



Syllabus: Biopharmaceutics (#131701342)

Summer Semester 2022 /2023

COURSE INFORMATION

Course Name: Biopharmaceutics (Blended education) Semester: Summer Department: Pharmaceutics and pharmaceutical technology Faculty: Pharmaceutical Sciences	Course Code: 131701342 Section: 1, 2 and 3 Core Curriculum: 2013 Study Plan
Day(s) and Time(s): Sun + Mon + Tues + Wed: 9:00 – 10:00 10:00 – 11:00 11:00 – 12:00 Classroom: Pharmaceutical Sciences	Credit Hours: 2 Prerequisites: 131702221

COURSE DESCRIPTION

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

Name	Dr Khaled Jamal ALROSAN
Academic Title:	Assistant Professor
Office Location:	Third Floor
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Email Address:	Kalrosan@hu.edu.jo
Office Hours:	According to the semester

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:

A.1 Explain the effect of physicochemical factors and physiological factors on ADME

A.2 Distinguish between bioavailability and bioequivalence

A.3 Use the regulations of the FDA in conducting experiments of bioavailability and bioequivalence

A.4 Explain the concept of pharmacogenetics and dose individualization

B. Intellectual skills (cognitive and analytical):

B.1 design experiment for in vitro, in situ and in vivo in GI diffusion

B.2 describe the role of biopharmaceutics in drug development

C. Transferable Skills

C.1 Use the physicochemical characteristics of drug to expect its fate in the body

C.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
					A	B	C	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 Care	Caregiver	2-5		B.1					
	Demonstrate specialized and conceptual skills in the field of study		Manager								
			Promoter								
	Practice evaluation in planning, design, technical and/or supervisory functions related to products, services or processes	Approach to Practice and Care	Provider								
			Creative Thinker & Problem-Solver	2-5		B.1- B.2	C.1- C.2				
			Educator	2-5							
			Advocate	2-5							
			Collaborator								
			Includer								
			Communicator	2-5							
Competencies	Management of activities and projects	Personal & Professional Development	Self-aware								
	Take responsibility for decision-making in work or study contexts		Leader								
	Take responsibility for group work and work effectively with peer guidance	Pharmaceutical Product Expert	Innovator	3-5			C.1- C.2				
	Transfer and apply diagnostic and creative skills in a range of contexts		Professional								
			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 Needs Section:

Tel: 00962-5-3903333

Extension: 4209

Location: Students Affairs Deanship/ Department of Student Welfare Services

Email: amalomoush@hu.edu.jo
amalomoush@staff.hu.edu.jo

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 should not miss more 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 forbidden. 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 misconduct, 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%	~ 3 th week
Second Exam	25%	~ 5 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
A		3.75
A-		3.50
B+	Very Good	3.25
B		3.00
B-		2.75
C+	Good	2.50
C		2.25
C-		2.00
D+	Pass	1.75
D	Pass	1.50
F	Fail	0.00
I	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.

		Course Content				
Week Number	No. of Hours	CILOs	Chapters in the main reference	Subject	Delivery Methods	Assessment Methods
1	2	A1,2	Ref 1&2	Introduction to biopharmaceutics	PowerPoint Lectures Active Classroom-Based Discussions	Exams
2-3	4	A1,2	Ref 1&2	Drug absorption and physiological factors affecting it	PowerPoint Lectures Active Classroom-Based Discussions	Exams
4	2	A, B, C, D	Ref 1&2	Drug distribution and protein binding	PowerPoint Lectures Active Classroom-Based Discussions	Exams
5	2	A, B, C, D	Ref 1&2	Hepatic metabolism	PowerPoint Lectures Active Classroom-Based Discussions	Exams Quizzes Homework

6	2	A, B, C, D	Ref 1&2	Renal excretion	PowerPoint Lectures Active Classroom-Based Discussions	Exams
7	2	A, B, C, D	Ref 1&2	Bioavailability and bioequivalence	PowerPoint Lectures Active Classroom-Based Discussions	Exams
8-9	4	A, B, C, D	Ref 1&2	Other routes of administration	Active Classroom-Based Discussions	Exams
10	2	A, B, C, D	Ref 1&2	Pharmacogenetics	Active Classroom-Based Discussions	Exams
11-12	4	A, B, C, D	Ref 1&2	Targeted drug delivery systems of biopharmaceuticals and radioactive drugs	Active Classroom-Based Discussions	Exams
13-14	4	A, B, C, D	Ref 1&2	Biopharmaceutical consideration in drug development	Active Classroom-Based Discussions	Exams
15	2	A, B, C, D	Ref 1&2	Guidelines of FDA and EMA	Active Classroom-Based Discussions	Exams

