



Ministry Of Higher Education and Scientific Research
AL-Mustansaria University/College of Pharmacy/Department of Pharmaceutics



(الخطّة الدراسية للمساق)

Course No.: 50303403

Course Name: Biopharmaceutics

Time Division:

2hr Theoretical and 2hr Practical

Course Website:

Semester & Year:

First , 2015 /2016

Course Description

(2 credit hours, Prerequisite No. and Name)

The coarse deals with the physical and chemical properties of drug substance, dosage form and the biological effectiveness of the drug or drug product upon administration, including drug availability in the human or animal body from a given dosage form. The pharmacokinetic part of the coarse deals with the time-course of the drug in the biological system, and quantification of drug concentration pattern in normal subjects and in certain disease states.

Course Intended Outcomes

At the end of the course, students are expected to learn:

From Theory

- 1- Be able to explain principle of pharmacokinetics of drug, according to one or two compartment model, its absorption, distribution and elimination from body when given by oral route.
- 2- Be able to explain dissolution of drug from different dosage form and physicochemical factors affecting it.
- 3- Be able to describe pharmacokinetics of drug after IV injection or IV infusion.
- 4- Be able to describe pharmacokinetics of drug after multiple dose regime.
- 5- Be able to describe and calculate bioavailability of drug from area under the curve of drug concentration in blood.
- 6- Be able to calculate elimination half live of drug and a number of important parameters using equations and curves.

From practical

- 1-Able to draw calibration curve
- 2-Solve problem and find unknown concentration using calibration curve
- 3-Able to use pH meter to evaluate different types of antacids
- 4-Able to evaluate different types of bulk forming laxative
- 5-Able to describe effect of pH and type of solvent on the solubility
- 6-Able to study the dissolution of drug from tablet using dissolution apparatus
- 7-Able to draw curve of dissolution profile of drug and find dissolution rate constant
- 8-Able to study hydrolysis of aspirin in solution at higher temperature to estimate hydrolysis rate constant and shelf life at room temperature using Arrhenius equation and plot
- 9- Able to find pharmacokinetics parameters from plasma and urine data.

Course Outline

Week	Tuesday Class A and B (Theory)	Sunday, Tuesday and Wednesday Classes: A1, A2, A3, B1, B2, B3 (Practical)
Sep. 29	-Introduction to biopharmaceutics: Definition of biopharmaceutics, one and two compartment models. -Significance of Measuring Plasma Drug Concentrations	

Oct. 4, 6, 7	-Physiologic factors related to drug absorption; Nature of cell membranes, Passive Diffusion, -Fick's law of diffusion -Carrier-Mediated Transport: Active transport, Facilitated diffusion -Vesicular transport, Pore Transport and Ion-Pair Formation	-Calibration curve: Regression analysis
Oct. 11, 13, 14	-Anatomic and physiologic considerations: Gastric Emptying Time, Intestinal motility, Perfusion of the gastrointestinal tract, Effect of food on gastrointestinal drug absorption, Double-peak phenomenon -Biopharmaceutics considerations in drug product design: Pharmaceutic factors affecting drug bioavailability, Disintegration, Dissolution and solubility -Noyes-Whitney equation -Physicochemical nature of the drug: Stability, pH, and drug absorption, Particle size and drug absorption, Polymorphism, solvates, and drug absorption	-Preparation calibration curve of salicylic acid
Oct.18, 20, 21	-Formulation factors affecting drug dissolution -One-compartment open model: intravenous bolus administration, elimination rate constant, apparent volume of distribution and Significance of the apparent volume of distribution	-Evaluation of prepared calibration curve -First Quiz -Evaluation of different types of antacid
Oct. 25, 27,28	-Clearance and drug elimination expression -Multicompartment models: Intravenous bolus administration -Two-compartment open model-	-Evaluation of different types of antacid
Nov. 1, 3, 4	-Pharmacokinetics of oral absorption: zero order absorption model, first order absorption model -Determination of absorption rate constant from oral absorption data -lag time and Flip-Flop of K_a and k	-Evaluation of a number of bulk forming laxative -oral discussion
Nov. 8, 10, 11	-Intravenous infusion: One-compartment model drugs, Steady-State Drug Concentration (C_{ss}) and Time Needed to Reach C_{ss}, loading dose plus IV infusion	-pH and solvent effect -Second Quiz
Nov. 15, 17, 18	- Multiple-Dose Regimens - Drug accumulation	-Dissolution of per oral tablet in artificial gastric juice

Nov. 22,24, 25	(First Exam In 22-11-2015)	
Nov. 29, 30 Dec. 2	- Nonlinear pharmacokinetic; Reasons for nonlinear pharmacokinetics -Saturable enzymatic processes; Michaelis-Menten kinetics -Effect of drug concentration on the elimination rate constant	-Dissolution of per oral tablet in artificial intestinal juice
Dec. 6, 8, 9	- Bioavailability and bioequivalence -Relative and absolute bioavailability -Protein binding; Kinetics of protein binding, Determination of binding constants and binding sites by graphic methods	-Study hydrolysis of aspirin
Dec. 13, 15, 16	-Hepatic clearance: evidence of first-pass effect, liver extraction ratio, relationship between blood flow, intrinsic clearance and hepatic clearance.	-Evaluation of aspirin hydrolysis and Arrhenius equation
Dec. 20, 22, 23	-Drug elimination and clearance. -Renal drug exaction	-Third Quiz and oral exam
Dec. 27, 29, 30	Quiz and oral discussion	-Determination of relative and absolute bioavailability
Jan. 3, 5, 6	- Review before final exam	-Final Quiz and oral exam
Jan. 16	<i>Final Exams</i>	

Textbooks

- 1- Shargel L., Yu AB., (Eds). **Applied Biopharmaceutics and Pharmacokinetics**, Fifth edition, International Edition 2005
- 2- Lab manual for biopharmaceutics.

Suggested references

1. Aulton's **Pharmaceutics: The Design and Manufacture of Medicines**, Third edition, Michael E. Aulton (Author). Churchill, Livingstone- Elsevier

Marking

First Exam	20 marks	practical	25 marks
Activity	5 marks	Final Exam	50 marks

Regulations

1. There will be one or two term exams given during this semester. Missing one of the two left exams means a ZERO grade will be given for that exam.
2. There is no markup for quizzes.
3. Attendance is mandatory and University regulations will be enforced.
4. All Cheating incidents will be reported to the chair. The following activities are considered cheating:
 - a. Turning in assignment that includes parts of someone else work.
 - b. Turning in someone else assignment as your own.
 - c. Giving assignment to someone else to turn in as their own.
 - d. Copying answers in a test or quiz.
 - e. Taking a test or quiz for someone else.
 - f. Having someone else take a test or quiz for you.
5. See student handbook for other regulations.

Assignments and/or Projects

Assignment/Project	Description	Due Date	Marking
H.W. 1	Frequently asked questions	Deadline 20 th Oct	1.5 Marks
H.W. 2	Learning questions	Deadline 15 th Nov	1.5 Marks
Quizzes	one or two quizzes	During the course	2 Marks

Instructor(s) information

Section: 3 Lecture Room: 4th Year class room Time: Tues 9:30-11:30 group A, 12:30-2:30 group B

Instructor's Name: *Dr. Wedad Kamal Ali* **E-Mail:** altuhafe@yahoo.com **Office No.:** Dep. of
Pharmaceutics

Office Hours: Sunday [12:30-2:30], Wednesday [8-9]
Tuesday [10:30-12:30], Thursday [8:30: -1:30]

Instructor's Name: *Ass. Lecturer Methaq Hamad Sabar* **E-mail:** Straw78berry@yahoo.com

Office No.: Dep. of Pharmaceutics

Office Hours: Sunday [12:30-2:30], Wednesday [10:30-2:30]
Thursday [8:30:-1:30]

Other office hours are available by appointment

Important: The content of this syllabus may not be changed during the current semester.

Lecturer Signature

Chair Signature