

Republic of Yemen
Ministry of Higher Education & Scientific Research
21 September University for Medicals and Applied Sciences



Faculty of Clinical Pharmacy

Bachelor of Clinical Pharmacy & Pharm. D.

Course Specification of

Biopharmaceutics and pharmacokinetics

Course Code. (02.01.214)

2022



T4: This Template is Developed and Approved by CAQA-Yemen, 2024

Prepared by:	Reviewed by:	Head of the Department:	Vice Dean for Quality affairs	Dean of College:
Dr. Mohammed Addoais	Dr. Hamoud Al-bayley	Dr. -----	Dr. Abdulelah Thabet	Dr. Ali Alyahawi



I. General Information:

1.	Course Title:	Biopharmaceutics and pharmacokinetics			
2.	Course Code:	02.01.214			
3.	Credit Hours:	Credit Hours	Theory Contact Hours		Practical Contact Hours
			Lecture	Tutorial/Seminar	Lab Clinical
		2	2		-
4.	Level/ Semester at which this Course is offered:	4 th Level / 1 st Semester			
5.	Pre –Requisite (if any):	Pharmaceutics (1,&2)			
6.	Co –Requisite (if any):	-			
7.	Program (s) in which the Course is Offered:	Bachelor of Clinical Pharmacy & Pharm. D.			
8.	Language of Teaching the Course:	English			
9.	Location of Teaching the Course:	Faculty of Clinical Pharmacy			
10.	Prepared by:	Mohammed Addoais			
11.	Date and Number of Approval by Council:				

II. Course Description:

This course provides a fundamental of principle of biopharmaceutics and pharmacokinetics that can be used in evaluation of drug therapy. It explores the effect of physicochemical properties of drug, the dosage form in which it is given , and route of administration on the rate and extent drug absorption into systemic circulation. It discuss the interrelationships of drug absorption, distribution, metabolism, and excretion. In addition to, studying and calculating pharmacokinetic parameters following drug administration which utilized in conducting of bioavailability and bioequivalence studies.



II. Course Intended Learning Outcomes (CILOs) : Upon successful completion of the course, students will be able to:		Referenced PILOs	
A. Knowledge and Understanding:		I, P or M/A	
a1	Describe the ADME and the mechanisms of gastrointestinal absorption of drugs.		A3
a2	Discuss the factors affecting drug absorption, distribution, metabolism and excretion.		A2
B. Intellectual Skills:			
b1	Design and interpret bioavailability and bioequivalence studies.		B3
b2	Predict the effect of excipients and food on drug absorption, distribution and elimination.		B2
C. Professional and Practical Skills:			
c1			
D. Transferable Skills:			
d1			
I= Introduced, P=Practiced or M/A= Mastered/Advanced			

(A) Alignment of Course Intended Learning Outcomes (Knowledge and Understanding) to Teaching Strategies and Assessment Methods:			
Course Intended Learning Outcomes		Teaching Strategies	Assessment Strategies
a1	Describe the ADME and the mechanisms of gastrointestinal absorption of drugs.	- Lecture - Instructor – student Interactive - Office hour	- Exam - Assignment - Quiz
a2	Discuss the factors affecting drug absorption, distribution, metabolism and excretion.	- Lecture - Instructor – student Interactive - Office hour	- Exam - Assignment - Quiz
(B) Alignment of Course Intended Learning Outcomes (Intellectual Skills) to Teaching Strategies and Assessment Methods:			
Course Intended Learning Outcomes		Teaching Strategies	Assessment Strategies
b1	Design and interpret bioavailability and bioequivalence studies.	- Lecture - Instructor – student Interactive	Problem-Solving



		- Exercises - Solving Problem Methods	- Exercises. - Assignment - Quiz
b2	Predict the effect of excipients and food on drug absorption, distribution and elimination.	- Lecture - Instructor – student Interactive - Exercises - Solving Problem Methods	- Problem-Solving Exercises. - Assignment - Quiz

(C) Alignment of Course Intended Learning Outcomes (Professional and Practical Skills) to Teaching Strategies and Assessment Methods:

Course Intended Learning Outcomes	Teaching Strategies	Assessment Strategies
c1	▪	▪

(D) Alignment of Course Intended Learning Outcomes (Transferable Skills) to Teaching Strategies and Assessment Methods:

Course Intended Learning Outcomes	Teaching Strategies	Assessment Strategies
d1	▪	▪

IV. Course Contents:

A. Theoretical Aspect:

Order	Units/Topics List	Learning Outcomes	Sub Topics List	Number of Weeks	Contact Hours
1	Introduction to Biopharmaceutics	a1, a2, b1, b2	- Definitions - ADME-system - Plasma –time level curve - Drug absorption Mechanisms	1	2
2	Drug absorption mechanisms	a1, a2, b1, b2	- Definitions - Mechanisms of drug absorption. - Factors affecting drug absorption	1	2
3	Physiological Factors affecting Drug Absorption	a1, a2, b1, b2	- Osmotic pumps. - Types of factors - pH, gastric and GIT factors	1	2
4	Physiochemical Factors affecting Drug Absorption	a1, a2, b1, b2	- Nature of drug, - drug solubility, - dissolution and - drug stability	1	2
5	Formulation Factors affecting Drug Absorption	a1, a2, b1, b2	- Formulation factors - Method of manufacture - Excipients - drug dosage and dosage regimen	1	2
6	Mid-term Exam			1	2
7	Drug Distribution	a1, a2, b1,	- Definitions	2	4



		b2	- Factors affecting drug distribution - Volume of distribution - Binding to plasma proteins - Factors affecting protein binding - Drug distribution to special tissue - Drug interaction in protein binding.		
8	Drug metabolism	a1, a2, b1, b2	- Definitions - Role of drug metabolism - Drug metabolism sites - Metabolic pathway - Metabolism enzymes - Metabolism phases - Factors affecting drug metabolism - Drug interaction in metabolism - Prodrugs	2	4
9	Drug excretion	a1, a2, b1, b2	- Definitions - Renal clearance - Role and pathway of excretion - Types of excretion - Factors Affecting Renal Excretion - Drug interaction	2	4
10	Bioavailability and Bioequivalence	a1, a2, b1, b2	- Definitions. - Objectives & significance of BA/BE studies. - Factors affecting Bioavailability. - Measurement of Bioavailability. - Methods for enhancing Bioavailability. - Introduction to Bioequivalence. - Limitations of BA/BE studies - Protocol design of bioavailability assessment. - Methods of bioequivalence determination	3	6
11	Final exam	a1, a2, b1, b2	-	1	2
Number of Weeks /and Units Per Semester				16	32



B. Practical Aspect (Lab/Clinical) (if any):

No.	Tasks/ Experiments	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1.	NA			
Number of Weeks /and Units Per Semester		16	32	

V. Assignments:

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)
1	Assignment 1		5	a1, a2, b1, b2
Total				5

VI. Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes
1	Assignments	6 th	5	5%	a1, a2, b1, b2
3	Midterm Exam	Week 7	20	20%	a1, a2, b1, b2
4	Quiz 2	12 th	5	5%	a1, a2, b1, b2
5	Final Exam (Theory)	Week 16	70	70%	a1, a2, b1, b2
Total			100	100%	

VII. Learning Resources:

1- Required Textbook(s):

- 1- Leon Shargel, (2017). Applied Biopharmaceutics and Pharmacokinetics, , 7th edition, MCGRAW McGraw-Hill Companies.
- 2- Sunil S. Jambekar and Phillip Breen (2012). Basic pharmacokinetics.2th ed. London, Pharma Press.
- 3- Gibaldi, milo (2005). Biopharmaceutics And Clinical Pharmacokinetics.4th ed. India, Pharma Med Press.
- 4- Notari, Robert E. (1986). Biopharmaceutics And Clinical Pharmacokinetics : An Introduction.UK, CRC press.

2- Essential References.



	1- Loyd V. allen (2015). Remington : The science of practice of pharmacy. 22nd ed. Pharmaceutical press. 2- Alison Brayfield (2017). Martindale the complete drug reference. 39th ed. Pharmace press.
3- Electronic Materials and Web Sites etc.	
	1. http://www.pharmatutor.org 2. http://www.uspbpep.com 3. http://www.usp.org

VIII. Course Policies: (Based on the Uniform Students' By law (2007))

1	Class Attendance: Class Attendance is mandatory. A student is considered absent and shall be banned from taking the final exam if his/her absence exceeds 25% of total classes.
2	Tardiness: A student will be considered late if he/she is not in class after 10 minutes of the start time of class.
3	Exam Attendance/Punctuality: No student shall be allowed to the exam hall after 30 minutes of the start time, and shall not leave the hall before half of the exam time has passed.
4	Assignments & Projects: Assignments and projects must be submitted on time. Students who delay their assignments or projects shall lose the mark allocated for the same.
5	Cheating: Cheating is an act of fraud that results in the cancelation of the student's exam or assignment. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply.
6	Forgery and Impersonation: Forgery/Impersonation is an act of fraud that results in the cancelation of the student's exam, assignment or project. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply.
7	Other policies: The University official regulations in force will be strictly observed and students shall comply with all rules and regulations of the examination set by the Department, Faculty and University Administration.

Faculty of Clinical Pharmacy

Bachelor of Clinical Pharmacy & Pharm. D.

Course Plan (Syllabus) of

Biopharmaceutics & Pharmacokinetics

Course Code. 02.01.214

I. Information about Faculty Member Responsible for the Course:						
Name of Faculty Member:	Mohammed addoais	Office Hours				
Location & Telephone No.:	776440327					
E-mail:	Addoais1@gmail.com	SAT	SUN	MON	TUE	WED THU

2022- 2023

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2.	Course Code:	02.01.214			
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IV. Course Intended Learning Outcomes (CILOs) :

Upon successful completion of the Course, student will be able to:

A. Knowledge and Understanding:

- | | |
|----|--|
| a1 | Describe the ADME and the mechanisms of gastrointestinal absorption of drugs. |
| a2 | Discuss the factors affecting drug absorption, distribution, metabolism and excretion. |

B. Intellectual Skills:

- | | |
|----|---|
| b1 | Design and interpret bioavailability and bioequivalence studies. |
| b2 | Predict the effect of excipients and food on drug absorption, distribution and elimination. |

C. Professional and Practical Skills:

c1	
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D. Transferable Skills:

d1	
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V. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
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3	Physiological Factors affecting Drug Absorption	- Osmotic pumps. - Types of factors - pH, gastric and GIT factors	1	2
4	Physiochemical Factors affecting Drug Absorption	- Nature of drug, - drug solubility, - dissolution and - drug stability	1	2
5	Formulation Factors affecting	- Formulation factors - Method of manufacture - Excipients	1	2

	Drug Absorption	▪ drug dosage and dosage regimen		
6	Drug Distribution	▪ Definitions ▪ Factors affecting drug distribution ▪ Volume of distribution ▪ Binding to plasma proteins ▪ Factors affecting protein binding ▪ Drug distribution to special tissue ▪ Drug interaction in protein binding.	2	4
7	Drug Metabolism	▪ Definitions ▪ Role of drug metabolism ▪ Drug metabolism sites ▪ Metabolic pathway ▪ Metabolism enzymes ▪ Metabolism phases ▪ Factors affecting drug metabolism ▪ Drug interaction in metabolism ▪ Prodrugs	2	4
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10	Final exam	-	1	2
Number of Weeks /and Units Per Semester			16	32

B. Practical Aspect (Lab/Clinical) (if any):

No.	Tasks/ Experiments	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1.				
Number of Weeks /and Units Per Semester		16	32	



VI. Assignments:

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)
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VII. Schedule of Assessment Tasks for Students During the Semester:

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