

Summer Semester 2021 /2022						
COURSE INFORMATION						
Course Name: Biopharmaceutics (Blended education)Course Code: 131701342Semester: SummerDepartment: Pharmaceutics and pharmaceutical technologySection: 1, 2 and 3Department: Pharmaceutical SciencesCore Curriculum: 2013 Stud Plan						
Day(s) and Time(s): Sun + Mon	+ Tues + Wed: 9:00 – 10:00 10:00 – 11:00 11:00 – 12:00	Credit Hours: 2 Prerequisites: 131702221				
Classroom: Fnarmaceutical Scien	COURSE DESCRIPTION	l V				
Introduces students to the concepts of biopharmaceutics. The processes of absorption, distribution, metabolism, and excretion of drugs are introduced with the purpose of improving the evaluation of drug delivery systems, and the therapeutic management of patients. An increased mechanistic understanding of how a drug can interact with an other drug and how food can influence drugs absorption from the intestine and the transport through the liver will be discussed. Additionally, the relevance to generic substitution of drugs and the regulatory aspects on the absorption, bioavailability and bioequivalence are described. DELIVERY METHODS The course will be delivered through a combination of active learning strategies. These include: • PowerPoint lectures and active classroom-based discussion • Video lectures						
FACULTY INFORMATION						
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Office Hours:	According to the semester					

According to the semester

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Syllabus: Biopharmaceutics (#131701342)

REFERENCES AND LEARNING RESOURCES

Required Textbook(s):

Either you list book as (Author *Title* (Publisher: 2009) ISBN: 1-4039-742x-x) or you can state: There is no required textbook for purchase. All compulsory weekly readings are available electronically on *Model/Microsoft Teams*

- 1. Applied Biopharmaceutics and Pharmacokinetics., Leon Shargel, Andrew Yu and Susanna Wu-pong., Appleton & Lange/MacGraw-Hill, New York., 6th edition 2004. ISBN-10: 007160393X
- 2. Bentley's Textbook of Pharmaceutics, Sanjay Jain, Vanada Soni, 2012, Elsevier India, ISBN:978-81-312-3266-8

Course Objectives

The students are expected to:

- 1. be able to explain biopharmaceutical, physiological, biochemical and cell biology-related aspects on the transport and metabolism of drugs in the gastrointestinal tract and in the liver
- 2. be able to explain mechanisms behind the transport of drug and metabolism and how drugs can interact with other drugs and food and methods to study these
- 3. having developed his ability to plan, compile, analyse and report experiment that has importance for biopharmaceutical issues
- 4. be able to account for regulatory requirements within the biopharmaceutical area
- 5. be able to describe the role of biopharmaceutics in drug development within the pharmaceutical industry

Intended Learning Outcomes

A. Knowledge and Understanding:

- 1. Explain the effect of physicochemical factors and physiological factors on ADME
- 2. Distinguish between bioavailability and bioequivalence
- 3. Use the regulations of the FDA in conducting experiments of bioavailability and bioequivalance
- 4. Explain the concept of pharmacogenitics and dose individualization

B. Intellectual skills (cognitive and analytical):

- 1. design and report experiment for in vitro, in situ and in vivo in GI diffusion
- 2. describe the role of biopharmaceutics in drug development

C. Transferable Skills

- 1. Use the physicochemical characteristics of drug to expect its fate in the body
- 2. Solve problems of drug absorption by physical and chemical modifications of drug

STUDENT LEARNING OUTCOMES MATRIX

An alignment matrix of the **program** ILOs of the Bachelor of Pharmacy at The Hashemite University, the **course** ILOs and knowledge, skills and competencies as mentioned in the Jordan National Qualifications Framework (JNQF)

Field according to (JNQF)	Required to achieve (according to (JNQF)	Core curriculum learning outcomes	B.Sc. Pharmacy Program ILOs	Course Objectives	Course Student ILOs					Assessment Method	
					Α	B	С	D			
Knowledge	A systematic understanding of the theories, concepts, principles and circulations related to the field of learning, some of which are within the limits of the latest scientific findings	Foundational Knowledge	Learner	1-5	A.1- A.4						First, Second and final exam
Skills	Mastering the skills and tools required to solve complex problems in a specialized field of study	Essentials for Practice and	Caregiver	2-5		B.1					
	Demonstrate specialized and conceptual skills in the field of study	Care	Promoter								
	Practice evaluation in planning, design, technical and/or		Provider								
	supervisory functions related to products, services or processes	Approach to Practice and Care	Creative Thinker & Problem-Solver	2-5		B.1- B.2	C.1-				
			Educator	2-5			0.2				
			Advocate	2-5							
			Collaborator								
			Includer								
			Communicator	2-5							
Competencies	Management of activities and projects	Personal & Professional	Self-aware								
	Take responsibility for decision-making in work or study contexts	Development Pharmaceutical Product Expert	Leader								
	Take responsibility for group work and work effectively		Innovator	3-5			C 1-				
	with peer guidance		Professional	5-5			C.2				
	Transfer and apply diagnostic and creative skills in a range of contexts		Manufacturer								

ACADEMIC SUPPORT

It is The Hashemite University policy to provide educational opportunities that ensure fair, appropriate and reasonable accommodation to students who have disabilities that may affect their ability to participate in course activities or meet course requirements. Students with disabilities are encouraged to contact their instructor to ensure that their individual needs are met. The University through its Special Need section will exert all efforts to accommodate for individual's needs.

Special Nee	ds Section:							
Tel:		00962-5	-3903333		Exte	ension:		4209
Location:	Students	Affairs	Deanship/	Department	of	Student	Welfare	Services
Email: ama	<u>lomoush@h</u>	u.edu.jo						
ama	lomoush@st	taff.hu.edu	<u>ı.jo</u>					

COURSE REGULATIONS

Participation

Class participation and attendance are important elements of every student's learning experience at The Hashemite University, and the student is expected to attend all classes. A student <u>should not miss more</u> than 15% of the classes during a semester. *Those exceeding this limit of 15% will receive a failing grade* regardless of their performance. It is a student's responsibility to monitor the frequency of their own absences. Attendance record begins on the first day of class irrespective of the period allotted to drop/add and late registration. It is a student's responsibility to sign-in; failure to do so will result in a non-attendance being recorded.

In exceptional cases, the student, with the instructor's prior permission, could be exempted from attending a class provided that the number of such occasions does not exceed the limit allowed by the University. The instructor will determine the acceptability of an absence for being absent. A student who misses more than 25% of classes and has a valid excuse for being absent will be allowed to withdraw from the course.

On average, students need to spend 15 hrs of study and preparation weekly. At the beginning of the lectures, be on time and don't leave before the end of the lecture without an accepted excuse. **If you missed a class, it is your responsibility to find out about any announcements or assignments you have missed.** For any clarification, please communicate your instructor at her posted office hours or by appointment. Listen well to the lecture, if you have a question, ask your instructor. You will find the course material at the course team after the lecture.

Sharing of course materials is <u>forbidden</u>. No course material including, but not limited to, course outline, lecture hand-outs, videos, exams, and assignments may be shared online or with anyone outside the class. Any suspected unauthorized sharing of materials, will be reported to the university's Legal Affairs Office. If a student violates this restriction, it could lead to student misconduct procedures.

Missed Assessments

In all cases of assessment, students who fails to attend an exam on the scheduled date without prior permission, and/or are unable to provide a medical note, will automatically receive a failure grade for this .part of the assessment

• In cases where a student misses an assessment on account of a medical reason or with prior permission; in line with university regulations an incomplete grade for the specific assessment will be awarded and an alternative assessment or extension can be arranged.

Cheating

Cheating, academic disconduct, fabrication and plagiarism will not be tolerated, and the university policy will be applied. Cheating policy: The participation, the commitment of cheating will lead to applying all following penalties together:

- Failing the subject, he/she cheated at
- Failing the other subjects taken in the same course
- Not allowed to register for the next semester
- The summer semester is not considered as a semester

Student Complaints Policy

Students at The Hashemite University have the right to pursue complaints related to faculty, staff, and other students. The nature of the complaints may be either academic or non-academic. For more information about the policy and processes related to this policy, you may refer to the students' handbook.

COURSE ASSESSMENT

Course Calendar and Assessment

Students will be graded through the following means of assessment and their final grade will be calculated from the forms of assessment as listed below with their grade weighting taken into account. The criteria for grading are listed at the end of the syllabus

Assessment	Grade Weighting	Deadline Assessment
First Exam	25%	$\sim 3^{\text{th}}$ week
Second Exam	25%	$\sim 5^{\text{th}}$ week
Final Exam	50%	~ 8 th week

Description of Exams

Test questions will predominately come from material presented in the lectures. Semester exams will be conducted during the regularly scheduled lecture period. Exam will consist of a combination of multiple choice, short answer, match, true and false and/or descriptive questions.

No make-up exams, homework or quizzes will be given. Only documented absences will be considered as per HU guidelines.

Grades are not negotiable and are awarded according to the following criteria:

Letter Grade	Description	Grade Points
A+	Excellent	4.00
А		3.75
A-		3.50
B+	Very Good	3.25
В		3.00
B-		2.75
C+	Good	2.50
С		2.25
C-		2.00
D+	Pass	1.75
D	Pass	1.50
F	Fail	0.00
Ι	Incomplete	-

WEEKLY LECTURE SCHEDULE AND CONTENT DISTRIBUTION

"Lecture hours and weeks are approximate and may change as needed"

Note: For the 2 lecture periods per week (S/T, M/W), one lecture period covers 1 lecture hours (60 minutes). The course content specifies chapters of the textbook that will be included in exams.

Topics	Topic details	Estimated no. of hours
Intro	Introduction to biopharmaceutics	2
ADME	Drug absorption and physiological factors affecting it	4
ADME	Drug distribution and protein binding	2
ADME	Hepatic metabolism	2
ADME	Renal excretion	2
Bioavailabiliy	Bioavailability and bioequivalence	2
Nonoal routes	Other routes of administration	2
Pharacogeneics	Pharmacogenetics	2
DDS	Targeted drug delivery systems of biopharmaceuticals and radioactive drugs	4
Drug development	Biopharmaceutical consideration in drug development	2
Guidelines	Guidelines of FDA and EMEA	2
	Revision	
	Final Exams	