MAY 2011

[KY 342] **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION

(Regulations 2010)
Candidates admitted from 2010-2011 onwards

FIRST YEAR

Branch I – PHARMACEUTICS

Paper III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

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

Answer All questions

I. Essay Questions : **(6 x10 = 60)**

1. Explain the steps involved in oxidation of xenobiotics.
2. Describe the *in vitro* dissolution testing models
3. The equation that best fits the plasma level time curve of a drug after an IV bolus dose of 500mg is: C=143e-0.87t. Assuming one compartment kinetics calculate (a) Vd (b) Cl (c) Half life (d) AUC
4. What are compartment models? Derive an expression for calculating various pharmacokinetic parameters for a drug administered by IV bolus administration.
5. Define Pharmacokinetics. Explain the various pharmacokinetic parameters that describes a typical plasma level –time curve.
6. What are drug interactions? Explain the various types of pharmacokinetic drug interactions

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

1. What is BCS? On what basis the drugs are classified under BCS?
2. Give the advantages of urinary excretion data in pharmacokinetic analysis.
3. Define dose-dependent kinetics. Give some tests to detect the same in a rate process.
4. Define Persistence factor and Loss factor.
5. What is the influence of protein binding and displacement interaction on half life of a drug?
6. Briefly explain the components of Mixed function oxidases.
7. Explain the Latin square cross-over design for bioequivalency study with an example.
8. Describe briefly the influence of genetic factors in pharmacokinetic variability.

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October 2011

[KZ 342] **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION

FIRST YEAR

BRANCH I – PHARMACEUTICS

PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

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. Explain Non-Linear pharmacokinetics. Derive an expression for Michaelis Menten equation.	17	40	20
2. Explain in detail about the designing and protocol of bioequivalence studies.	17	40	20
II. Write notes on :			
1. With a neat diagram and explain G.I membrane.	4	10	6
2. Explain the significance of plasma protein binding in drug distribution and effects.	4	10	6
3. Explain any one Invitro method for studying drug absorption by non-oral route.	4	10	6
4. Write a note on (i) Blood Brain Barrier (ii) Cerebro spinal fluid barrier.	4	10	6
5. Write a note on therapeutic drug monitoring.	4	10	6
6. Explain the Pharmacokinetic variability in body weight and age.	4	10	6
7. Write a note on dosage adjustment in Renal disease.	4	10	6
8. Explain pH partition hypothesis.	4	10	6
9. Write a note on passive diffusion of drugs.	4	10	6
10. Explain the following (i) AUMC (ii) MRT.	4	10	6

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[LA 342] **MAY 2012** **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION

FIRST YEAR

BRANCH I – PHARMACEUTICS

PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code: 262903

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. Explain Excretion of drugs in detail.	17	40	20
2. Define Pharmacokinetics and Therapeutic index. Describe two compartment open model and derive suitable equations to assess Pharmacokinetic parameters of two compartment open model.	17	40	20

II. Write notes on :

1. Mechanism of absorption.	4	10	6
2. Volume of Distribution.	4	10	6
3. Hydrolytic reactions.	4	10	6
4. First order Kinetics.	4	10	6
5. *In vitro-in vivo* correlation.	4	10	6
6. Maintenance dose.	4	10	6
7. Dose adjustment in renal disease.	4	10	6
8. Formulation factors in absorption.	4	10	6
9. Subjects for Bioequivalence study.	4	10	6
10. Drug binding in tissues.	4	10	6

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[LB 342] **NOVEMBER 2012** **Sub. Code: 2903**

M.PHARM. DEGREE EXAMS

FIRST YEAR

BRANCH I – PHARMACEUTICS

PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

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. Explain Phase I and Phase II biotransformation reactions.	17	40	20
2. Discuss various physico-chemical and biological factors affecting drug absorption in the gastrointestinal tract.	17	40	20
II. Write Notes on :			
1. Passive and active transport of drugs.	4	10	6
2. Causes of non-linear pharmacokinetics and Michaelis-Menten equation.	4	10	6
3. Factors influencing drug clearance.	4	10	6
4. Methods of studying drug protein binding.	4	10	6
5. Volume of distribution and factors affecting it.	4	10	6
6. Non-compartmental methods of estimating pharmacokinetic parameters.	4	10	6
7. Methods of measurement of bioavailability.	4	10	6
8. Therapeutic drug monitoring and its significance.	4	10	6
9. Classification of drug-drug interactions with examples.	4	10	6
10. Any three methods of enhancing bioavailability of poorly water soluble drugs.	4	10	6

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[LC 342] **APRIL 2013** **Sub. Code: 2903**

M.PHARM. DEGREE EXAMS

FIRST YEAR

BRANCH I – PHARMACEUTICS

PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

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

I. Elaborate on : **(2x20=40)**

1. Define Biotransformation of drugs. Explain Phase I reactions and the factors affecting Biotransformation.
2. What is Relative Bioavailability? Describe the protocols of Bioequivalence study.

II. Write notes on : **(10x6=60)**

1. Drug related factors in absorption.
2. Factors affecting distribution of drugs.
3. Oxidation of Carbon-Nitrogen system.
4. Non renal excretion.
5. Wagner-Nelson method.
6. Glucuronidation.
7. Drug accumulation.
8. Dosing of drugs in obese patients.
9. Topical absorption of drugs.
10. Protein binding.

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[LD 342] **OCTOBER 2013** **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATIONS

FIRST YEAR

BRANCH I – PHARMACEUTICS

PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

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

Answer ALL questions in the same order.

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

1. Describe the mechanism of drug absorption and Biological factors influencing drug absorption.

2. What is clinical Pharmacokinetics? Write a detailed account on individualization of dosage regimen

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

1. Kinetics of protein drug binding
2. Reductive Reactions
3. Entero Hepatic cycling
4. Factors contributing to drug interactions
5. Wagner Nelsen method
6. Bioavailability enhancement through enhancement of Solubility and Dissolution rate
7. Therapeutic Drug Monitoring
8. Drug food interactions
9. Absorption from non- oral routes
10. Michelis Menten equation

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[LE 342] **APRIL 2014** **Sub. Code: 2903**

M.PHARM. DEGREE EXAMS
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

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

I. Elaborate on : **(2x20=40)**

1. Explain the designing and protocol of bioequivalence studies as per CDSCO guidelines.

2. Discuss various pharmaceutical dosage form factors and physiological factors affecting drug absorption in the gastrointestinal tract.

II. Write notes on : **(10x6=60)**

1. Volume of distribution of drugs.
2. Methods of drug dosage adjustments in renal impairment.
3. Phase II biotransformation of drugs.
4. Pharmacokinetic variability in thyroid disease.
5. Pharmacokinetic drug interactions.
6. Area under first moment curve and mean residence time.
7. Drug penetration to CNS.
8. Plasma protein binding of drugs.
9. Concept of loading dose and maintenance dose.
10. Any 6 methods to improve bioavailability of poorly water soluble drugs.

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[LF 342] **OCTOBER 2014** **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

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

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

1. Define Biotransformation of drugs. Explain phase II reactions.

2. a) Explain the methods of adjusting the dose and dosage regimen in patients with Renal and Hepatic diseases.
   b) Describe Pharmacodynamic parameters.

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

1. Topical administration of drugs.
2. Factors affecting distribution of drugs.
3. Hydrolytic reactions.
4. Renal excretion of drugs.
5. Causes of non-linearity.
6. *Invitro invivo* correlation
7. Dosing of drugs in neonates, infants and children.
8. Mechanism of drug interactions.
9. Non compartment method.
10. Volume of distribution

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[LG 342] **APRIL 2015** **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION

FIRST YEAR

BRANCH I – PHARMACEUTICS

PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

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

Answer ALL questions

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

1. a) Write about the biological factors affecting drug absorption.

   b) Mention an *In vitro* and *In vivo* method for determining drug absorption.

2. a) Derive Michaelis Menten equation.

   b) Describe about *In Vitro* and *In vivo* correlation method.

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

1. Differentiate Active and Passive transport.
2. Write about placental drug distribution.
3. Explain any two phase II reaction with example.
4. Describe Non renal excretion.
5. Explain first order kinetics.
6. Explain Area under first moment curve and mean residence time.
7. Specify the CDSCO protocol for bioequivalence study.
8. Write the concept involved in pharmacokinetic modeling.
9. Mention the concept behind multiple dosing in oral administration.
10. Describe the dosage adjustment procedure during cardiovascular and liver disorders.

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[LH 342] **OCTOBER 2015** **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

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

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

1. a) Draw the structure of cell membrane with the emphasis on composition.
   b) Explain the different mechanism involved in drug absorption.

2. a) Describe the Pharmacokinetic and Pharmacodynamic methods meant for the measurement of bioavailability.
   b) Add a note on non compartmental methods.

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

1. Volume of distribution.
2. Drug penetration approaches to central nervous system.
3. Explain oxidative reaction (phase I) with a suitable examples.
4. Differentiate renal and non renal excretion.
5. Derive the equation for open one compartment model, intravenous bolus administration.
6. Mention the reasons for non linear pharmacokinetics.
7. Specify GCP guidelines related to bioequivalence studies.
8. How to determine loading dose and maintenance dose?
9. Explain the pharmacokinetic variability during renal disease.
10. Discuss drug – drug interaction with example.

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[LI 342] APRIL 2016 **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

Time : Three hours **Maximum : 100 Marks**

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

1. Explain the Physiological and Physiochemical factors affecting Drug Absorption.
2. Describe Protein Binding with respect to drug distribution and effect.

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

1. Mention the factors affecting Bio Transformation. Explain any one method.
2. Add a note on Renal Excretion. Explain any one process.
3. Derive the equation for open two compartment model.
4. Describe total body clearance and organ clearance.
5. Write about the Bioavailability enhancement techniques.
6. Explain Biopharmaceutical classification system.
7. Write the concept behind therapeutic drug monitoring.
8. Write the principle behind intravenous multiple dosing.
9. Explain pharmacokinetic variability with respect to body weight and genetic factor.
10. Write about drug – food interaction.

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[LJ 342] OCTOBER 2016 **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

Time : Three hours **Maximum : 100 Marks**

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

1. Define Biotransformation of drugs. Explain phase I reactions with suitable examples.

2. a) Explain the following factors influencing pharmacokinetic variability of the drug in the patients : age, sex and genetic factors.

   b) Describe therapeutic drug monitoring and its significance.

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

1. Explain causes of nonlinearity.
2. Renal clearance of drugs.
3. Discuss any two phase II reaction.
4. Protocols of bio equivalence studies.
5. Area under first moment curve and mean resident time.
6. Determination of bioavailability.
7. Biological factors influencing absorption of drugs.
8. Drug distribution in body fluids.
9. Michaelis – Menton equation and its applications.
10. Loading dose, maintenance dose and accumulation index.

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[LK 342] MAY 2017 **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

Time : Three hours **Maximum : 100 Marks**

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

1. How to determine urinary excretion rate constant by excretion rate method and sigma minus method for a dry administered by IV bolus and which follows one compartment open model?

2. Write the protocol for conducting bioequivalence studies. What are the techniques adopted for bioavailability enhancement of poorly water soluble drugs?

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

1. Write the pharmaceutical dosage form factors affecting drug absorption.
2. Explain the role of placental and blood brain barrier in drug distribution.
3. Write about glucuronic acid conjugation with example.
4. Explain the kinetics of drug–protein binding.
5. Write any two methods meant for the determination of K_m and V_{max}.
6. How to determine absorption rate constant by curve fitting method?
7. Differentiate active and passive tubular re-absorption.
8. Pharmacodynamic methods to measure bioavailability.
9. Discuss the effect of multiple drug dosing after oral administration.
10. Write about the dosage adjustment techniques followed in liver disease patients.

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[LL 342] OCTOBER 2017 **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

Time : Three hours **Maximum : 100 Marks**

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

1. Explain the phase II bio-transformation reactions with suitable examples.

2. How to determine the pharmacokinetic parameters for a extra vascular by administered drug which obeys open one compartment model?

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

1. Write the methods for determining drug absorption.
2. Write the strategies involved in the transport of the drug across blood brain barrier.
3. Write the factors affecting bio-transformation.
4. Write the principle involved in enterohepatic cycle of drug with an example.
5. Define and derive the first order rate equation and half like equation.
6. Add a note on In vitro – In vivo correlation.
7. Write concept involved in total clearance.
8. Write the importance of therapeutic drug monitoring.
9. How to determine dose for renal disease patients?
10. Write the factors affecting pharmacokinetic variability.

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

[LM 342] MAY 2018 **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

Time : Three hours **Maximum : 100 Marks**

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

1. Explain in detail the mechanisms involved in the Gastrointestinal absorption of drugs.

2. Enumerate the Pharmacokinetic and Pharmacodynamic methods involved in the determination of bio-availability.

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

1. Mention the physico-chemical factors affecting drug absorption.
2. Differentiate apparent and real volume of distribution.
3. Write the effect of protein – drug binding on pharmacokinetic parameters.
4. Write the role of oxidation and reduction process in bio-transformation.
5. Discuss the principle involved in renal excretion of drugs.
6. Derive zero order rate constant equation.
7. Explain the concept involved in one compartment i.v bolus drug administration.
8. State the reasons for non linearity.
9. Write the formula to calculate loading dose and maintenance dose.
10. Write a note on drug – food interactions.

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

[LN 342] OCTOBER 2018 **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

Time : Three hours **Maximum : 100 Marks**

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

1. Classify and enumerate the factors influencing Bioavailability of drug from its dosage form.

2. Explain Phase I reaction with examples.

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

1. Discuss differences between passive and facilitated diffusion.
2. Define protein binding. Explain plasma protein binding and drug distribution.
3. Classify factors affecting biotransformation of drug. Explain chemical factor.
4. Define excretion. Discuss glomerular filtration with neat labeled diagram in urinary excretion of drugs.
5. Explain zero order kinetics.
6. Explain Michaelis Menten equation.
7. What are the objectives and approaches in developing in vitro-in vivo correlation?
8. Discuss concept of loading and maintenance dose.
9. Give suitable examples of drug- drug interaction.
10. The apparent volume of distribution of a drug is 37 L. If at a given time the concentration of drug in plasma is 3.2 mcg/ml. Calculate the amount of drug in body at the time.

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

[LO 342] MAY 2019 **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

Time : Three hours **Maximum : 100 Marks**

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

1. Explain two compartment open model. Derive suitable equations for calculating pharmacokinetic parameters for extra vascular administration of drug that follows two compartment open model.

2. a) Explain principal involved in renal excretion of drug with suitable example.
   b) Describe drug binding in tissues.

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

1. GCP guidelines for bio equivalence studies.
2. Loading dose, maintenance dose and accumulation index.
3. Explain any two Phase II reactions.
4. Non Renal excretion of drugs.
5. Explain passive transport and facilitated diffusion.
6. Measurement of bio availability.
7. Non linear Pharmacokinetics.
8. Factors affecting bio transformation of drugs.
9. Non compartmental models.
10. Drug distribution in body fluids.

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

[LP 342] OCTOBER 2019 **Sub. Code: 2903**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH I – PHARMACEUTICS
PAPER III – BIOPHARMACEUTICS AND PHARMACOKINETICS

Q.P. Code : 262903

Time : Three hours **Maximum : 100 Marks**

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

1. Define drug metabolism. Explain oxidative, reductive and hydrolytic reactions with suitable examples.

2. Give different approaches to pharmacokinetic analysis. Explain one compartment open model intravenous bolus administration and intravenous infusion.

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

1. Explain endocytosis.
2. Define distribution. Explain apparent volume of distribution.
3. Discuss acetylation and methylation reaction.
4. Explain active tubular secretion.
5. Why are first order processes said to follow linear kinetics? Explain them.
6. Define clearance. Explain total body clearance.
7. Explain with significance the parameters used in bioavailability determination by plasma level studies.
8. Explain biopharmaceutical classification system.
9. Discuss therapeutic drug monitoring.
10. Explain non compartmental analysis.

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