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

**[LM 936]** MAY 2018 **Sub. Code: 2936**

**M.PHARM. DEGREE EXAMINATION**
**(PCI New regulations 2016)**
**SEMESTER-II**
**BRANCH–I – PHARMACEUTICS – MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**

***Q.P. Code : 262936***

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

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

1. Discuss the physico-chemical factors influencing drug absorption.

2. Derive all possible pharmacokinetic parameters using one compartment model for IV Bolus.

**II. Write notes on:** **(7 x 5 = 35)**

1. Discuss compendial methods of dissolution.
2. Effect of protein-binding interactions.
3. Role of solution, suspension, tablet dosage form in gastrointestinal absorption.
4. Define bioequivalence and list the various methods involved in determination of bioequivalence.
5. Explain pharmacokinetic and pharmacodynamics characteristics essential for a drug in the design of controlled release products.
6. Explain Noyes–Whitney equation and factors affecting dissolution rate.
7. A drug has a volume of distribution of 12 L and a k of $0.18hr^{-1}$. A steady state concentration (Css) of 12 mg/ml is desired.

   a) What is the infusion rate needed to maintain this concentration?
   b) How long it takes to achieve 90% of Css?
   c) If the elimination rate constant K, in a patient with a renal impairment is $0.1hr^{-1}$, what is the infusion rate required to maintain the same Css in this patient?

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

**[LN 936]** NOVEMBER 2018 **Sub. Code: 2936**

**M.PHARM. DEGREE EXAMINATION**
**(PCI New regulations 2016)**
**SEMESTER-II**
**BRANCH–I – PHARMACEUTICS – MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**

***Q.P. Code : 262936***

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

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

1. Explain the methods to assess bio-availability.
2. Define non-linear pharmacokinetics? What are the causes for non-linearity? Explain Michalis Menten equation with respect to the estimation of $K_m$ and $V_{max}$.

**II. Write notes on:** **(7 x 5 = 35)**

1. Explain the formulation factors affecting drug absorption.
2. Explain the testing performance of drug product in vitro-in vivo correlation.
3. Discuss cytochrome P450-based drug interactions.
4. Discuss the cross over design to perform bioequivalence studies.
5. Explain rate limiting steps in drug absorption.
6. Explain the equation involved in calculating the loading dose in an IV infusion using the steady state drug concentration.
7. Four different drug products containing the same antibiotic.
   Where given to 12 volunteers adult males (age 19-28 years, average weight 73 kg) in a four-way cross over design. The volunteers were fasted for 12 hours prior to taking the drug product. Urine samples were collected up to 72 hours after the administration of the drug to obtain the maximum urinary excretion $D_U^{\infty}$. The datas are presented in Table 1 as follows.

   Table 1 Urinary drug excretion data summary

| Drug Product | Dose (mg/kg) | Cumulative urinary drug excretion ($D_U^{\infty}$) 0-72hr(mg) |
|---|---|---|
| IV solution | 0.2 | 20 |
| Oral solution | 4 | 380 |
| Oral tablet | 4 | 340 |
| Oral capsule | 4 | 360 |

   a) What is the absolute bioavailability of the drug from the tablet?

   b) What is the relative bioavailability of the capsule compared to the oral solution?

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

**[LO 936]** MAY 2019 **Sub. Code: 2936**

**M.PHARM. DEGREE EXAMINATION**
**(PCI New regulations 2016)**
**SEMESTER-II**
**BRANCH–I – PHARMACEUTICS – MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**

***Q.P. Code : 262936***

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

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

1. a) Explain in detail about Two compartment open model of IV Bolus and derive suitable equations to assess Pharmacokinetic parameters.

   b) A new drug was given in a single intravenous dose of 200 mg to an 80-kg adult male patient. After 6 hours, the plasma drug concentration of drug was 1.5 mg/100 mL of plasma. Assuming that the apparent VD 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?

2. a) Discuss about various rate limiting steps of drug absorption.

   b) Explain in detail Biopharmaceutical considerations in drug product design.

**II. Write notes on:** **(7 x 5 = 35)**

1. Describe various factors affecting dissolution rate.
2. Role of transporters in drug absorption.
3. Sigma-minus method.
4. Discuss dose accumulation in multiple dosage regimen.
5. Write short notes on method of assessing bioavailability.
6. Biopharmaceutics classification system.
7. Discuss about physiological pharmacokinetic model.

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

**[LP 936]** NOVEMBER 2019 **Sub. Code: 2936**

**M.PHARM. DEGREE EXAMINATION**
**(PCI New regulations 2016)**
**SEMESTER-II**
**BRANCH–I – PHARMACEUTICS – MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**

***Q.P. Code : 262936***

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

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

1. a) Explain in details about various physicochemical factors affecting the Gastro Intestinal tract drug absorption.
   b) Write a note on various dissolution methods.
2. a) Explain in detail about one compartment open model both IV Bolus and IV infusion and derive suitable equations to assess Pharmacokinetic parameters.
   b) A new antibiotic drug was given in a single intravenous bolus of 4 mg/kg to 5 healthy male adults ranging in age from 23 to 38 years (average weight 75 kg). The pharmacokinetics of the plasma drug concentration–time curve for this drug fits a one-compartment model. The equation of the curve that best fits the data is $C_p = 78e^{-0.46t.}$

   Determine the following (assume units of mg/ml for Cp and hours for t)
   a) What is the $t_{1/2}$?
   b) What is the $V_D$?
   c) What is the plasma level of the drug after 4 hours?
   d) How much drug is left in the body after 4 hours?

**II. Write notes on:** **(7 x 5 = 35)**

1. Discuss about various types of pharmacokinetic models.
2. Michaelis-menten equation – estimation of $k_{max}$ and $V_{max}$.
3. Define Bio-availability and write a note on relative and absolute availability.
4. pH partition hypothesis and its limitations.
5. Pharmacokinetics of bio-technology drugs.
6. Protein binding interactions of drug molecules.
7. *In vitro-in vivo* correlation.

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

**[LQ 0121] JANUARY 2021 Sub. Code: 2936**

**(APRIL 2020 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**

**SEMESTER-II (PCI New regulations 2016)**

**PHARMACEUTICS – MPH**

**PAPER II – ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**

***Q.P. Code : 262936***

**Time : Three hours** **Answer ALL Questions** **Maximum : 75 Marks**

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

1. Discuss in detail the biopharmaceutical considerations in designing the drug product. Add a note on *in vitro* drug product performance using suitable methods.

2. Write a note on:
   a) Non linear Pharmacokinetics including factors causing on non linearity.
   b) The design and evaluation of bio equivalence studies and its significance.

**II. Write notes on:** **(7 x 5 = 35)**

1. pH partition hypothesis and its limitations.
2. Methods for assessing the bio availability of a drug.
3. Derive the pharmacokinetic equations of two compartment model of IV bolus administration.
4. Effect of drug- protein and drug-tissue binding interactions.
5. Biosimilar drug (generic biologics) products and their applications.
6. Factors affecting the dissolution rate of dosage forms.
7. Pharmacokinetic models and their significance.

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

**[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2936**
**(OCTOBER 2020 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER-II (PCI New regulations 2016)**
**PHARMACEUTICS - MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**
***Q.P. Code : 262936***

**Time : Three hours** **Answer ALL Questions** **Maximum : 75 Marks**

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

1. Discuss in detail the biopharmaceutical considerations in designing the drug product, add a note on *in vitro* drug product performance using suitable methods.

2. a) Detail note about methods to determine the bioavailability.
   b) What are compartment models? Derive an expression for calculating various pharmacokinetic parameters for a drug administered by IV bolus administration.

**II. Write notes on:** **(7 x 5 = 35)**

1. Define dose-dependent kinetics. Give some tests to detect the same in a rate process.
2. Explain pH partition hypothesis.
3. *In vitro-in vivo* correlation.
4. Bioequivalence testing.
5. Compendial methods of drug dissolution.
6. Drug food interactions.
7. Applications of pharmacokinetics on modified Release drug products.

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

**[MPHARM 0122] JANUARY 2022 Sub. Code: 2936**
**(APRIL 2021 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER-II (PCI New regulations 2016)**
**PHARMACEUTICS - MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**
***Q.P. Code : 262936***

**Time : Three hours** **Answer ALL Questions** **Maximum : 75 Marks**

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

1. a) Write a note on various dissolution methods.
   b) Non linear Pharmacokinetics including factors causing on non linearity.

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:** **(7 x 5 = 35)**

1. Mechanism of absorption.
2. Maintenance dose.
3. Biopharmaceutics classification system.
4. Explain Michaelis Menten equation.
5. Application of pharmacokinetics in targeted drug delivery systems.
6. Loading dose, maintenance dose and accumulation index.
7. What are the objectives and approaches in developing in vitro-in vivo correlation?

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

**[MPHARM 0422] APRIL 2022 Sub. Code: 2936**
**(OCTOBER 2021 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER-II (PCI New regulations 2016)**
**PHARMACEUTICS - MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**
***Q.P. Code : 262936***

**Time : Three hours** **Answer ALL Questions** **Maximum : 75 Marks**

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

1. Discuss the concept of compartment kinetics and its role in understanding drug distribution pattern. Sketch out various types of compartment models.

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

**II. Write notes on:** **(7 x 5 = 35)**

1. What is the absolute bioavailability of the drug from the tablet?
2. Volume of distribution and factors affecting it.
3. Biopharmaceutics Classification system.
4. Causes of non-linearity.
5. Mechanism of drug interactions.
6. Add a note on monoclonal antibodies.
7. Write the principle behind intravenous multiple dosing.

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

**[M.PHARM 0922] SEPTEMBER 2022 Sub. Code: 2936**
**(APRIL 2022 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER - II (PCI New regulations 2016)**
**PHARMACEUTICS - MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS**

***Q.P. Code : 262936***

**Time : Three hours** **Answer ALL Questions** **Maximum : 75 Marks**

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

1. Explain briefly bioequivalence studies with various designs.

2. Derive pharmacokinetic parameters for one compartment model by IV bolus administration.

**II. Write notes on:** **(7 x 5 = 35)**

1. Applications of gene therapy.
2. Discuss briefly about Michaelis-Menton kinetics.
3. Compendial dissolution methods.
4. Write about clinical significance of bioavailability studies.
5. Applications of Oligonucleotides.
6. Explain briefly about physiological model.
7. pH partition hypothesis.

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

**[M.PHARM 0423] APRIL 2023 Sub. Code: 2936**
**(OCTOBER 2022 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER - II (PCI New regulations 2016)**
**PHARMACEUTICS - MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS**

***Q.P. Code: 262936***

**Time : Three hours** **Answer ALL Questions** **Maximum : 75 Marks**

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

1. Enlist physic-chemical factors influencing drug absorption and explain them briefly.

2. Derive Pharmacokinetic parameters for one compartment model by extravascular route administration.

**II. Write notes on:** **(7 x 5 = 35)**

1. Explain briefly IVIVC.
2. Cytochrome p450 drug interaction in transportation.
3. Role of dosage forms in gastrointestinal absorption.
4. Discuss various methods involved in determination of bioavailability.
5. Application of monoclonal antibodies.
6. Explain Noyes-Whitney equation and factors affecting dissolution rate.
7. Application of cross-over design.

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

**[M.PHARM 0823]** **AUGUST 2023** **Sub. Code: 2936**
**(APRIL 2023 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER - II (PCI New Regulations 2016)**
**PHARMACEUTICS - MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS**

***Q.P. Code: 262936***

**Time : Three hours** **Answer ALL Questions** **Maximum : 75 Marks**

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

1. Explain the properties of Gastro intestinal tract and discuss in detail the various factors affecting drug absorption from the Gastro intestinal tract.

2. Answer the following:
   a) Discuss the effect of protein binding, tissue binding and cytochrome p450-based drug interactions and its significance.
   b) Write a note on problems of variable control in dissolution testing performance of drug products.

**II. Write notes on:** **(7 x 5 = 35)**

1. Derive equation to calculate the pharmacokinetic parameters of two compartment open model.
2. Methods for assessing the bio availability of a drug.
3. Compendial methods of dissolution studies.
4. Biological factors affecting the drug bioavailability.
5. Mechanism of drug absorption in bio environmental system.
6. Biopharmaceutical classification system and its significance.
7. Correlation of in vivo data with in vitro dissolution data.

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

**[M.PHARM 1223] DECEMBER 2023 Sub. Code: 2936**
**(OCTOBER 2023 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER - II (PCI New Regulations 2016)**
**PHARMACEUTICS - MPH**
**PAPER II – ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS**

***Q.P. Code: 262936***

**Time : Three hours** **Answer ALL Questions** **Maximum : 75 Marks**

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

1. Explain various mechanism of drug absorption with sketch diagrams.

2. Derive pharmacokinetic parameters for two compartments by V bolus administration.

**II. Write notes on:** **(7 x 5 = 35)**

1. Explain Noyes-Whitney equation with dissolution.
2. Causes for nonlinearity.
3. Role of stability in design of drug product.
4. Discuss briefly about tissue binding of drugs.
5. Mention PK-PD drug interactions with examples.
6. Alternate methods of dissolution testing.
7. Biopharmaceutical classification system.

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