

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
Ethics and Pharmacy regulations

Course Code. (05.02.224)

2023



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

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

I. General Information:

1.	Course Title:	Ethics and Pharmacy regulations			
2.	Course Code:	05.02.224			
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:	5 th Year -2 nd Semester			
5.	Pre –Requisite (if any):	-			
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:	Dr. Ali Alyahawi			
11.	Date and Number of Approval by Council:	2022			

II. Course Description:

This course aimed to study laws and regulations pertaining to pharmacy practice. Students will be given an introduction to dispensing and the legal and ethical responsibilities of pharmacists. This course also introduces code of ethics for pharmacists that should consider during practicing of their professions. Regulations of selected pharmaceutical products preparation and practice will be covered.

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	Describe the legal and ethical implications within a pharmacy setting.	I	A1, A4
a2	Discuss the legal and ethical responsibilities of pharmacists.	I	A1, A4
B. Intellectual Skills:			
b1	Identify the differences between the various global regulations	P	B4
b2	Compare and contrast the processes required to establish laws, regulations, professional practice standards, and ethical principles	P	B5
C. Professional and Practical Skills:			
c1	Apply legal and ethical standards to a pharmacy setting.	P	C3
c2	Present and report his/her works correctly based on documented regulations and professional ethics	P	C4
D. Transferable Skills:			
d1	Comply to pharmacy laws and ethics with his/her colleagues and patients during practicing practical and professional works in pharmacy practice settings	A	D1, D2
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 legal and ethical implications within a pharmacy setting.	- Lecture - Instructor – student Interactive - Office hour	- Exam - Assignment - Quiz
a2	Discuss the legal and ethical responsibilities of pharmacists.	- Lecture - Instructor – student	- Exam - Assignment

		Interactive ▪ Office hour	▪ 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	Identify the differences between the various global regulations	▪ Lecture ▪ Instructor – student Interactive ▪ Exercises ▪ Solving Problem Methods	▪ Problem-Solving Exercises. ▪ Assignment ▪ Quiz
b2	Compare and contrast the processes required to establish laws, regulations, professional practice standards, and ethical principles	▪ 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	Apply legal and ethical standards to a pharmacy setting.	▪ Lecture ▪ Instructor – student Interactive ▪ Self-Learning	▪ Exam ▪ Assignment ▪ Quiz
c2	Present and report his/her works correctly based on documented regulations and professional ethics	▪ 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	Comply to pharmacy laws and ethics with his/her colleagues and patients during practicing practical and professional works in pharmacy practice settings	- Discussion - Assignment ▪ Seminar	Presentation Assignment

IV. Course Contents:

A. Theoretical Aspect:

Order	Units/Topics List	Learning Outcomes	Sub Topics List	Number of Weeks	Contact Hours
1	Introduction	a 1, a2	- General Principles of Law - History and various Act to Drugs and Pharmacy profession - History of medical regulations	2	2
2	Patients and healthcare professional Rights	a 1, a3, c1, c2, d1	- Rights vs. Responsibilities: • Patient rights and responsibilities - Medical workers rights and responsibilities	2	2
3	Regulations of Medical Professions	a 1, a2, b1, b2, d1	- The main organizations controlling code of ethics: locally, Arabic countries, and globally. - Standards of Professional Conduct - Regulations and acts controlling medical professions: - o Local - o Arabic - o International	2	2
4	Code of Ethics	a 1, a2, a3, b1, b2, d1	- Principles of Medical Ethics	1	1
5	Midterm Exam	a 1, a2, b1, b2, c1, c2, b2	-	1	1
6	Code of Ethics	a 1, a2, a3, b1, b2, d1	- For medical professions and regulation: - o Old (Oath of Hippocrates) - o Arab countries - o Asian - o Europe - o USA - o Local (Yemeni) Code of ethics	3	3

			- Code of Ethics for Pharmacists (ASHP)		
7	Regulations for selected pharmaceutical preparations	a 1, a2, a3, b1, b2, c1, c2, b2, d1	- Regulations of manufacturing sites - Regulations of the Importation and use of Medical Supplies - Regulations of pharmaceutical Registration - Regulations of Herbal Preparations and Natural License - The Regulations and Criteria Related to Pharmaceutical prices - Regulations of Pharmaceutical Preparations involving Vitamins and/or Minerals - Regulations of Medical Prescription - Others	3	3
8	Pharmacy Organizations	a 1, b1, c1, d1	APhA, ASHP, and FIP	1	1
9	Final Exam	a 1, a2, b1, b2, c1, c2		1	1
Number of Weeks /and Units Per Semester				16	16

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	

C. Tutorial Aspect (if any):

No.	Tutorial	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1	NA			

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

VII. Assignments:

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)
1	Assignment 1: Each students group will be assigned to provide seminar one regulation of selected pharmaceutical preparation and practice	Week 9	5	a 1, a2, b1, b2, c1, c2, d1
2	Assignment 2: Each group of students will be assigned to provide a search-based report for comparison of regulations of medical professions between Yemen, Arabic countries, and international regulations	Week 12	5	a 1, a2, b1, b2, c1, c2, d1
Total			10	

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	9 th , 12 th	10	10%	a 1, a2, b1, b2, c1, c2, d1
2	Quiz 1	6 th	5	5%	a 1, a2, b1, b2, c1, c2
3	Midterm Exam (Theory)	Week 7	20	20%	a 1, a2, b1, b2, c1, c2
4	Quiz 2	12 th	5	5%	a 1, a2, b1, b2, c1, c2
5	Final Exam (Theory)	Week 16	60	60%	a 1, a2, b1, b2, c1, c2
Total			100	100%	

IX. Learning Resources:

1- Required Textbook(s):

- 1- Pharmacy council of New Zealand, 2011, code of ethics
- 2- S.P. Agarwal & Rajesh Khanna, 2008, Pharmaceutical Jurisprudence & Ethics, 9788186270486

2- Essential References.

	1- FDA Regulations 2- EMA Regulations 3- Pharmaceutical legislation in Yemen
3- Electronic Materials and Web Sites etc.	
	- www.who.int/about/ethics - https://www.pharmacist.com/code-ethics - https://www.ashp.org - https://www.psa.org.au/wp-content/uploads/2018/07/PSA-Code-of-Ethics

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.

Faculty of Clinical Pharmacy

Department of Pharmacy

Program of Bachelor of Clinical Pharmacy & Pharm. D.

Course Plan (Syllabus) of **Ethics and Pharmacy regulations**

Course Code. 05.02.224

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

2022- 2023

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Dr. Ali Alyahawi	Dr. Ali Alkaf	Dr. -----	Dr. Abdulelah Thabet	Dr. Ali Alyahawi

II. Course Identification and General Information:

11.	Course Title:	Pharmacy Regulations & Ethics				
12.	Course Code:	05.02.224				
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 / 2 nd Semester				
15.	Pre –Requisite (if any):					
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				
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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 legal and ethical implications within a pharmacy setting. |
| a2 | Discuss the legal and ethical responsibilities of pharmacists. |

B. Intellectual Skills:

- | | |
|----|---|
| b1 | Identify the differences between the various global regulations |
| b2 | Compare and contrast the processes required to establish laws, regulations, professional practice standards, and ethical principles |

C. Professional and Practical Skills:

- | | |
|----|--|
| c1 | Apply legal and ethical standards to a pharmacy setting. |
| c2 | Present and report his/her works correctly based on documented regulations and professional ethics |

D. Transferable Skills:

- | | |
|----|--|
| d1 | Comply to pharmacy laws and ethics with his/her colleagues and patients during practicing practical and professional works in pharmacy practice settings |
|----|--|

V. Course Contents:

A. Theoretical Aspect:

Order	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
1	Introduction	- General Principles of Law - History and various Act to Drugs and Pharmacy profession - History of medical regulations	2	2
2	Patients and healthcare professional Rights	- Rights vs. Responsibilities: • Patient rights and responsibilities - Medical workers rights and responsibilities	2	2
3	Regulations of Medical Professions	- The main organizations controlling code of ethics: locally, Arabic countries, and globally. - Standards of Professional Conduct - Regulations and acts controlling	2	2

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		medical professions: ○ Local ○ Arabic ○ International		
4	Code of Ethics	- Principles of Medical Ethics	1	1
5	Midterm Exam	-	1	1
6	Code of Ethics	- For medical professions and regulation: ○ Old (Oath of Hippocrates) ○ Arab countries ○ Asian ○ Europe ○ USA ○ Local (Yemeni) Code of ethics - Code of Ethics for Pharmacists (ASHP)	3	3
7	Regulations for selected pharmaceutical preparations	- Regulations of manufacturing sites - Regulations of the Importation and use of Medical Supplies - Regulations of pharmaceutical Registration - Regulations of Herbal Preparations and Natural License - The Regulations and Criteria Related to Pharmaceutical prices - Regulations of Pharmaceutical Preparations involving Vitamins and/or Minerals - Regulations of Medical Prescription - Others	3	3
8	Pharmacy Organizations	APhA, ASHP, and FIP	1	1
9	Final Exam		1	1
Number of Weeks /and Units Per Semester			16	16

B. Case Studies and Practical Aspect:

No.	Tasks/ Experiments	Number of Weeks	Contact Hours
1	NA		
Number of Weeks /and Units Per Semester		16	32
No.	Tasks/ Experiments	Number of Weeks	Contact Hours

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No.	Tasks/ Experiments	Number of Weeks	Contact Hours
1	- NA		
Number of Weeks /and Units Per Semester		16	32

No.	Tutorial	Number of Weeks	Contact Hours
1	NA		

VI. Teaching Strategies of the Course:

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

VII. Assessment Methods of the Course:

خطأ! لم يتم العثور على مصدر المرجع.

- Assignments
- Quiz
- Exam
- Oral Presentation

VIII. Assignments:

No.	Assignments	Week Due	Mark
1	Assignment 1: Each students group will be assigned to provide seminar one regulation of selected pharmaceutical preparation and practice	Week 9	5
2	Assignment 2: Each group of students will be assigned to provide a search-based report for comparison of regulations of medical professions between Yemen, Arabic countries, and international regulations	Week 12	5
Total			10

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

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment
1	Assignments	6th, 12th	10	10%
2	Quiz 1	6 th	5	5%
3	Midterm Exam	Week 7	20	20%
4	Quiz 2	12 th	5	5%
5	Final Exam (Theory)	Week 16	60	60%
Total			100	100%

X. Learning Resources:

1- Required Textbook(s):

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2- Essential References.

- 4- FDA Regulations
- 5- EMA Regulations
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