[KD 270]

M.Pharmacy DEGREE EXAMINATION.

(New Regulations)

First Year

Common to Branch I — Pharmaceutics and Branch VII — Pharmacy Practice

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Answer any FOUR questions.

All questions carry equal marks.

1. Discuss the factors influencing drug absorption. (25)

2. (a) Explain the first order kinetics.

(b) What are the advantages and disadvantages of compartment modelling?

(c) Explain the non–compartmental analysis method to study the time course of drugs in the body. (25)

3. (a) Define 'equivalence', 'chemical equivalence', 'pharmaceutic equivalence' and 'bioequivalence'.

(b) Describe the protocol, procedure and statistical interpretation of bioequivalence studies. (25)

4. (a) What are conjugation reactions? Give examples for each type of conjugation reaction.

(b) What are the routes of drug excretion?

(c) Explain the terms 'Prodrug' and 'Soft drug'. (25)

5. How do the following parameters influence the pharmacokinetic pattern of a drug?

(a) Obesity

(b) Protein binding

(c) Renal function

(d) Disease state and

(e) Metabolism. (25)

6. Write notes on :

(a) Blood Brain Barrier

(b) Inhibition of drug metabolising enzymes

(c) Drug pKa

(d) Interactions affecting absorption and distribution of drugs. (25)

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[KD 291]

M.Pharmacy DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Answer ALL the questions.

All questions carry equal marks.

1. What is the usefulness of pharmacokinetic models? Discuss in detail about the pharmacokinetic and pharmacodynamic parameters. Explain Zero–order kinetics with examples. (25)

2. (a) What is meant by 'ideal drug dosage regimen'?

(b) Explain the Phase I reactions of drug biotransformation with suitable examples. (25)

3. (a) Define Clearance.

(b) What are the factors influencing renal excretion of drugs? (25)

4. (a) What are the causes of variability in human drug response?

(b) Discuss the importance of therapeutic drug monitoring with particular reference to anticonvulsants.

(c) What are the advantages and limitations of individualisation of drug dosage? (25)

NOVEMBER 2001

[KE 270]

M.Pharm. DEGREE EXAMINATION.

(New Regulations)

First Year

Common to Branch I — Pharmaceutics and
Branch VII — Pharmacy Practice

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Answer any FOUR questions.

All questions carry equal marks.

1. Discuss various pharmaceutic factors influencing GI absorption of Drugs from its dosage form. (25)

2. (a) Describe the open one compartment pharmacokinetic model for a single dose orally administered drug.

(b) Explain the stripping technique for the determination of absorption rate constant ka, from the above model. (25)

3. Write notes on : $(4 \times 6\frac{1}{4} = 25)$

(a) Hepatic clearance

(b) Renal clearance

(c) Active transport drug absorption

(d) Blood level curves.

4. Give brief accounts of the following : $(4 \times 6\frac{1}{4} = 25)$

(a) Effect of disease state on drug absorption

(b) Significance of plasma protein binding on the pharmacokinetics of drugs.

(c) Role of dosage forms on G.I. absorption of drugs

(d) AUC and AUMC.

5. Distinguish between bioequivalence and clinical equivalence.

What are the parameters considered in evaluating the bioequivalency of two or more formulations of the same drug? Explain in detail the importance of each. (25)

6. Define bioavailability. Give a detailed account of experimental design and protocol for bioavailability studies. (25)

[KE 291]

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

All questions carry equal marks.

1. Discuss various Patient Related Factors influencing G.I. absorption of drugs. (25)

2. (a) Describe the open two compartment pharmacokinetic model for a drug administered as I.V. bolus dose.

(b) Give an account of various pharmacokinetic parameters that can be determined from it. (25)

3. Write notes on : (25)

(a) Passive diffusion mechanism of drugs absorption.

(b) pH partition theory.

(c) Phase two reactions.

(d) Enterohepatic cycling.

4. Give brief accounts of the following : (25)

(a) Individualization of drugs in therapy.

(b) Noncompartmental pharmacokinetics.

(c) Dissolution test and apparatus.

(d) MRT and biological half–life.

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[KH 291]

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Answer ALL questions.

All questions carry equal marks.

1. What are different theories to explain drug dissolution from solid particles? Explain with neat labelled diagram diffusion layer model. Classify and describe different in–vitro dissolution models.(7 + 10 + 8)

2. What are major causes of intersubject variability in drug response? On what factors do maintenance of drug concentration within therapeutic range depend? (15 + 10)

3. Which physicochemical properties of the drug limit its distribution? How are body tissues classified on the basis of perfusion rate? Illustrate. (10 + 5)

4. An adult male patient (43 yr; 80 kg) is to be given an antibiotic by I.V. infusion. The drug is supplied in 5 ml ampoules containing 150 mg/L. Recommend starting infusion rate in mg/hr and lit/hr.

[Elimination half–life : 2 hrs; Volume of distribution 1.25 L/kg; Effective plasma drug conc. 14 mg/L;]

Blood samples were taken at 12, 16 and 24 hours after beginning of infusion. From the recorded values calculate total body clearance and elimination half–life for the antibiotic. (25)

Time (hr)	12	16	24
Concentration (mg/L)	16.1	16.3	16.5

[KI 291] APRIL 2003 Sub. Code : 1003

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Answer ALL questions.

All questions carry equal marks.

1. (a) Enlist the mechanisms of drug absorption and explain passive diffusion and active transport with suitable examples. (12)

(b) Discuss the factors affecting protein binding and its significance and kinetics. (13)

2. (a) Discuss the pharmacokinetic methods of assessing bioavailability. (13)

(b) Explain the methods of enhancing bioavailability of drugs. (12)

3. (a) Discuss the rate of tissue permeability as rate determining step in distribution of drugs. (12)

(b) Explain configuration pathways of detoxification. (13)

4. (a) Give the cause of non–linearity in pharmacokinetics. Write the applications of principles of pharmacokinetics. (12)

(b) How do you obtain K_e (elimination rate constant) by rate of excretion method? Briefly describe dissolution testing of drugs. (13)

OCTOBER 2003

[KJ 291] Sub. Code : 1003

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Answer ALL questions.

All questions carry equal marks.

1. (a) "Phase II reactions are the real drug detoxification pathways". Justify the statement with suitable examples. (13)

(b) Enlist non-renal routes of drug excretion and explain the biliary excretion of drugs. (12)

2. (a) Explain the biological factors influencing drug absorption. (12)

(b) Enlist the mechanisms of drug absorption and discuss the passive diffusion and active transport with suitable examples. (13)

3. (a) Explain the method of residual to calculate absorption rate constant of a drug following one compartment kinetics. (12)

(b) Give the criteria for obtaining valid urinary excretion data and explain sigma minus method to calculate Ke for a drug given by iv bolus and following one compartment kinetics. (13)

4. (a) Define bioavailability. What are the objectives of bioavailability studies? Explain pharmacokinetic method to measure bioavailability. (13)

(b) Explain the compendial methods of invitro dissolution testing. (12)

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[KK 291] APRIL 2004 Sub. Code : 1003

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours | Maximum : 100 marks

Sec. A & B : Two hours and forty minutes | Sec. A & B : 80 marks

M.C.Q. : Twenty minutes | M.C.Q : 20 marks

Answer ALL questions.

SECTION A

Long Essay : (2 × 15 = 30)

1. (a) Describe the blood level curves for one and two compartment open models for intravenous bolus administration.

(b) Explain determination of different pharmaco–kinetic parameters for oral administration assuming one compartment open model. (5 + 10)

2. Explain the various factors affecting distribution of drugs.

SECTION B

Short notes. (10 × 5 = 50)

3. Discuss pH–partition hypothesis.

4. Describe enterohepatic recycling and its significance.

5. Explain the significance of conjugation reactions with examples.

6. Describe the characteristics of non–compartmental pharmacokinetics. Add a note on mean residence time.

7. Describe the concept of clearance.

8. How is bioavailability estimated from urinary excretion studies?

9. Describe the factors to be considered in designing dissolution test and apparatus.

10. How is bioequivalency testing performed and evaluated?

11. Describe the effect of age on the pharmacokinetics of a drug.

12. Derive an equation for steady state concentration after an intravenous infusion assuming one compartment open model.

[KL 291] AUGUST 2004 Sub. Code : 1003

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours | Maximum : 100 marks

Sec. A & B : Two hours and forty minutes | Sec. A & B : 80 marks

M.C.Q. : Twenty minutes | M.C.Q. : 20 marks

Answer ALL questions.

SECTION A — (2 ×15 = 30 marks)

Long Essay :

1. Define biotransformation of drugs and discuss various processes involved with examples.

2. What are the main factors that influence drug dosing in renal disease? Name and contrast two methods for adjusting drug dose in renal disease.

SECTION B — (10 × 5 = 50 marks)

Short Notes :

3. Explain K & N values of protein binding and how they are determined.

4. Explain Mechalis Menton equation and how do you determine Km & Vm.

5. What are the factors effecting renal clearance.

6. Write the concept of protein binding.

7. Discuss the various factors affecting dosage regimen.

8. Explain various pharmacodynamic parameters.

9. Write the significance of bio equivalency testing.

10. Discuss the dosage adjustment in neonates and obese patients.

11. What is volume of distribution and explain its significance?

12. Explain briefly conjugation methods of drug detoxification processes.

FEBRUARY 2005

[KM 291] Sub. Code : 1003

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Sec. A & B : Two hours and forty minutes Sec. A & B : 80 marks

M.C.Q. : Twenty minutes M.C.Q. : 20 marks

Answer ALL questions.

SECTION A — (2 × 15 = 30 marks)

Long Essay :

1. List the physicochemical factors of drug distribution and explain the barriers of drug distribution.

2. Derive and compute mathematically the number of half-life required to attain 90% of steady state concentration after i.v. infusion.

SECTION B — (10 × 5 = 50 marks)

Write short notes on :

3. Dissolution mechanisms and models.

4. Invitro–Invivo correlations, objectives and approaches.

5. Therapeutic drug monitoring of digoxin.

6. Active drug absorption across GIT.

7. How are body tissues classified on the basis of perfusion rate?

8. What are the different theories to explain drug dissolution from solid particles?

9. Describe the concept of clearance.

10. List the routes of drug administration.

11. What is meant by a 'random' population?

12. How are body tissues classified on the basis of perfusion rate?

[KN 291] AUGUST 2005 Sub. Code : 1003

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Theory : Two hours and forty minutes Theory : 80 marks

M.C.Q. : Twenty minutes M.C.Q. : 20 marks

Answer ALL questions.

I. Long Essay : (2 × 15 = 30)

1. Define bioavailability and discuss various methods to enhance the bioavailability of poorty soluble drugs.

2. Explain various physiological barriers to the drug distribution in the body.

II. Short notes : (10 × 5 = 50)

1. Explain phase-I reactions of bio-transformation of drugs with examples.

2. Discuss official methods of drug dissolution for uncoated tablets.

3. With the help of diagram explain the structure and functions of Nephron.

4. Explain non-renal routes of clearance of drug molecules from the body.

5. Write a note on biological half life.

6. Explain various pharmacokinetic parameters.

7. Write the factors influencing dosage regimen.

8. Discuss various methods to determine absorption rate constant.

9. Write the factors responsible for non-linear pharmacokinetics.

10. Explain the phenomenon of drug accumulation.

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MARCH 2006

[KO 291] **Sub. Code : 1003**

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Theory : Two hours and forty minutes Theory : 80 marks

M.C.Q. : Twenty minutes M.C.Q. : 20 marks

Answer ALL questions.

I. Long Essay : $(2 \times 15 = 30)$

1. Explain the methods of enhancing bio availability of drugs.

2. Explain configuration pathways of drug detoxification.

II. Write short notes on : $(10 \times 5 = 50)$

1. What is volume of distribution and how it is determined?

2. Explain biological half life and how it is determined.

3. Explain the methods to identify non–linearity in biological process.

4. How do you determine AUC?

5. Explain mechalis menton equation.

6. Explain does adjustment in renal impairment.

7. Discuss various pharmaco dynamic parameters.

8. Write briefly subdermal implantable dosage forms.

9. Write the assumptions and limitations of one compartmental model.

10. Write briefly on carrier mediated transport.

SEPTEMBER 2006

[KP 291] **Sub. Code : 2807**

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours — Maximum : 100 marks

Theory : Two hours and forty minutes — Theory : 80 marks

M.C.Q. : Twenty minutes — M.C.Q. : 20 marks

Answer ALL questions.

I. Long Essay :

(1) (a) Write a note on urinary excretion studies.

(b) Describe the kinetics of protein binding of drugs and its implications. (10 + 10 = 20)

(2) Discuss the concept of compartment kinetics and its role in understanding drug distribution pattern. Sketch out different types of compartment models. (15)

(3) Explain renal clearance of drugs and how is it determined. Explain dosage adjustment in patients with renal insufficiency with examples. (5 + 10 = 15)

II. Short notes : (6 × 5 = 30)

(1) Explain passive diffusion of drugs in the body and factors determining passive diffusion.

(2) Explain biological half-life and how is it determined?

(3) Write a note on transcutaneous adsorption of drugs.

(4) Explain phase-II reactions of bio-transformation of drugs with examples.

(5) How do you determine absorption rate constant by method of 'residuals'?

(6) Write a note on invitro-invivo correlation.

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MARCH 2007

[KQ 291] Sub. Code : 2807

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Theory : Two hours and forty minutes Theory : 80 marks

M.C.Q. : Twenty minutes M.C.Q. : 20 marks

Answer ALL questions.

I. Long Essay :

1. Explain the Pharmaceutical and Physiological factors affecting drug absorption (20)

2. Explain the difference in apparent volume of distribution of drugs administered by IV bolus in one and two compartment models. (15)

3. Define bioavailability and bioequivalence. Describe the study design and methods for bioequivalence studies. (3+12)

II. Short notes on : (6 × 5 = 30)

1. Explain non compartment analysis in pharmacokinetics.

2. Define clearance and explain non renal routs of drug clearance.

3. Describe the kinetics of intravenous infusion.

4. What is the indication of renal failure? Explair the dose adjustment in renal failure.

5. Explain the phase II biotransformation pathways of drugs.

6. Discuss Wagner Nelson methods to determine absorption rate constant in one compartment model with 1st order absorption and 1st order elimination.

MARCH 2007

[KQ 317] **Sub. Code : 2853**

M.Pharm. DEGREE EXAMINATION.

(Regulation 2006)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours — Maximum : 100 marks

Theory : Two hours and forty minutes — Theory : 80 marks

M.C.Q. : Twenty minutes — M.C.Q. : 20 marks

Answer ALL questions.

I. Long Essay :

1. (a) Write a note on bioequivalence, chemical equivalence, therapeutic equivalence and pharmaceutical equivalence.

(b) Discuss the various factors that effect biotransformation. (10 + 10)

2. Explain the methods for enhancing bioavailability of drugs. (15)

3. Explain the pharmacokinetic variabilities in renal disease and mention how dose adjustment is done in renal disease. (15)

II. Short notes : (6 × 5 = 30)

1. Explain the concept of loading dose and maintenance dose.

2. How you determine the testing of bioequivalence of dosage forms?

3. Write a note on factors affecting drug absorption.

4. Explain volume of distribution and plasma protein binding.

5. Explain zero order and first order kinetics.

6. Write about Michaelis Menten equation.

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SEPTEMBER 2007

[KR 291] **Sub. Code : 2807**

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Theory : Two hours and forty minutes Theory : 80 marks

M.C.Q. : Twenty minutes M.C.Q. : 20 marks

Answer ALL questions.

I. Long Essay :

1. What are the main factors that influence drug dosing in renal disease? Name and contrast two methods for adjusting drug dose in renal diseases. (20)

2. What are the different methods of absorption of drugs? Explain the major methods. (15)

3. (a) Explain the blood level curves for one and two compartment open models for intravenous bolus administration.

(b) Explain various approaches to improve dissolution of poorly water soluble drugs. (15)

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

1. Protein binding of drugs — Explain.

2. Write short notes on Percutaneous absorption.

3. What are the main reasons for giving a drug by infusion by slow IV infusion? What are some of the complications involved with IV infusions?

4. Describe the effect of age on pharmacokinetics of a drug.

5. Describe the effect of disease states on drug disposition.

6. Explain the concept of clearance.

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SEPTEMBER 2007

[KR 317] **Sub. Code : 2853**

M.Pharm. DEGREE EXAMINATION.

(Regulations 2006)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Time : Three hours Maximum : 100 marks

Theory : Two hours and forty minutes Theory : 80 marks

M.C.Q. : Twenty minutes M.C.Q. : 20 marks

Answer ALL questions.

I. Long Essay :

(1) How do age, sex, body weight and genetic factors cause pharmacokinetic variability? (20)

(2) Discuss the physicochemical and pharmaceutic factors affecting the GI absorption of drugs. (15)

(3) Explain in detail about barriers to drug distribution. Add a note on physicochemical properties influencing the tissue permeability of drug. (15)

II. Short notes : (6 × 5 = 30)

(1) Loading dose

(2) Chemical equivalence

(3) Cyclodextrin complexes

(4) Phase I reactions

(5) Prodrug

(6) Protein binding.

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September 2008

[KT 291] **Sub. Code : 2807**

M.Pharm. DEGREE EXAMINATION.

(Revised Regulations)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262807

Time : Three hours Maximum : 100 marks

Answer ALL questions.

I. Long Essays : (3 × 20 = 60)

1. Define and distinguish Bioavailability and Bioequivalence. Detail the testing protocols for bioequivalence of dosage forms and their interpretations.

2. Discuss physicochemical factors affecting drug absorption.

3. Explain briefly :-

(a) Concept of clearance

(b) Volume of Distribution

(c) Mean Residence Time (MRT)

(d) Phase II Biotransformation Reactions.

II. Short Notes : (8 × 5 = 40)

1. How pre-systemic metabolism affects drug bioavailability?

2. Dissolution Rate Tests for solid dosage forms.

3. Role of Gastric emptying in drug absorption.

4. Non-Compartmental Pharmacokinetics.

5. Therapeutic Drug Monitoring of phenytoin.

6. Kinetics of First – order process and Half – life.

7. Calculation of Loading Dose.

8. Bioavailability of Iron.

September 2008

[KT 317] **Sub. Code : 2853**

M.Pharm. DEGREE EXAMINATION.

(Regulations 2006)

First Year

Branch I — Pharmaceutics

Paper III — BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262853

Time : Three hours Maximum : 100 marks

Answer ALL questions.

I. Essay : (3 × 20 = 60)

1. Explain in detail the importance of Bioequivalence and methods of quantifying bioequivalence.

2. Discuss about principles of drug absorption and methods of determining absorption.

3. (a) Explain with suitable examples the significance of phase-II biotransformation reactions.

(b) Discuss the significance of non-renal excretion of drugs.

II. Short notes : (8 × 5 = 40)

(1) Drug binding in tissues.

(2) Mean residence time and its significance.

(3) Concept of loading dose, maintainance dose.

(4) Pharmaceutical equivalence.

(5) Open two compartment model.

(6) Pharmacokinetic variabilities in disease states.

(7) Volume of distribution.

(8) Explain Noyes-Whitney's equation.

March 2009

[KU 317] **Sub. Code: 2853**

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

Branch I – PHARMACEUTICS

Paper III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262853

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. a) Explain the significance of Bioavailability studies. Enumerate the criterias for establishing bioequivalence requirement.

   b) Discuss the importance of invitro,invivo correlation in the bioavailability studies.

2. a) Discuss and compare the various approaches available for the pharmacokinetic analysis of the experimental data following intravenous bolus administration in one compartment open model.

   b) What are the causes of non linearity. How will you detect non-linearity. Explain Michaelis menton equation.

3. a) Discuss the mechanism of drug absorption.

   b) Explain in detail the physiological and physico chemical factors effecting gastro intestinal drug absorption.

II. Write Short Notes : **(8 x 5 = 40)**

1. Two compartment model
2. Volume of distribution
3. Discuss the diffusion layer theory.
4. Area and first movement curve
5. Renal clearance
6. Concept of loading dose and maintenance dose.
7. Enhancement of bio availability of drugs.
8. Pharmacokinetic variability factors.

*****

September 2009

[KV 317] **Sub. Code: 2853**

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

Branch I – PHARMACEUTICS

Paper III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262853

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. Define the term drug absorption and explain in detail the various mechanisms of drug absorption.

2. Define bio-availability and how will you measure bioavailability by pharmacokinetic methods (i.e. by indirect methods).

3. Explain two compartment open model. Give suitable expressions for pharmacokinetic parameters for a drug given as I.V. bolus administration that follow two compartment model.

II. Write Short Notes : **(8 x 5 = 40)**

1. Dosage form related factors influencing drug absorption.
2. Phase –I reactions in biotransformation of drugs.
3. Volume of distribution.
4. Hepatic clearance.
5. Define the various types of equivalence terms that come under bioequivalence studies.
6. Concept of loading and maintenance doses in multiple dosage regimen with respect to oral route.
7. Write a note on First-Order kinetics.
8. Discuss the effects of ‘Formulation additives’ and ‘nature and types of dosage form’ on the drug absorption.

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March 2010

[KW 317] **Sub. Code: 2853**

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

Branch I – PHARMACEUTICS

Paper III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262853

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. Define drug absorption, explain the various physicochemical factors influencing drug absorption and write a note on active transport mechanism of drug absorption.

2. Explain one compartment open model. Give suitable expressions for calculating pharmacokinetic parameters for a drug given extravascularly that follows one compartment model.

3. What is biotransformaion and explain phase-I and phase-II reactions of biotransformation with suitable examples?

II. Write Short Notes : **(8 x 5 = 40)**

1. Michael-Menten equation.
2. Drug permeability through blood brain barrier (BBB).
3. Apparent volume of distribution (VD).
4. Renal clearance of drugs.
5. Write about bioavailability enhancement by ‘Use of surfactants’ and preparation of ‘salt form of the drug’.
6. Define pharmacokinetic and pharmacodynamic variability in drug response and write a note on dosing of drugs in: a) Hepatic disease b) Sex.
7. Write a note on plasma protein binding of drugs and its distribution.
8. Effect of ‘Gastric emptying time’ and ‘intestinal transit time’ on the drug absorption.

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September 2010

[KX 317] **Sub. Code: 2853**

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

Branch I – PHARMACEUTICS

Paper III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262853

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. Discuss in detail about Invitro and Invivo methods of determining absorption.

2. Define Pharmacokinetic variability. Discuss in detail how body weight, genetic factors, age contribute to the pharmacokinetic variability.

3. Explain the Multicompartment model and derive expression for Pharmacokinetic parameters for a drug given as I.V. bolus administration.

II. Write Short Notes : **(8 x 5 = 40)**

1. Presystemic and Gut wall presystemic metabolism.
2. Testing of Bioequivalence of dosage forms.
3. Factors affecting Bio-Transformation.
4. Volume of distribution.
5. Non Renal excretion.
6. Multiple dosing with respective oral route.
7. Bioavailability of Aetazolamide, Carbamazepine.
8. Drug binding in tissues.

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MAY 2011

[KY 317] **Sub. Code: 2853**

M.PHARM. DEGREE EXAMINATION

(Regulations 2006)

Candidates admitted from 2006-2007 onwards

FIRST YEAR

Branch I – PHARMACEUTICS

Paper III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262853

Time : Three hours **Maximum : 100 marks**

Answer All questions

I. Essay Questions : **(3 x 20 = 60)**

1. Discuss the various biological and pharmaceutical factors influencing oral absorption of drugs. **(15+5)**

2. Give an account of the types & kinetics of protein binding of drugs, significance of protein binding on disposition of drugs in body and factors affecting plasma protein binding.

3. Give an account of non compartmental kinetics and the determination of pharmacokinetic parameters using AUMC and AUC.

II. Write Short Notes : **(8 x 5 = 40)**

1. pH partition hypothesis.
2. Prodrugs and solubilisaton in bioavailability enhancement.
3. Hepatic and Biliary clearance.
4. Absolute and relative bioavailability.
5. Wagner Nelson Method.
6. Estimation of K_m and V_{max} in non linear pharmacokinetics.
7. Factors leading to Pharmacokinetic variability.
8. Mechanisms of drug transport in renal excretion.

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