Course Specifications

University	Beni-Suef
Faculty	Pharmacy
Dept.	Pharmaceutics

1-Course Info.
Programme(s) on which the course is given: General
Course Name and code No.: Biopharmaceutics and Pharmacokinetics (111)
Academic year/ Level: 2015-2016 / FOURTH YEAR SECOND TERM
Credit hours: Lecture (…2..) hour + Practical (…1..) hour

2-Overall Aim of the C	This course will introduce students to the basic concepts of pharmacokinetics and biopharmaceutics with a special emphasis on drug absorption, distribution, metabolism and excretion processes; different pharmacokinetic models; calculation of pharmacokinetic parameters of these processes and models; effects of drug physicochemical properties, formulation factors, and route of administration on the rate and extent of systemic drug absorption; drug clearance; bioavailability and bioequivalence. Graphical and mathematical data analysis will be employed throughout the curse using on appropriate computer software (e.g. Excel).
3-Intended Learning Outcomes of the course (ILOs)	
a. Knowledge and understanding	At the end of this course, the students must be able to: 1. Define and understand the meaning of pharmacokinetics, biopharmaceutics, pharmacodynamics, absorption, distribution, metabolism, and excretion. 2. Understand the components of a standard pharmacokinetic study. 3. Understand the differences between the pharmacokinetic models and know the advantages and limitations of each model. 4. Demonstrate understanding of the physiological and biological factors that affect drug absorption. 5. Relate the physicochemical properties of the drug to its systemic absorption. 6. Appreciate the effects of the formulation factors and the dosage form on drug systemic absorption. 7. Understand the bases for assessing bioavailability and bioequivalence. 8. Demonstrate understanding of the factors that affect drug distribution, and clearance.
b. Intellectual Skills	At the end of this course the student must be able to: 1. Solve different pharmacokinetic problems that depend on data

	graphing. 2. Solve different problems related to drug pharmacokinetics. 3. Solve different problems related to drug clearance, and bioavailability. 4. Correlate quantitatively the pharmacokinetic theories with development, evaluation and preparation of effective and safe dosage form. 5. Compare absorption products of different products. 6. Suggest alternative dosage forms.
c. Professional and Pr Skills	At the end of this course each student should be able to: 1. Estimate the values of different pharmacokinetic parameters from plasma drug concentration and urinary excretion data. 2. Write pharmacokinetic analysis reports. 3. Predict systemic drug absorption based on the biological environment in which it is located, the physiochemical properties of the drug, the formulation factors and the dosage form. 4. Evaluate patient characteristics that may influence drug selection and the delivery system. 5. Estimate the absolute and relative drug bioavailabilities using plasma and urinary data. 6. Design and evaluate of bioequivalence studies.
d. General and Trans Skills	**Communication:** At the end of this course the student must be able to: 1- Demonstrate good oral and written communication. 2- Write well-structured reports. 3- Work independently and in groups. **IT Skills:** At the end of this course the student must be able to: 1. Use relevant software (e.g. MS Word and Excel). 2. Use current IT facilities, including on-line internet information 3. Practice and demonstrate literature retrieval skills. **Group working:** During the course, the students will: 1. Work as part of a group in order to produce the written presentation. 2. Work within groups and separately in carrying out experiments.
4-Course Contents	

Topic	Lecture	Hours
Introduction to Pharmacokinetics	1	2
Elimination kinetics + One compartment model with IV bolus administration	1	2
One compartment model with IV infusion administration	1	2
Absorption kinetics + One compartment model with	1	2

extravascular administration		
Distribution kinetics + Two compartment model with IV bolus administration	1	2
Multiple administration	1	2
Introduction to Biopharmaceutics	1	2
Physicochemical factors affecting drug absorption	1	2
Formulation factors affecting drug absorption	1	2
Drug dissolution	1	2
Bioavailability and Bioequivalence	1	2
Clearance concepts	1	2
Practical/Tutorials	**Lab**	**Hours**
Introduction to biopharmaceutics	1	1
Zero order kinetics + First order kinetics	1	1
One compartment model IV bolus + plasma data analysis	1	1
Urine analysis	1	1
Intravenous infusion	1	1
One-compartment model with first-order absorption + residual method	1	1
Two compartment + residual method	1	1
Multiple dosing	1	1
Drug clearance	1	1
Bioavailability + Trapezoidal rule	1	1
Computer intensive problem solving	1	1
Review	1	1

5- Teaching and learn Strategies	1. Lectures 2. Practical laboratory sessions
6- Teaching and learning Methods for Special Needs Students.	
7- Student Assessmen Methods	
a-Methods	1. Laboratory work 2. Practical sheet examination 3. Final practical examination

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<tr><td></td><td>4. Final written examination
5. Final oral examination</td></tr>
<tr><td>b- Assessment Sched</td><td>Assessment 1: Laboratory work Week: 1 - 10
Assessment 2: Sheet examination Week: 6
Assessment 3: Practical Exam Week: 10
Assessment 4: Final Written Exam Week: 10 - 12
Assessment 5: Final Oral Exam Week: 10 - 12</td></tr>
<tr><td>c- Weighting of Assessment Marks</td><td>
<table>
<tr><th>Type of Assessment</th><th>Marks</th><th>Weight (%)</th></tr>
<tr><td>Laboratory work</td><td>5</td><td>3.3%</td></tr>
<tr><td>Sheet examination</td><td>15</td><td>10%</td></tr>
<tr><td>Practical exam</td><td>30</td><td>20%</td></tr>
<tr><td>Final written exam</td><td>80</td><td>53.3%</td></tr>
<tr><td>Final oral exam</td><td>20</td><td>13.3%</td></tr>
<tr><td>Total</td><td>150</td><td>100%</td></tr>
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<tr><td>8-List of References</td><td></td></tr>
<tr><td>a.Notes</td><td>Biopharmaceutics, The Staff of Pharmaceutics Department.</td></tr>
<tr><td>b.Mandatory Books</td><td></td></tr>
<tr><td>c.Suggested Books</td><td>▪ Biopharmaceutics and Clinical Pharmacokinetics, Gibaldi M, Lea & Febiger, 4th edition, 1991.
▪ Applied Biopharmaceutics and Pharmacokinetics, Shargel L and Yu C., Appleton & Lange, 4th edition, 1999.</td></tr>
<tr><td>d.Journals</td><td></td></tr>
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Course Coordinators: Dr. Mohammed Elkomy

Head of department: Dr. Shahira El-Menshawe

Date: 24-11-2016