

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.

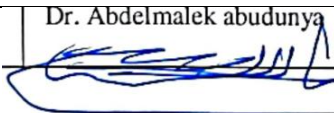
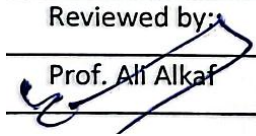
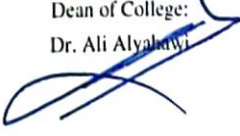
Course Specification of
Pharmaceutical Biotechnology

Course Code. (02.03.241)

2022



T4: This Template is Developed and Approved by CAQA-Yemen, 2023

Prepared by: Dr. Abdelmalek abudunya 	Reviewed by: Prof. Ali Alkaf 	Head of the Department: Dr. -----	Vice Dean for Quality affairs Dr. Abdulelah Thabet 	Dean of College: Dr. Ali Alyahawi 
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I. General Information:

1.	Course Title:	Pharmaceutical Biotechnology			
2.	Course Code:	02.03.241			
3.	Credit Hours:	Credit Hours	Theory Contact Hours		Practical Contact Hours
			Lecture	Tutorial/Seminar	Lab
		2	2		--
4.	Level/ Semester at which this Course is offered:	5 th Level / 1 st Semester			
5.	Pre –Requisite (if any):	- Pharmacology I, II, III			
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:	Prof. Dr. Ali Gamal Al-kaf.			
11.	Date and Number of Approval by Council:	2022			

II. Course Description:

The course deals with the study of principles & techniques of advance biotechnology and the drugs produced by those techniques.

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III. 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	Define biotechnology and recognize its main purposes and techniques.		A1
a2	State the pharmaceutical applications of biotechnology and employing biotechnology techniques in pharmacy practice.		A5
B. Intellectual Skills:			
b1	Classify and Compare between classical drugs & biotechnology-produced drugs and also between various types of biotechnology techniques.		B2, B5
b2	Select appropriate biotechnology techniques to produce drugs.		B4
C. Professional and Practical Skills:			
c1	Search efficiently for information using documented and electronic sources of information.		C5
c2	Present and report his/her works correctly using appropriate writing rules and technologies media.		C1
D. Transferable Skills:			
d1	Communicate effectively and ethically in team-work		D1
d2	Apply computerized programs effectively for continues education.		D3
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	Define biotechnology and recognize its main purposes and techniques.	- Exam - Assignment - Quiz
a2	State the pharmaceutical applications of biotechnology and employing biotechnology techniques in pharmacy practice.	- Exam - Assignment - Quiz
(B) Alignment of Course Intended Learning Outcomes (Intellectual Skills) to Teaching		

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Strategies and Assessment Methods:			
Course Intended Learning Outcomes		Teaching Strategies	Assessment Strategies
b1	Classify and Compare between classical drugs & biotechnology-produced drugs and also between various types of biotechnology techniques.	- Lecture - Instructor – student Interactive - Exercises - Solving Problem Methods	- Problem-Solving Exercises. - Assignment - Quiz
b2	Select appropriate biotechnology techniques to produce drugs.	- 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	Search efficiently for information using documented and electronic sources of information.	- Lecture - Instructor – student Interactive - Self-Learning	- Exam - Assignment - Quiz - Practical Reports
c2	Present and report his/her works correctly using appropriate writing rules and technologies media.	- Lecture - Instructor – student Interactive - Self-Learning	- Exam - Assignment - Quiz
(D) Alignment of Course Intended Learning Outcomes (Transferable Skills) to Teaching Strategies and Assessment Methods:			
Course Intended Learning Outcomes		Teaching Strategies	Assessment Strategies
d1	Communicate effectively and ethically in team-work.	- Self-Learning - Seminar - Exercises	- Presentation - Assignment - Quiz
d2	Apply computerized programs effectively for continues education	- Seminar - Instructor–student Interactive - Exercises	Presentation

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IV. Course Contents:

A. Theoretical Aspect:

Order	Units/Topics List	Learning Outcomes	Sub Topics List	Number of Weeks	Contact Hours
1	Introduction to Biotechnology	a1, a2, b1, b2, c1, c2, d1, d2	- definition & purposes & brief history. - Relation of biotechnology to advancement in intracellular chemistry, molecular biology, rDNA technology, pharmacogenomics and immunopharmacology, - living organisms used in biotechnology - advantage and disadvantages of biotechnology drug products as compared to classical medications	2	4
	Techniques of Biotechnology		- Classification of biotechnology techniques - Principles, equipments, pharmaceutical applications, comparison , advantages and disadvantages of : - recombinant DNA (rDNA). - Monoclonal antibodies - Polymerase chain Reaction (PCR) - Nucleotide blockade/antisense - Peptide technology	4	8
2	Midterm exam	a1, a2, b1, b2, c1, c2, d1, d2	7 th	1	2
3	Biotechnology produced- Drugs	a1, a2, b1, b2, c1, c2, d1, d2	- Classification of biotechnology drugs - Proteins as the first biotechnology products of biotechnology - Physicochemical properties, Indication,	8	16

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			mechanism of action, dose, route of administration, precautions, biotechnology by which is obtained for the following products, : ○ Anticoagulant drug: Lepirudin (Refludan) ® ○ Antisense drugs : Fomivirsen sodium (Vitravene), efavirenz (Sustiva)® ○ Clotting factors : Systemic antihemophilic factors (Kogenate) ® ○ colony-stimulating factors: granulocyte colony– stimulating factor (Filgrastim)® ○ Erythropoietins : Epoetin alfa (Epogen, Procrit) ® ○ Fusion inhibitors: Enfuvirtide (Fuzeon) ® ○ Growth factor: becaplermin (Regranex) ® ○ Human growth hormone: systemic growth hormone (Humatrope, protropin) ○ Interferons: interferon beta- 1b (betaseron), interferon beta-1a (Avonex) ○ Interleukins: Aldesleukin (Proleukin) ○ tissue plasminogen activators: recombinant Alteplase (Activase) ○ Vaccines: hepatitis B vaccine recombinant (Engerix-b) , haemophilus B conjugate vaccine (Hibtiter)		
8	Final exam	a1, a2, b1, b2, c1, c2		1	2

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Number of Weeks /and Units Per Semester	16	32
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VII. Assignments:

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)
1	Assignment Individual: every student is assigned to provide a search-based report on one drug produced by biotechnology	4 th	2.5	a1, a2, b1, b2, c1, c2, d1, d2
2	Assignment 2: Group : each group of students will be assigned to provide a search-based report on one recent advances in one biotechnology techniques	9 th	2.5	a1, a2, b1, b2, c1, c2, d1, d2
Total				5

VIII. 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	4th, 9th	5	5%	a1, a2, b1, b2, c1, c2, d1, d2
2	Quiz 1	6 th	2.5	2.5%	a1, a2, b1, b2, c1, c2
3	Midterm Exam (Theory)	Week 7	20	20%	a1, a2, b1, b2, c1, c2,
4	Quiz 2	12 th	2.5	2.5%	a1, a2, b1, b2, c1, c2
5	Final Exam (Theory)	Week 16	70	70%	a1, a2, b1, b2, c1, c2
Total			100	100%	

IX. Learning Resources:

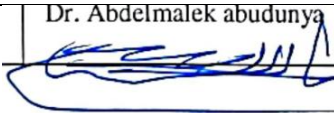
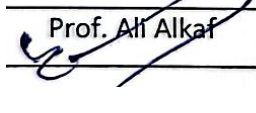
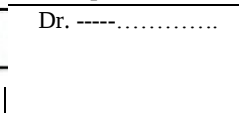
1- Required Textbook(s) (maximum two).

1. Ansel's Pharmaceutical dosage forms and drug delivery system, 2011, Lippincott Williams and Wilkins, USA: Chapter: Biotechnology

2- Essential References.

1. Nagori. Foundations in pharmaceutical biotechnology
2. R.S. pharmaceutical biotechnology

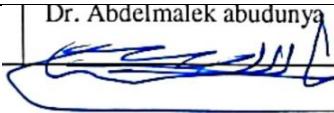
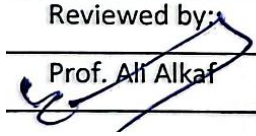
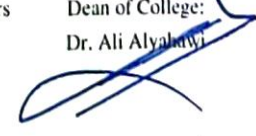
3- Electronic Materials and Web Sites etc.

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www.en.wikipedia.org/

X. 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.

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Faculty of Clinical Pharmacy

Bachelor of Clinical Pharmacy & Pharm. D.

Course Plan (Syllabus) of

Pharmaceutical Biotechnology

Course Code. 02.03.241

I. Information about Faculty Member Responsible for the Course:						
Name of Faculty Member:	Dr. Ali Al-kaf			Office Hours		
Location & Telephone No.:						
E-mail:				SAT	SUN	MON TUE WED THU

2022- 2023

Prepared by: Dr. Abdelmalek abudunya	Reviewed by: Prof. Ali Alkaf	Head of the Department: Dr. -----	Vice Dean for Quality affairs Dr. Abdullelah Thabet	Dean of College: Dr. Ali Alyahawi
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II. Course Identification and General Information:

11.	Course Title:	Pharmaceutical Biotechnology				
12.	Course Code:	02.03.241				
13.	Credit Hours:	Credit Hours	Theory Contact Hours		Practical Contact Hours	
			Lecture	Tutorial/ Seminar	Lab	Clinical
		2	2			--
14.	Level/ Semester at which this Course is offered:	5 th Level / 1 st Semester				
15.	Pre –Requisite (if any):	- Pharmaceutics I, II & III - Pharmacology I, II, III - Biochemistry				
16.	Co –Requisite (if any):	-				
17.	Program (s) in which the Course is Offered:	Bachelor of Clinical Pharmacy & Pharm. D.				
18.	Language of Teaching the Course:	English				
19.	Location of Teaching the Course:	Faculty of Clinical Pharmacy				
20.	Prepared by:	Prof. Dr. Ali Gamal Al-kaf.				
11	Date and Number of Approval by Council:	2022				

III. Course Description:

The course deals with the study of principles & techniques of advance biotechnology and the drugs produced by those techniques.

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جامعة 21 سبتمبر للعلوم الطبية والتطبيقية
كلية الصيدلة السريرية
قسم
وحدة التطوير وضمان الجودة

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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 Define biotechnology and recognize its main purposes and techniques.
a2 State the pharmaceutical applications of biotechnology and employing biotechnology techniques in pharmacy practice.

B. Intellectual Skills:

- b1 Classify and Compare between classical drugs & biotechnology-produced drugs and also between various types of biotechnology techniques.
b2 Select appropriate biotechnology techniques to produce drugs.

C. Professional and Practical Skills:

- c1 Search efficiently for information using documented and electronic sources of information.
c2 Present and report his/her works correctly using appropriate writing rules and technologies media.

D. Transferable Skills:

- d1 Communicate effectively and ethically in team-work
d2 Apply computerized programs effectively for continues education.

I= Introduced, P=Practiced or M/A= Mastered/Advanced

V. Course Contents:

A. Theoretical Aspect:

Order	Units/Topics List	Learning Outcomes	Sub Topics List	Number of Weeks	Contact Hours
1	Introduction to Biotechnology	a1, a2, b1, b2, c1, c2, d1, d2	- definition & purposes & brief history. - Relation of biotechnology to advancement in intracellular chemistry, molecular biology, rDNA technology, pharmacogenomics and immunopharmacology, - living organisms used in biotechnology - advantage and disadvantages of biotechnology drug products as compared to classical medications	2	4

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	Techniques of Biotechnology		- Classification of biotechnology techniques - Principles, equipments, pharmaceutical applications, comparison , advantages and disadvantages of : - recombinant DNA (rDNA). - Monoclonal antibodies - Polymerase chain Reaction (PCR) - Nucleotide blockade/antisense - Peptide technology	4	8
2	Midterm exam	a1, a2, b1, b2, c1, c2, d1, d2	- 7 th	1	2
3	Biotechnology produced- Drugs	a1, a2, b1, b2, c1, c2, d1, d2	• Classification of biotechnology drugs • Proteins as the first biotechnology products of biotechnology • Physicochemical properties, Indication, mechanism of action, dose, route of administration, precautions, biotechnology by which is obtained for the following products, : ○ Anticoagulant drug: Lepirudin (Refludan) ® ○ Antisense drugs : Fomivirsen sodium (Vittravene), efavirenz (Sustiva)® ○ Clotting factors : Systemic antihemophilic factors (Kogenate) ® ○ colony-stimulating factors: granulocyte colony–stimulating factor (Filgrastim)® ○ Erythropoietins : Epoetin alfa (Epogen, Procrit) ®	8	16

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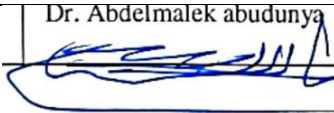
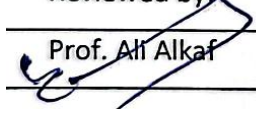
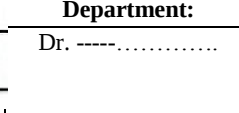
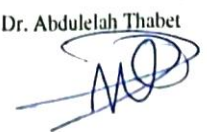
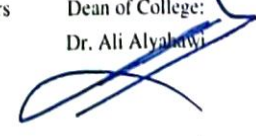
			○ Fusion inhibitors: Enfuvirtide (Fuzeon) ® ○ Growth factor: becaplermin (Regranex) ® ○ Human growth hormone: ystemic growth hormone (Humatrope, protropin) ○ Interferons: interferon beta-1b (betaseron), interferon beta-1a (Avonex) ○ Interleukins: Aldesleukin (Proleukin) ○ tissue plasminogen activators: recombinant Alteplase (Activase) ○ Vaccines: hepatitis B vaccine recombinant (Engerix-b) , haemophilus B conjugate vaccine (Hibtiter)		
8	Final exam	a1, a2, b1, b2, c1, c2		1	2
Number of Weeks /and Units Per Semester				16	32

VI. Teaching Strategies of the Course:

- Lecture
- Instructor – student Interactive
- Exercises
- Presentation
- Office hours
- Seminar
- Assignment
- Self-Learning

VII. Assessment Methods of the Course:

- Assignments
- Quiz
- Exam
- Oral Presentation
- Practical Reports

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VIII. Assignments:

No.	Assignments	Week Due	Mark
1	Assignment Individual: every student is assigned to provide a search-based report on one drug produced by biotechnology	4th	2.5
2	Assignment 2: Group : each group of students will be assigned to provide a search-based report on one recent advances in one biotechnology techniques	9th	2.5
Total			

IX. 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	4th, 9th	5	5%	a1, a2, b1, b2, c1, c2, d1, d2
2	Quiz 1	6 th	2.5	2.5%	a1, a2, b1, b2, c1, c2
3	Midterm Exam (Theory)	Week 7	20	20%	a1, a2, b1, b2, c1, c2,
4	Quiz 2	12 th	2.5	2.5%	a1, a2, b1, b2, c1, c2
5	Final Exam (Theory)	Week 16	70	70%	a1, a2, b1, b2, c1, c2
Total			100	100%	

X. Learning Resources:

1- Required Textbook(s) (maximum two).

- Ansel's Pharmaceutical dosage forms and drug delivery system, 2011, Lippincott Williams and Wilkins, USA: Chapter: Biotechnology

2- Essential References.

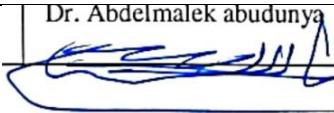
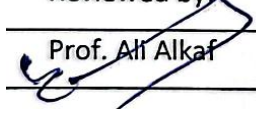
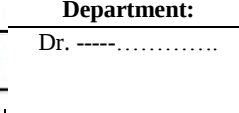
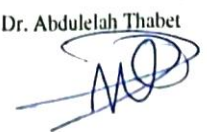
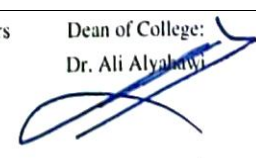
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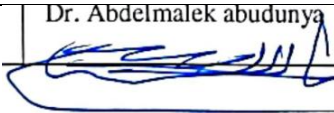
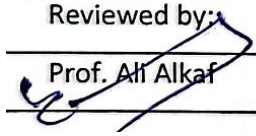
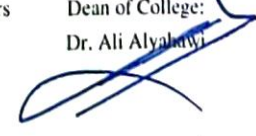
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XI. Course Policies: (Based on the Uniform Students' Bylaw (2007))

1 Class Attendance:

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	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.

Prepared by: Dr. Abdelmalek abudunya 	Reviewed by: Prof. Ali Alkaf 	Head of the Department: Dr. -----	Vice Dean for Quality affairs Dr. Abdulelah Thabet 	Dean of College: Dr. Ali Alyahawi 
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