



**Hashemite University**  
**Faculty of Pharmaceutical Sciences**  
**Department of Pharmaceutics and Industrial Pharmacy**

Semester: First

Year: 2019/2020

Course Information	
Course Title	Biopharmaceutics
Course Number	131701342
Credit Hours	2
Prerequisites	131702221

Instructor	
Name	Dr. Muna Oqal
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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.

Course Objectives
The students are expected to: <ol style="list-style-type: none"><li>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</li><li>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</li><li>3. having developed his ability to plan, compile, analyse and report experiment that has importance for biopharmaceutical issues</li><li>4. be able to account for regulatory requirements within the biopharmaceutical area</li><li>5. be able to describe the role of biopharmaceutics in drug development within the pharmaceutical industry</li></ol>

Intended Learning Outcomes
A. Knowledge and Understanding: <ol style="list-style-type: none"><li>1. Explain the effect of physicochemical factors and physiological factors on ADME</li><li>2. Distinguish between bioavailability and bioequivalence</li><li>3. Use the regulations of the FDA in conducting experiments of bioavailability and bioequivalence</li></ol>

4. Explain the concept of pharmacogenetics 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

### Reading List

<b>1 (textbook)</b>	Introduction to Biopharmaceutics and its Role in Drug Development; Rajesh Krishna and Lawrence Yu. Springer Science+Business Media, New York, 2008. ISBN: 978-0-387-72378-5.
<b>2 (textbook)</b>	Applied Biopharmaceutics and Pharmacokinetics., Leon Shargel, Andrew Yu and Susanna Wu-pong., Appleton & Lange/MacGraw-Hill, New York., 6th edition 2004. ISBN-10: 007160393X
<b>3</b>	Bentley's Textbook of Pharmaceutics, Sanjay Jain, Vanada Soni, 2012, Elsevier India, ISBN:978-81-312-3266-8
<b>4</b>	Websites: Moodle

### Course Contents

Topics	Topic Details	Reference No.	Chapter	Estimated no. of hours	Assessment
<b>Intro</b>	Introduction to biopharmaceutics	1	1	2	
<b>ADME</b>	Drug absorption and physiological factors affecting it	1	13	4	
<b>ADME</b>	Drug distribution and protein binding	1	10	2	1 <sup>st</sup> exam
<b>ADME</b>	Hepatic metabolism	1	11	2	
<b>ADME</b>	Renal excretion	1	11	2	
<b>Bioavailability</b>	Bioavailability and bioequivalence	1	15	2	2 <sup>nd</sup> exam
<b>Nonoral routes</b>	Other routes of administration	2		2	
<b>Pharmacogenetics</b>	Pharmacogenetics	1	12	2	
<b>DDS</b>	Targeted drug delivery systems of biopharmaceuticals and radioactive drugs	1	18	4	
<b>Drug development</b>	Biopharmaceutical consideration in drug development	1	14	2	
<b>Guidelines</b>	Guidelines of FDA and EMEA	3	-	2	
	Revision				
	Final Exams				

### Grade Distribution

Assessment	Grade	Date
- First Exam	30	The 5 <sup>th</sup> week
- Second Exam	30	The 11 <sup>th</sup> week
- Final Exam	40	The 16 <sup>th</sup> week

### Important regulations

- ◆ On average, students need to spend 4 hrs of study and preparation weekly.
- ◆ Excellent attendance is expected. According to the university policy, students who miss more than 15% of the lecture hours with or without excuse will be dismissed from the course
- ◆ 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 his posted office hours or by appointment
- ◆ Switch off your mobile or keep it silent throughout the lecture
- ◆ Listen well to the lecture and avoid side discussions, if you have a question, ask your instructor and not your colleague
- ◆ If you have any information, document your reference, if you didn't, then you broke the intellectual property rights law and the law will be applied
  - For more informations, visit the website:
    - <http://www.plagiarism.org/>
- ◆ Exams are scheduled to be given three times throughout the semester, your are expected to attend all. If not, make-up exams will be offered for valid reasons. It may be different from regular exams in content and format.
- ◆ Cheating, academic diconduct, fabrication and plagiarism will not be tolerated, and the university policy will be applied

Last updated on 1/9/2019 by : Dr. Muna Oqal