write the importance of Wagner Nelson method in pharmacokinetics?	4	10	6
8. Write a note on Non Compartmental Pharmacokinetics	4	10	6
9. What are the formulation factors that affect drug absorption?	4	10	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	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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[LC 823] **APRIL 2013** **Sub. Code: 3823**

PHARM. D / POST BACCALAUREATE) DEGREE EXAMS

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS

AND PHARMACOKINETICS

Q.P. Code : 383823

Time : 3 hours **Maximum : 100 marks**

I. Elaborate on : **(2x20=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 : **(10x6=60)**

1. Write a note on drug –drug interactions in Gastro intestinaltract?
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 theAUC was 50.9 mcghr/L. The dose of suspension was 500 mg and the AUC is 61.93 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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[LD 823] **OCTOBER 2013** **Sub. Code: 3823**

PHARM.D / POST BACCALAUREATE DEGREE EXAMINATIONS

FOURTH YEAR

PAPER V – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 383823

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

Answer ALL questions in the same order

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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[LE 823] **APRIL 2014** **Sub. Code: 3823**

PHARM. D / POST BACCALAUREATE) DEGREE EXAMS
FOURTH YEAR
PAPER V – BIOPHARMACEUTICS
AND PHARMACOKINETICS

Q.P. Code : 383823

Time : 3 hours **Maximum : 70 marks**

I. Elaborate on : **(2x20=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 : **(10x3=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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[LF 823] **OCTOBER 2014** **Sub. Code: 3823**

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 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 28.6 mg/L. Find out Km and Vmax. Determine the dosing rate to achieve steady state concentration of 15 mg/L.

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