University: Thamar University
Faculty: Medical Sciences
Program: Bachelor of Pharmacy

Research Methodology

I. Course Identification and General Information:

1	**Course Title:**	*Research Methodology*			
2	**Course Number and Code:**	PH1125184			
3	**Credit hours: 2 CH**		Lecture/Tutorial	Practical session	TOTAL
		Contact hours/week	1 hours		30 contact hours
		Duration of term	15 weeks		
		Total Number of Contact hours/term	30 hours		
4	**Study level/ semester at which this course is offered:**	5th level/ Semester 1			
5	**Pre –requisite (if any):**	*Biostatistics*			
6	**Co –requisite (if any):**				
7	**Program (s) in which the course is offered:**	Bachelor of Pharmacy			
8	**Language of teaching the course:**	English			
9	**Location of teaching the course:**	Faculty of Medical Sciences, Thamar University Main Campus, Dhamar City.			
10	**Prepared By:**	Dr. Abdulelah H. Al-Adhroey			
11	**Approved By:**				

I. Course Description:

Research Methodology course is aimed to assist students to develop fundamental skills in medical research and scientific communication. This course offers medical students an opportunity to assemble their preclinical and clinical knowledge and skills have acquired during the earlier medical sciences levels to realize a minor medical research (clinical, laboratory or epidemiological reports). This course aimed in offering students with skills required to formulate a research proposal related to faculty's planned or ongoing researches.

III. Intended learning outcomes (ILOs) of the course:

(A) Knowledge and Understanding Skills:

By the end of the course, the student should be able to:

A1- Recognize a research proposal following a responsible research methodology in identifying research problem, objectives, design, variables, ethics and data collection techniques; and in planning data analysis and interpretation as well as project management.

(B) Intellectual Skills:

By the end of the course, the student should be able to:

b1- Formulate a research proposal including the main components of the scientific research.

© Professional and Practical Skills:

By the end of the course, the student should be able to:

c1- Apply a scientific method in collecting and recording research data in laboratory, field, or clinical setting, or from existing data set.

c2- Plan for management of research proposal, data analysis and interpretation meeting an acceptable scientific justification.

c3- Prepare a preliminary research proposal following an acceptable academic writing style.

(D) Transferable and General Skills:

By the end of the course, the student should be able to:

d1- Utilize statistical computer programs and information technology required to personal and professional development.

Theoretical and Practical Aspect:

Order	Tasks/ Experiments	Number of Weeks	contact hours	Learning Outcomes
1.	• Outline the faculty planned or ongoing researches related topics and distribution of students by research topics to small research groups, six each.	1	1	**b1 c1- c3**
2.	• Identifying and prioritizing problems	1	1	
3.	• Identifying problems statement and analysis	1	1	
4.	• Studying literature review of research problems	1	1	
5.	• Deciding objectives of research	1	1	
6.	• Overviewing research design	1	1	
7.	• Selecting type of study	1	1	

8.	• Compose a research report following an acceptable academic writing style	1	1	
9.	• Recognizing ethical issues	1	1	
10.	• Describing research variables	1	1	
11.	• Deciding study sample and sample	1	1	
12.	• Asserting techniques for collection and pretesting	1	1	
13.	• Planning for data analysis and interpretation	1	1	
14.	• Project management	1	1	
15.	• Submitting the research proposal	1	1	
Number of Weeks /and Units Per Year			**15 h**	

V- Teaching strategies of the course:

1- Lectures
2- Supervised training sessions
3- Small research group activities

VI- Assignments:

No	Assignments	Aligned CILOs(symbols)	Week Due	Mark
1	Research proposal progress report	b1- b3 c1	7	40
2	Submission of research proposal	b1-b3 c1	13	40
3	Oral presentation of research proposal	d1-d2	15	20

VII- Schedule of Assessment Tasks for Students During the Year:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes
1	Research proposal progress report	7	40	40%	b1- b3 c1
2	Submission of research proposal	13	40	40%	b1-b3 c1
3	Oral presentation of research proposal	15	20	20%	d1-d2
	Total		100	100%	

VIII- Learning Resources:

- *Written in the following order: (Author - Year of publication – Title – Edition – Place of publication – Publisher).*

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

1. Amar-singh, H.S.S., Bakar, A.A., Sararaks, S., (2008). The Medical Research Handbook: Planning a Research Project. Perak, Malaysia. Clinical Research Center Perak and the Institute for Health Systems Research.
2. منظمة الصحة العالمية. (٢٠١١). طب المجتمع: الكتاب الطبي الجامعي. بيروت، لبنان: اكاديميا انترناشيونال.

2- Essential References.

1. Sanyal, P. (2015). Community Medicine: A Students Manual, 1st edition. New Delhi, London, Philadelphia, Panama: Jaypee Brothers Medical Publishers (P) Ltd.
2. Park, K. (2015) Park's Textbook of Preventive and Social Medicine, 23th edition, Jabalpur, India: Bhanot.

3- Electronic Materials and Web Sites *etc*.

1. World Health Organization: www.who.int
2. Centers for Disease Control and Prevention: www.cdc.gov

IX. Course Policies:

1	**Class Attendance:** **- Attendance of students is taken at the beginning of lecture time as it is required for the assessments of students.**
2	**Tardy:** **- The student will be regarded as absent if he/she is 15 minutes late in attending to the class.** **- Absence from lectures and/or tutorials shall not exceed 25%. Students who exceed the 25% limit without a medical or emergency excuse acceptable to and approved by the dean of the college shall not be allowed to enter the final examination.**
3	**Exam Attendance/Punctuality:** **- All examination and their roles will be according to students-affairs**

	regulations.
4	**Assignments & Projects:** **- Student who is submitting the assignments or the projects on time, will be awarded good percentage in grading of participation**
5	**Cheating:** **- All students must be an ideal behavior and respect each other and their teachers.** **- Students who has been caught in any cheating case will be punished according to the students-affairs regulations.**
6	**Plagiarism:** **- Student will be punished according to student-affairs regulations which can reach to the separation.**
7	**Other policies:** **- The student should follow the instructions of exams' entrance.** **- The student should follow all the systems & laws of the university.**

Course Specification

Pharmacy Marketing and communication skills

I. Course Identification and **General Information**:						
1	**Course Title:**	**Pharmacy Marketing and communication skills**				
2	**Course Number & Code:**	**PH1125166**				
3	**Credit hours:**	C.H	TOTAL			
		Th.	Seminar	Pr	Tr.	
		2			2	
4	**Study Level/ Semester at which this Course is offered:**	**Level 5/ semester 1**				
5	**Pre –Requisite (if any):**					
6	**Co –Requisite (if any):**					
7	**Program (s) in which the Course is Offered:**	Bachelor of Pharmacy				
8	**Language of Teaching the Course:**	English				
9	**Study System:**	semester				
10	**Mode of Delivery:**	Full Time				
11	**Location of Teaching the Course:**	Faculty of Medical Science				
12	**Prepared by:**					
13	**Date of Approval:**					

II. Course **Description**:

This course is composed of marketing and promotion concepts and teach pharmacy students the advanced prin of marketing and promotion in order to apply them in a pharmaceutical practical context. It prepares students t variety of careers in the pharmacy field including pharmaceutical sales, health information management, and pharmacy distribution system development.

III. Aims and Intended learning outcomes (**ILOs**) of **the** course:

1. Aims of The Course:

The overall aims of the course are:

- **To a**chieve advanced understanding of the marketing environment and promotion activities within a market, their implications and usage in practice within all pharmaceutical marketing professions..

2. Intended learning outcomes (ILOs) of the course:

A. Knowledge And Understanding:

- **After successful completion the course, students will be able to:**

(A) Alignment Course Intended Learning Outcomes of Knowledge and Understanding to Teaching Strategies and Assessment Strategies:

Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
a1- Understand the Pharmaceutical Marketing Functions.	• Lectures • Discussion Sessions • Assignments	• Periodic exam (Quizzes) • Home Assignments • Exams
a2- Explain the Principles of sales promotion, advertising and the ethics of sales.		
a3- Know the principles of accounting		
a4- Understand and explain the major components of the marketing management process.		
a5- Recognize the process and legal steps of new product development and promotion		

(B) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
b1- Suggest theoretical concepts and applied techniques marketing analysis, planning, and management	• Discussion Sessions • Problem solving • Group Discussion	• Oral presentations • Home assignments
b2- Develop critical thinking and decision-making skills		
b3- Identify the marketing relating problems and solve it		
b4- Develop marketing and communication activities for a specific product		
©Alignment Course Intended Learning Outcomes of Professional and Practical Skills to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
c1- Apply a variety of marketing concepts.	• Discussion Sessions • Assignments	• Oral presentations • Exams • LAB report
c2- Create pharmaceutical promotion composition.		
c3- Collect, analyze and interpret information and data from different segments of the pharmaceutical marketplace.		
c4- Design a suitable marketing plan		
(D) Alignment Course Intended Learning Outcomes of Transferable Skills to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
d1- Enhance communication skills	• iscussion Sessions • ssignments that require collecting information from the internet.	• ral presentations • riting
d2- Adapt with the ever-changing external environment		

IV. Course Content**:**

A. Theoretical Aspect:

Order	Topic List / Units	Sub Topics List	Week Due	Contact Hours	ILOs
1	**Introduction to pharmaceutical marketing**		1	2	a1, a4,b1,c3, d1,d2
2	**Selling General Concepts**	- What's selling? And why do pharmacy students study it? - Role of salespeople in society, Role of Medical Reps. - Mythology of selling "common Myths in selling" - Characteristics of sale careers and its paths - Personal characteristic of salespeople and some important personality elements	2	4	a2,b2,c3,d2

3	**Selling and prescribing process Pharmaceutical Detailing**	- Introduction to the job of pharmaceutical detailing - Detailing Sequence and how to ask for Business (AFTB) - Classification of Doctor's call and setting objectives - Classification of Doctor's in your working area - Management of time and territory (MTT) - Identifying and Developing Doctor's need - Relating and reinforcing customers needs - Matching products benefits to Doctor's expressed needs(FAB concept) - The use of reprints and samples during business call - Obtaining feedback , both positive and negative - Art of listening during doctor call, including guides to good listening and disciplines of this art - Handling various Doctor's attitudes - Types of doctor's objectives - Handling doctor's objectives - Gaining commitment and following up - Evaluation of the doctor call "Post Call analysis"	**5**	**10**	a2,a3,a5,c1 ,c4,d2
4	**Retail Selling in Pharmacies**	- Introduction and general concepts - Problems in retail selling - Ways and methods on increasing the pharmacy sales - Striking the balance between profits and ethics in pharmacy business - The approach in retailing - Making the sale - Technique of substitution for (OTC) and consumable Products not pharmaceuticals	**3**	**6**	b3,c3,d2
5	**Marketing Principles and Concepts**	- Selling versus Marketing and Marketing function - Product management in pharmaceutical companies - Marketing principles and some useful function	**3**	**6**	a1,b1,b2,b5 ,c2,c4,d1,d 2
	Number of Weeks /and Units Per Semester		**14**	**28**	

V. Schedule of Assessment Tasks for Students During the Semester:					
No	**Assessment Tasks**	**Week Due**	**Mark**	**Proportion of Final Assessment**	**Aligned CILOs(symbols)**
1	**Participation, quizzes**	**Each week**	**10**	**10%**	a1, a2, a4, b1,b2, c3,d2
2	**Research, assignments**	**6th week**	**10**	**10%**	a1, a3, b1, b2, c4, d2
3	**Mid –Exam**	**7th week**	**20**	**20%**	a1.a2,a3, b1,b2, d1,d2
4	**Final Exam (theoretical)**	16th week	**60**	**60%**	a1.a2,a3, b1,b2, d1,d2
	Total		**100**	**100%**	

VI. Learning Resources:	
1. Required Textbook(s) (maximum two).	
	1. 1984 Principles and Practice of Management - Peter Drucker. 2. Principles of Management - Koontz O'Donnel. 3. Business Organization and Management - Shukla. 4. Business Organization - Ghosh. 5. Double Entry Book Keeeping - Batliboi. 6. Professional Pharmacy - Jain and Sharma.
2. Recommended Readings and Reference Materials.	
	1. Understanding and Responding to Pharmaceutical Promotion- a practical guide, 1st ed., World Health Organization/ Health Action International collaborative project. 2. Preparing the marketing plan, AMA marketing toolbox, American Marketing Association marketing toolbox. Parmerlee, David, 2000. ISBN: 0658001345
3. Essential References.	
	1. Marketing, Kerin, Roger A.**, International edition., 2006. ISBN: 0-07-111608-7** 2. Pharmaceutical Marketing, Brent L. Rollins & Matthew Perri, 2013, **ISBN-10:** 1449697992 **ISBN-13:** 978-1449697990
4. Other Learning Material.	
	- Data show projector

I. Course **Policies**:	
1	**Class Attendance:** □ Absence from lectures and/or tutorials shall not exceed 25%. Students who exceed the 25% limit without a medical or emergency excuse acceptable to and approved by the Dean of the relevant college shall not be allowed to take the final examination and shall receive a mark of zero for the course.

2	**Tardy:** - Students should be attending the classes as its required for the assessments if the student is 15 minutes late in attending to the class for more than two classes he will loss 50% of quizzes mark.
3	**Exam Attendance/Punctuality:** - All examination and their roles will be according to Students affairs regulations
4	**Assignments & Projects:** - Student who is submitting the assignments or the projects on time, will be awarded good percentage in grading of participation.
5	**Cheating**: - All students must be an ideal behavior and respect each other, their teachers and respect the roles of the colleague. In addition, students should follow safety roles while working in the lab. Those who has been caught in any cheating case will be punished according to the Students affairs regulations
6	**Plagiarism**: - Student will be punished depend upon gravity of the action and according to Students affairs regulations which might be ranged from rewriting the homework to suspension or dismissal
7	**Other policies:** - Using mobile or another electronic device capable to store or transfer data in class during the lecture or the exam is forbidden.

Council of Academic Accreditation & Quality Assurance of Higher Education (CAQA)

مركز التطوير الأكاديمي وضمان الجودة
Center of Academic Development and Quality Assurance

Faculty of Medical sciences

Department of Pharmacy

Program of B. Pharmacy

Course Specification of

Industrial Pharmacy I

Course Code. (PH1125178)

2024

I. General Information:

1.	**Course Title:**	**Industrial Pharmacy I**				
2.	**Course Code:**	PH1125178				
3.	**Course Type:**	**Compulsory course**				
4.	**Credit Hours:**	**Credit Hours**	**Theory Contact Hours**		**Practical Contact Hours**	
			Lecture	**Tutorial/ Seminar**	**Lab**	**Clinical**
		2	2	--		--
5.	**Level/ Semester at which this Course is offered:**	Fifth Level / First Semester				
6.	**Pre –Requisite (if any):**	Pharmaceutics III				
7.	**Co –Requisite (if any):**	------				
8.	**Program (s) in which the Course is Offered:**	Bachelor of pharmacy				
9.	**Language of Teaching the Course:**	English				
10.	**Location of Teaching the Course:**	Faculty of Medical Science				
11.	**Prepared by:**	Dr. Abdulkarim K. Alzomor				
12.	**Reviewed By:**					
13.	**Date and Number of Approval by Council:**					

II. Course Description:

This course provides an overview of FDA guidelines and cGMP's. The course imparts to the student the principles of drug development and production and equips the student with basic skills in the good manufacture of pharmaceuticals process validation and packaging selection and quality by design.

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**	**Referenced PILOs**	
a1	Identify the concept and scope of good manufacturing practice, validation, packaging materials, sterilization and quality by design.	**A**	**A3**	Clearly distinguishes the foundations of the design of medicines & their development, using the various equipment and techniques, as well as, the tests that use in the pharmaceutical industry.
B. Intellectual Skills:				
b1	Investigate all pharmaceutical process during drug manufacturing according to GMP guidelines.	**A**	**B1**	Correctly choose of the appropriate methods to isolate & purification and titration accurately of active substances from different sources according to the standards and policy of medicines.
C. Professional and Practical Skills:				
c1	Design diagram for plant of pharmaceutical drugs manufacturing according to GMP guidelines.	**A**	**C3**	Extract the active substances from their various sources by correct scientific methods whether in their isolation, purification, titration and preparation.
D. Transferable Skills:				

d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team	**A**	**D1**	Works effectively in a unique team.
d2	Employ the technologies services to solve problems of pharmaceuticals and develop his skills.	**A**	**D2**	Correctly uses, the means of the technology, information, programs of computer and the statistical programs, which contribute in raising the health level.

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

IV. Alignment of Course Intended Learning Outcomes

(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	Identify the concept and scope of good manufacturing practice, validation, packaging materials, sterilization and quality by design.	- Lectures and Groups discussion. - Self – learning	▪ Quizzes, Presentation and Written exam.

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

	Course Intended Learning Outcomes	Teaching Strategies	Assessment Strategies
b1	Investigate all pharmaceutical process during drug manufacturing according to GMP guidelines.	- Discussions and Training - Field visits - Problem solving	- Quizzes, Homework - Observation - Task's Evaluates

(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	Design diagram for plant of pharmaceutical drugs manufacturing according to GMP guidelines.	- Lectures - Simulation & presentations	▪ Performance, Report

(D) Alignment of Course Intended Learning Outcomes (Transferable Skills) to Teaching

Strategies and Assessment Methods:			
Course Intended Learning Outcomes		**Teaching Strategies**	**Assessment Strategies**
d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team	- Group discussions - Cooperative learning. - Self – learning	- Homework - Evaluates of oral Presentation
d2	Employ the technologies services to solve problems of pharmaceuticals and develop his skills.		

V. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1	Introduction	- Quality, principles, source of risk in drug manufacturing and fit drugs to be used. - Define the quality assurance, GMP and quality control and relationship between them. • Quality management and total quality management.	1	2	a1, b1, c1, d1, d2
2	Good Manufacture Practice (GMP)	- GMP: define. Sources, Changes and important. - Quality assurance responsibility in drugs manufacturing - GMP Responsibility in drugs manufacturing. - Quality control responsibility in drugs manufacturing	1	2	a1, b1, c1, d1, d2
3	Good Manufacture Practice **(Premises)**	❖ Premises: - List of location for factory. - Important of design and layout of plant for drugs manufacturing. • Design for plant for drugs manufacturing according to GMP. (Chart)	1	2	a1, b1, c1, d1, d2

4	Premises - Area in plant	- Sampling and weighing area - Maintenance area - Ancillary area - Storage area, - Production area Quality control area	2	4	a1, b1, c1, d1, d2
5	Sterile preparation	- Design of Sterile Area. - Sterile area and its classification; - Air control, (Laminar flow etc.). Air locks, environmental monitoring methods.	1	2	a1, b1, c1, d1, d2
6	- Mid Exam		1	2	a1, b1, c1
7	Terminology and Personal	❖**Terminology**: (Quarantine, Reject, Air Lock, Contamination, Cross-contamination, Raw Material, Intermediate, Bulk Product, Finished Product, Batch, Sub-Batch, Batch Number, Batch Record, Recall, Return, Master file, SOP). ❖**Personal**: - Responsibility -Training -Key Person - Production manger -Quality control manger -Shear responsibility between quality control and production mangers. ❖ Visitors ❖ Inspectors	2	4	a1, b1, c1, d1, d2
88	Dispensing of material from storage to production for manufacturing process & Validation	❖ Dispensing - Stages for inter and store raw materials, excipients and packaging materials. - Stages for exit and dispense raw materials, excipients and packaging materials to production for manufacturing process. - SOP stated. ❖ Validation: - Definition - Types - Important	1	2	a1, b1, c1, d1, d2

9	Sterilization	- Terminology - Classification of Sterilization • Moist heat: Advantage, Disadvantage and Application • Dry heat: Advantage, Disadvantage and Application • Filtration: Advantage, Disadvantage and Application • Radiation: Advantage, Disadvantage and Application • Chemical Gases sterilization: Advantage, Disadvantage and Application.	2	4	a1, c1, d2
10	Pharmaceutical Packaging	- Define of packaging materials, Important of pharmaceutical packaging, - Types of packaging materials: • Glasses: Advantage, disadvantage, constituents, Method of manufacturing. Types, glass problems. • Plastic: Advantage, disadvantage, constituents, Method of manufacturing. Types, plastic problems • Rubber: Advantage, disadvantage, constituents, manufacturing. characters, rubber problems • Metals and Aluminum • Papers • Cotton • Ink • Closers: important Evaluate and Quality control of pharmaceutical packaging materials.	2	4	a1, c1, d2
11	Quality by Design	- Define - Methods - Important	1	2	a1, c1, d1,
12	**Final exam**		**1**	2	a1, b1, c1, d1, d2
Number of Weeks /and Units Per Semester			**16**	**32**	

VI. Assignments:

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)
1	**Assignment 1: Attendance**	1-14	10	a1, b1, c1, d1, d2
2	**Assignment 2: Homework, Research & Quizzes.**	6&12	10	a1, b1, c1, d1, d2
Total			**20**	

VII. 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**	1-14	20	20%	a1, b1, c1, d1, d2
2	**Mid-Term Theoretical Exam**	8	30	30%	a1, b1, c1, d1, d2
5	**Final Theoretical Exam**	16	50	50%	a1, b1, c1, d1, d2
Total			**100**	**100%**	

VIII. Learning Resources:

- *Written in the following order:* Author, Year of publication, Title, Edition, Place of publication, Publisher.

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

1. Michael E. Aulton; (2006). Pharmaceutics; the Science of Dosage Form Design.
2. Jhon Sharp;(2006). Good pharmaceutical manufacture practice, rational and compliance.

2.Essential References:

1. Williams and Wilkins (2005). Remington; the Science and Practice of Pharmacy (2first edition). Publisher: Lippincott.
2. Patrick J. Sinko (2006). Martin's Physical Pharmacy and Pharmaceutical Sciences.

Electronic Materials and Web Sites *etc.*

1. www. Pharmaceutical manufacturing process.com

IX.	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 Medical sciences

Department of Pharmacy

Program of B. Pharmacy

Course Specification of

Industrial Pharmacy I

Course Code. (PH1125178)

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	

2024

II. Course Identification and General Information:

1.	**Course Title:**	Industrial **Pharmacy I**				
2.	**Course Code:**	PH1125178				
3.	**Course Type:**	Compulsory **course**				
4.	**Credit Hours:**	**Credit Hours**	**Theory Contact Hours**		**Practical Contact Hours**	
			Lecture	**Tutorial/ Seminar**	**Lab**	**Clinical**
		2	2	--		--
5.	**Level/ Semester at which this Course is offered:**	Fifth Level / First Semester				
6.	**Pre –Requisite (if any):**	Pharmaceutics III				
7.	**Co –Requisite (if any):**	------				
8.	**Program (s) in which the Course is Offered:**	Bachelor of pharmacy				
9.	**Language of Teaching the Course:**	English				
10.	**Location of Teaching the Course:**	Faculty of Medical Science				
11.	**Prepared by:**	Dr. Abdulkarim K. Alzomor				
12.	**Reviewed By:**					
13.	**Date and Number of Approval by Council:**					

III. Course Description:

This course provides an overview of FDA guidelines and cGMP's. The course imparts to the student the principles of drug development and production and equips the student with basic skills in the good manufacture of pharmaceuticals process validation and packaging selection and quality by design.

IV. Course Intended Learning Outcomes (CILOs) :

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

A. Knowledge and Understanding:	
a1	Identify the concept and scope of good manufacturing practice, validation, packaging materials, sterilization and quality by design.
B. Intellectual Skills:	
b1	Investigate all pharmaceutical process during drug manufacturing according to GMP guidelines.
C. Professional and Practical Skills:	
c1	Design diagram for plant of pharmaceutical drugs manufacturing according to GMP guidelines.
D. Transferable Skills:	
d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team
d2	Employ the technologies services to solve problems of pharmaceuticals and develop his skills.

V. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
1	**Introduction**	• Quality, principles, source of risk in drug manufacturing and fit drugs to be used. - Define the quality assurance, GMP and quality control and relationship between them. • Quality management and total quality management.	1	2
2	**Good Manufacture Practice (GMP)**	GMP: define. Sources, Changes and important. - Quality assurance responsibility in drugs manufacturing - GMP Responsibility in drugs manufacturing. - Quality control responsibility in drugs manufacturing	1	2
3	**Good Manufacture Practice (Premises)**	• Premises: - List of location for factory. - Important of design and layout of plant for drugs manufacturing. • Design for plant for drugs manufacturing according to GMP. (Chart)	1	2
4	Premises - Area in plant	Sampling and weighing area - Maintenance area - Ancillary area - Storage area, - Production area Quality control area	2	4
5	Sterile preparation	Design of Sterile Area. - Sterile area and its classification; - Air control, (Laminar flow etc.). Air locks, environmental monitoring	1	2

		methods.		
6	Mid Exam		1	2
7	Terminology and Personal	Terminology: (Quarantine, Reject, Air Lock, Contamination, Cross-contamination, Raw Material, Intermediate, Bulk Product, Finished Product, Batch, Sub-Batch, Batch Number, Batch Record, Recall, Return, Master file, SOP). ❖ **Personal**: - Responsibility -Training -Key Person - Production manger -Quality control manger -Shear responsibility between quality control and production mangers. ❖ Visitors ❖ Inspectors	2	4
88	Dispensing of material from storage to production for manufacturing process & Validation	• **Dispensing** - Stages for inter and store raw materials, excipients and packaging materials. - Stages for exit and dispense raw materials, excipients and packaging materials to production for manufacturing process. - SOP stated. ❖ Validation: - Definition - Types - Important	1	2
9	Sterilization	• **Terminology** - Classification of Sterilization • Moist heat: Advantage, Disadvantage and Application • Dry heat: Advantage, Disadvantage and Application • Filtration: Advantage, Disadvantage and Application • Radiation: Advantage, Disadvantage and Application • Chemical Gases sterilization: Advantage, Disadvantage and Application.	2	4
10	Pharmaceutical	• **Define** of packaging materials, Important of pharmaceutical packaging,	2	4

	Packaging	- Types of packaging materials: • Glasses: Advantage, disadvantage, constituents, Method of manufacturing. Types, glass problems. • Plastic: Advantage, disadvantage, constituents, Method of manufacturing. Types, plastic problems • Rubber: Advantage, disadvantage, constituents, manufacturing. characters, rubber problems • Metals and Aluminum • Papers • Cotton • Ink • Closers: important Evaluate and Quality control of pharmaceutical packaging materials.		
11	Quality by Design	- **Define** - Methods - Important	1	2
12	**Final** exam		1	2
Number of Weeks /and Units Per Semester			16	32

VI. Assignments:

No.	Assignments	Week Due	Mark
1	**Assignment 1:** Attendance	1-14	10
2	**Assignment 2:** Homework**, Research & Quizzes.**	6&12	10
Total			**20**

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

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment
1	**Assignments**	1-14	20	20%
2	**Mid-Term Theoretical Exam**	8	30	30%
5	**Final Theoretical Exam**	16	50	50%
Total			100	100%

VIII. Learning Resources:

- *Written in the following order: Author, Year of publication, Title, Edition, Place of publication, Publisher.*

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

Michael E. Aulton; (2006). Pharmaceutics; the Science of Dosage Form Design.

Jhon Sharp;(2006). Good pharmaceutical manufacture practice, rational and compliance.

2.Essential References:

1- Williams and Wilkins (2005). Remington; the Science and Practice of Pharmacy (2first edition). Publisher: Lippincott.

2- Patrick J. Sinko (2006). Martin's Physical Pharmacy and Pharmaceutical Sciences.

Electronic Materials and Web Sites etc.

www. Pharmaceutical manufacturing process.com

IX. Course Policies: (Based on the Uniform Students' Bylaw (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.

Course Specification Medicinal Chemistry IV

I. Course Identification and General Information:						
1	**Course Title:**	**Medicinal Chemistry IV**				
2	**Course Code &Number:**	**PH1125134**				
3	**Credit hours:**	C.H				TOTAL Credit Hours
		Th.	Seminar	Pr	Tr.	
		2		1		3
4	**Study level/ semester at which this course is offered:**	Level 5 / 1st Semester				
5	**Pre –requisite (if any):**	Pharmaceutical Organic Chemistry I, II, and III, Pharmacology IV				
6	**Co –requisite (if any):**					
7	**Program (s) in which the course is offered:**	Pharmacy				
8	**Language of teaching the course:**	English				
9	**Location of teaching the course:**	Faculty of Medical Sciences				
10	**Prepared By:**	Assistant Prof. Dr. Sam Dawbaa				
11	**Date of Approval**					

II. Course Description:

This course aims to provide the students with basic knowledge about classification, mechanism of action, chemical properties, structure-activity relationships, metabolism, and chemical synthesis of chemotherapeutic agents.

III. Course Objectives:

1. To provide the student with basic knowledge regarding the chemical properties and SARs and their contribution to the biological activity of antibacterial antibiotics, antifungals, antivirals, anti-cancer agents, antiprotozoal drugs, antimalarial drugs, anthelmintic agents, and antimycobacterial drugs.
2. To explain some methods of chemical synthesis of selected drugs.
3. To compare the chemical structures and properties between classes of drugs.
4. To explain the metabolic pathways of those drugs.

IV. Course Intended Learning Outcomes (CILOs) :

Knowledge and Understanding:

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

Knowledge and Understanding PILOs	Knowledge and Understanding CILOs	Teaching Strategies
After completing this program, students would be able to:	**After completing this course, students would be able to:**	**Lectures, Discussions, Self-learning.**
A1 Explain the relationship between the structural activity relationship (SAR)and its pharmacokinetics and pharmacological activity.	a1: Explain the structure-activity relationship (SAR) of various chemotherapeutic classes.	Lectures, Discussions, Self-learning.
A2 Understand the chemistry of drug-receptor interaction.	a2: • Discuss the relationship between chemical properties and drug activity. • Discuss methods of chemical synthesis of selected drugs.	Lectures, Discussions, Self-learning.
A3: Understand the metabolic pathways of drugs in the body.	a3: • Explain the metabolism and biosynthesis of various chemotherapeutic classes.	Lectures, Discussions, Self-learning.

Intellectual Skills :

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

Intellectual Skills PILOs	Intellectual Skills CILOs	Teaching Strategies
After completing this program, students would be able to:	**After completing this course, students would be able to:**	**The following strategies should be used:**
B1 Discuss the structure activity relationships (SAR) that control the pharmacokinetics and pharmacodynamics	b1: Identify the structural features of drugs responsible for their therapeutic and adverse effets.	Lectures, Discussions, Seminars, Self-learning.
	b2: Predict the pharmacokinetics of drugs based on their physicochemical properties.	Lectures, Discussions, Seminars, Self-learning.

Professional and Practical Skills		
Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)		
Professional and Practical Skills PILOs	**Professional and Practical Skills CILOs**	**Teaching Strategies**
After completing this program, students would be able to:	**After completing this course, students would be able to:**	**The following strategies should be used:**
C1. Use efficiently equipment and suitable methods for determination of physicochemical properties and assay of drugs and synthetical methods for some important pharmacophores.	c1: Achieve assays of selected drugs based on pharmacopeial methods.	Lectures, Lab. experiments, Presentations, Brain-storming.
	c2: Chemically synthesize pharmacophore parts of selected drugs.	Lectures, Lab. experiments, Presentations, Brain-storming.

Transferable (General) Skills :		
Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)		
Transferable (General) Skills PILOs	**Transferable (General) Skills CILOs**	**Teaching Strategies**
After completing this program, students would be able to:	**After completing this course, students would be able to:**	**The following strategies should be used:**
D1 Use chemistry-related softwares and search efficiently for medical information from professional medical sites.	d1: To use famous websites used in medicinal chemistry research including SwissADME, ChemBL, PubChem, Siencedirect, and Google Scholar. d2: Use important software such as ChemDraw, ChemSketch, and has some knowledge about Molecular Docking software.	Discussions, Presentations, Self-learning.

V. Course Content:

A – Theoretical Aspect:

Order	Units/Topics List	Sub Topics List	Number of Weeks	contact hours	Learning Outcomes (CILOs)
1	**Introduction to chemotherapy**	• Classification of chemotherapeutic agents. • Chemistry of cell wall synthesis inhibitors: penicillins	1	2	a1, a2, a3, b1, b2, d1, d2
2	**Antibiotics: Chemistry of cell wall synthesis inhibitors**	• Penicillins and Cephalosporins: classes, MOA, uses, adverse effects, chemical properties, biosynthesis, chemical synthesis, modes of bacterial resistance, and metabolism.	1	2	a1, a2, a3, b1, b2, d1, d2
		• β-lactamase inhibitors, carbapenems and monobactams: classes, MOA, uses, adverse effects, chemical properties, SARs, modes of bacterial resistance, and metabolism.	1	2	a1, a2, a3, b1, b2, d1, d2
3	**Antibiotics: Chemistry of protein synthesis inhibitors**	• Aminoglycosides and tetracyclines: classes, MOA, uses, adverse effects, chemical properties, modes of bacterial resistance, and metabolism.	1	2	a1, a2, a3, b1, b2, d1, d2
		• Macrolides: classes, MOA, uses, adverse effects, chemical properties, SARs, modes of bacterial resistance, and metabolism.	1	2	a1, a2, a3, b1, b2, d1, d2
4	**Antibacterials: Chemistry of DNA synthesis inhibitors**	• Quinolones: classes, MOA, uses, adverse effects, chemical properties, SARs, chemical synthesis, modes of bacterial resistance, and metabolism.	1	2	a1, a2, a3, b1, b2, d1, d2
		• Sulphonamides: classes, MOA, uses, adverse effects, chemical properties, SARs, chemical synthesis, modes of bacterial resistance, and metabolism.	1	2	a1, a2, a3, b1, b2, d1, d2

	Mid-term	Mid-term exam	1	2	
5	**Antifungal agents**	• Antibiotics, azoles, and allylamines: MOA, uses, adverse effects, chemical properties, SARs, chemical synthesis, modes of resistance, and metabolism.	1	2	a1, a2, a3, b1, b2, d1, d2
6	**Antiviral agents**	• Classes, MOA, uses, adverse effects, chemical properties, SARs, chemical synthesis, modes of resistance, and metabolism.	1	2	a1, a2, a3, b1, b2, d1, d2
7	**Antineoplastic agents**	• Classification. • General modes of resistance. • MOA, uses, adverse effects, chemical properties, SARs, chemical synthesis, and metabolism of: o Alkylating agents	1	2	a1, a2, a3, b1, b2, d1, d2
		• MOA, uses, adverse effects, chemical properties, SARs, chemical synthesis, and metabolism of: o Antimetabolites o Antibiotics and natural products	1	2	a1, a2, a3, b1, b2, d1, d2
		• MOA, uses, adverse effects, chemical properties, SARs, chemical synthesis, and metabolism of: o Protein kinase inhibitors o Miscellaneous	1	2	a1, a2, a3, b1, b2, d1, d2
8	**Anthelmintics and antimycobacterial agents**	• Classification and modes of resistance. • MOA, uses, adverse effects, chemical properties, SARs, chemical synthesis, and metabolism.	1	2	a1, a2, a3, b1, b2, d1, d2
9	**Antiprotozoal agents**	• Classification and modes of resistance. • MOA, uses, adverse effects, chemical properties, SARs, chemical synthesis, and metabolism of: o Various antiprotozoal drugs	1	2	a1, a2, a3, b1, b2, d1, d2

		○ Antimalarial drugs			
10	**Final Exam**	Final Exam	1	2	
Number of Weeks /and Units Per Semester		**16**		**32**	

B – Case Studies and Practical Aspect: (if any)

Order	Tasks/ Experiments	Number of Weeks	contact hours	Learning Outcomes (CILOs)
1	Assay of Amoxicillin Capsule	1	2	c1, c2, d1, d2
2	Assay of Sulfasalazine Tablets	1	2	c1, c2, d1, d2
3	Assay of Dapsone Tablets	1	2	c1, c2, d1, d2
4	Synthesis of Hexamine	1	2	c1, c2, d1, d2
5	Synthesis of a sulfonamide antibacterial agent	1	2	c1, c2, d1, d2
6	Chemical synthesis and assay of selected drugs	1	2	c1, c2, d1, d2
7	Assay of hydrolyzed ampicillin tablets	1	2	c1, c2, d1, d2
8	Assay of hydrolyzed aspirin tablets	1	2	c1, c2, d1, d2
9	Chemical synthesis and assay of selected drugs	1	2	c1, c2, d1, d2
10	Chemical synthesis and assay of selected drugs	1	2	c1, c2, d1, d2
11	Chemical synthesis and assay of selected drugs	1	2	c1, c2, d1, d2
12	Chemical synthesis and assay of selected drugs	1	2	c1, c2, d1, d2
13	Chemical synthesis and assay of selected drugs	1	2	c1, c2, d1, d2
14	Chemical synthesis and assay of selected drugs	1	2	c1, c2, d1, d2
15	Final Exam	1	2	
Number of Weeks /and Units Per Semester		**15**	**30**	

VI. Teaching strategies of the course:

Lectures, Discussions, Simulated software program, Self-learning, Seminars, Lab Experiments

VII. 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 (Homework and class discussion activity)		1-12	5	5%	a1,a2,
2	Quiz 1		4	2.5	2.5%	a1,a2, ,b1,b2
3	Mid-semester exam of theoretical part (written exam)		8	10	10%	c1,c2,
4	Quiz 2		12	2.5	2.5%	c1,c2,
5	Lab. Term works	Attitude	1-14	5	5%	c1, c2,d1,d2
6		Accomplishments		5	5%	
7	Final exam (practical)		15	20	20%	c1, c2,d1,d2
8	Final exam of theoretical part		16	50	50%	a1,a2,b1,b2,c1, d1,d2
Total				100	100%	

VIII. Learning Resources:

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

1. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, 13th edition, J. N. Delgado and W. A. Remers, Lippincott, 2017.
2. Foye's Principles of Medicinal Chemistry, 7th edition, Thomas L. Lemke and David A. Williams, Lippincott Williams & Wilkins, 2013.

2- Essential References.

1. An Introduction to Medicinal Chemistry, 5th edition, Graham Patrick, Oxford University Press, 2013.
2. Kar, A. (2007). Advanced practical medicinal chemistry. New Age International.
3. Pedersen, O. (2006). Pharmaceutical Chemical Analysis: Methods for Identification and

Limit Tests. Ukraine: CRC Press.

3- Electronic Materials and Web Sites *etc*.

http://www.swissadme.ch/index.php

https://orgsyn.org/

https://www.ebi.ac.uk/chembl/

https://pubchem.ncbi.nlm.nih.gov/

https://go.drugbank.com/drugs/DB00605

https://guides.library.vcu.edu/c.php?g=47681&p=298306

Course Specification
Clinical Pharmacy I

*I. Course Identification and **General Information**:*						
1	**Course Title:**	**Clinical Pharmacy I**				
2	**Course Number & Code:**	PH1125158				
3	**Credit hours:**	C.H				TOTAL
		Th.	Seminar	Pr	Tr.	
		2		1		3
4	**Study Level/ Semester at which this Course is offered:**	**Level 5/ semester 1**				
5	**Pre –Requisite (if any):**	Physiology, pharmacology				
6	**Co –Requisite (if any):**					
7	**Program (s) in which the Course is Offered:**	Bachelor of Pharmacy				
8	**Language of Teaching the Course:**	English				
9	**Study System:**	semester				
10	**Mode of Delivery:**	Full Time				
11	**Location of Teaching the Course:**	Faculty of Medical Science Thamar university				
12	**Prepared by:**					
13	**Date of Approval:**					

*II. Course **Description**:*

This course provides the student with a overview in selected topics of clinical pharmacy. It makes the student familiar with common diseases and clinical situations they may encounter in their practical and professional life. The course focuses mainly on the etiology, epidemiology, pathophysiology, clinical features and laboratory tests and their interpretation the requirements of therapy of selected diseases. In addition, the selecting and applying medication, dose calculation, administering, monitoring and evaluating medication for drug interactions, side effects, as well as advising and educating patients are involved. The diseases of the following course include: cardiovascular disorders i.e. Hypertension, Heart Failure, Ischemic Heart Disease, Acute Coronary Syndromes, Arrhythmias, GIT and respiratory diseases, and Anemias.

Practical : The course also train the student to solve clinical cases and prevent drug-related problems. Student will visit hospital during the course to interact with other health professionals in relation to clinical case selection, discussion, presentation and reflection in an interprofessional environment.

*III. Aims and Intended learning outcomes (ILOs) of the **course**:*

1. Aims of The Course:

The overall aims of the course are:

1. *To provide the opportunity for the student to have direct contact with patients in clinical settings (hospital wards) and participate in associated Pharmacy experiences.*
2. *To enable the student to assimilate and apply her/his previously acquired pharmaceutical knowledge in a patient care environment.*
3. *To teach student the new patient oriented concept of pharmacy.*
4. *To focus on the duties of the student and how he is involved in the health team.*
5. *To train the student to solve clinical cases simulating actual situations in clinical pharmacy practice.*

2. Intended learning outcomes (ILOs) of the course:		
A. Knowledge And Understanding: • ***After successful completion the course, students will be able to:***		
(A) Alignment Course Intended Learning Outcomes of Knowledge and Understanding to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
a1- Define clinical pharmacy, patient care and medicine	• Lectures • Discussion Sessions • Assignments	• Periodic exam (Quizzes) • Home Assignments • Exams
a2- Recognize how effectively take the patient history.		
a3- Recognize the Clinical features & laboratory tests and their interpretations for each case study .		
a4- Understand the epidemiology, etiology, risk factors for cardiovascular diseases.		
a5- Mention in details, the therapeutic approaches, both non-pharmacological and pharmacological, for CV, GI ,and respiratory diseases		
a6- Identify the mechanism of action, side effects, drug interactions of the drugs used in the treatment of the condition under study		
(B) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
b1- Interpret the clinical features, and LAB investigations and the diseases related to them.	• Discussion Sessions • Problem solving • Group Discussion	• Oral presentations • Home assignments
b2- Select the drug of choice for treatment of CV diseases .		
b3- Assess the influence of some physiological parameters on the use of drugs for treatment of asthma and anemia		
b4- Access and evaluate literature to solve drug-related problems		
b5- Select and justify the most appropriate therapeutic options for GI tract diseases		
©Alignment Course Intended Learning Outcomes of Professional and Practical Skills to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
c1-Collect and appraise patient	• Discussion	• Oral presentations

specific data from case scenarios with increasing degrees of difficulty over the duration of the course	Sessions • Assignments	• Exams • LAB report
c2- Give advises for the patients and others on the safe and effective use of medicines		
c3- Formulate and justify therapeutic plans to solve and prevent drug-related problems		
c4- Formulate and justify monitoring plans .		
c5- Summarize and document therapeutic plans for specific patients		

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

Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
d1- Interact effectively with patients, the public and health care professionals; including communication both written and oral.	• *iscussion Sessions* • *ssignments that require collecting information from the internet.*	• *ral presentations* • *riting*
d2- Give effective decisions concerning drug regimen		
d3- Organize himself for continuous education and long-life learning.		

IV. Course Content:

A. Theoretical Aspect:

Order	Units/Topics List	Sub Topics List	Number of Week	contact hours	ILOs
1	**Introduction in Clinical Pharmacy**	- *Definition* - *Difference between pharmaceutical care and clinical pharmacy* - *Difference between pharmacy and clinical pharmacy* - *Level of action of Clinical Pharmacists* - *Activities of clinical pharmacists* - *Etiology , Pathologenesis, Pathophysiology, Epidemiology*	1	2	**a1,a2,a3**
	Taking Patient's History	- *Clinical manifestations* - *Interpretation of clinical laboratory tests* - *Diagnosis* - *Management (Aims, Modes,*	1	2	**a2, a3,b1, c1,**

		Monitoring) *- Prognosis* *- Interpretation of clinical laboratory tests*			
2	**Cardiovascular diseases (CVD)**	**Hypertension**	1	2	a4,a5,a6 b2,b4, d2
3		*- Ischemic heart diseases (IHD)* *○ Angina* *○ Myocardial Infraction (MI)*	2	4	
4		Congestive heart failure (CHF)	1	2	
5		Arrhythmia	1	2	
6	**GI tract disorders**	Peptic Ulcer	1	2	a5,a6,b1,b5, d3
7		Nausea and Vomiting	1	2	
8		Constipation and Diarrhea	1	2	
9		Irritant bowel Syndrome	1	2	
10	**Respiratory disorders**	Bronchial Asthma and COPD	1	2	a5, a6,b3,b3,b4, c3,d1
11		Cough	1	2	
12	**Anemia**		1	2	b1, b3,b4,d1
Number of Weeks /and Units Per Semester			**14**	**28**	

B. Practical Aspect: (if any)

Order	Tasks/ Experiments	Number of Weeks	contact hours	ILOs
1	Take patient history ○ *Students will be introduced to the different forms that are used in interviewing patients*	1	**2**	c1,c5
2	LAB investigation interpretation	1	**2**	c1, c5
3	Cases study in CV diseases (hypertension, angina, arrhythmia, heart failure	3	**6**	c2,c3,c4
4	Cases study in GIT disorders	**3**	**6**	c2,c3,c4
5	Cases study in respiratory disorders	**3**	**6**	c2,c3,c4
6	Case study in anaemia	**1**	**2**	c2,c3,c4
7	Review	**1**	**2**	c2,c3,c4
Number of Weeks /and Units Per Semester		**13**	**26**	

V. Teaching strategies of the course:
• *Lectures*
• *Search topic and discussion sessions*
• *LAB Class*
• *Media Presentations: Power Point, Video*
• *Assignments*

VI.	*Assignments:*				
no	**Assessment Tasks**	**Week Due**	**Mark**	**Proportion of Final Assessment**	**Aligned CILOs(symbols)**
1	**Participation, quizzes**	Each week	5	5%	a1, a2, a4, b1,b2, c3,d2
2	**Research, assignments**	6th week	5	5%	a1, a3, b1, b2, c4, d2
3	**Mid – Exam (theoretical)**	7th week	20	20%	a1.a2,a3, b1,b2, d2
4	**Final Exam (practical)**	15th week	30	30%	a1.a2,a3, b1,b2, c5, d1,d2
5	**Final Exam (theoretical)**	16th week	40	40%	a1.a2,a3, b1,b2, d3
	Total		100	100%	

VII. *Learning Resources:*

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

1. *Pharmacotherapy - a pathophysiologic approach 8th edition*
2. *Drug Information Hand book.*

2. Recommended Readings and Reference Materials.

1. *Clinical pharmacy and hospital drug management by: Lawson.*
2. *Developing clinical practice skills for pharmacists by: Kimberly Galt.*

3. Essential References.

1. *Pharmacy practice Manual (The classification system approved in the manual is Aburuzet al classification system)*
2. *Pharmaceutical Care Practice: The Patient-Centered Approach to Medication Management Services (3rd e Cipolle, RJ, Strand, LM, & Morley, PC, McGraw-Hill, 2012.*

4. Electronic Materials and Web Sites *etc*.

- www.PubMed.com
- ***www.uptodate.com (for drug-drug interactions)***
- ***www.guideline.gov***
- *http://www.medscape.com/druginfo/druginterchecker?src=ads*

5. Other Learning Material.

- *Data show projector*

VIII. *Course Policies:*

1 **Class Attendance:**

- Absence from lectures and/or tutorials shall not exceed 25%. Students who exceed the 25% limit without a medical or emergency excuse acceptable to and approved by the Dean of the relevant college shall not be allowed to take the final examination and shall receive a mark of zero for the course.

2 **Tardy:**

- Students should be attending the classes as its required for the assessments if the student is 15 minutes late in attending to the class for more than two classes he will loss 50% of quizzes mark.

3 **Exam Attendance/Punctuality:**

- All examination and their roles will be according to Students affairs regulations

4 **Assignments & Projects:**

- Student who is submitting the assignments or the projects on time, will be awarded good percentage

	in grading of participation.
5	**Cheating**: - All students must be an ideal behavior and respect each other, their teachers and respect the roles of the colleague. In addition, students should follow safety roles while working in the lab. Those who has been caught in any cheating case will be punished according to the Students affairs regulations
6	**Plagiarism**: □ Student will be punished depend upon gravity of the action and according to Students affairs regulations which might be ranged from rewriting the homework to suspension or dismissal
7	**Other policies:** - Using mobile or another electronic device capable to store or transfer data in class during the lecture or the exam is forbidden.

Council of Academic Accreditation &

Quality Assurance of Higher Education (CAQA)

مركز التطوير الأكاديمي وضمان الجودة
Center of Academic Development and Quality Assurance

Faculty of Medical sciences

Department of Pharmacy

Program of B. Pharmacy

Course Specification of

Pharmacy Legislation and Ethics

Course Code. (PH1123263)

2024

I. General Information:

1.	**Course Title:**	**Pharmacy Legislation and Ethics**				
2.	**Course Code:**	**PH1123263**				
3.	**Course Type:**	**Compulsory course**				
4.	**Credit Hours:**	**Credit Hours**	**Theory Contact Hours**		**Practical Contact Hours**	
			Lecture	**Tutorial/ Seminar**	**Lab**	**Clinical**
		2	2	--		--
5.	**Level/ Semester at which this Course is offered:**	Fifth Level / First Semester				
6.	**Pre –Requisite (if any):**	Pharmaceutics III, Pharmacology IV amd Toxicology				
7.	**Co –Requisite (if any):**	------				
8.	**Program (s) in which the Course is Offered:**	Bachelor of pharmacy				
9.	**Language of Teaching the Course:**	English				
10.	**Location of Teaching the Course:**	Faculty of Medical Science, Thamar University				
11.	**Prepared by:**	Dr. Abdulkarim K. Alzomor				
12.	**Reviewed By:**					
13.	**Date and Number of Approval by Council:**					

II. Course Description:

This course will give students a general understanding of the laws and regulations that govern pharmacy practice. This course will also cover the ethical principles governing the pharmacy technician and the roles they play in a practice setting.

III. Course Intended Learning Outcomes (CILOs) :

Upon successful completion of the course, students will be able to:		I, P or M/A	Referenced PILOs	
A. Knowledge and Understanding:				
a1	Illustrate the law and code of ethics for pharmacists.	**M**	**A6**	Recall pharmaceutical laws & legislations & as well as, ethics of pharmacy profession.
a2	Explain the dispense of drugs and narcotics ethically and importance of the pharmacist's final check in reducing medication errors.	**M**	**A8**	High accurately, determines the pathological conditions & their symptoms & the medicines used in their treatment, as well as, the drug interactions & their side effects.
B. Intellectual Skills:				
b1	Differentiate between acts, regulations and rules.	**M**	B6	Clearly distinguishes between the rational use or misuse and illegal for medicines & narcotic preparations
C. Professional and Practical Skills:				
c1	Analyze drugs according to restrict regulations and ethically use marketing skills for promoting.	**M**	**C2**	Applies the concepts of pharmacovigilance in the dispensing and the preparation, storage and distribution of medicines safely and effectively.
c2	Dispense the narcotics drug ethically	**M**	**C5**	Effectively communicate, with patients and the healthcare team

	according to the regulation.			about the safety use of medicines
	D. Transferable Skills:			
d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team	**M**	**D6**	Efficiently contribute in continuance of the continuous education & improvement of his self-abilities
I= Introduced, P=Practiced or M/A= Mastered/Advanced				

IV. Alignment of Course Intended Learning Outcomes

(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	Illustrate the law and code of ethics for pharmacists.	- Lectures and Groups discussion. - Self – learning	▪ Quizzes, Presentation and Written exam.
a2	Explain the dispense of drugs and narcotics ethically and importance of the pharmacist's final check in reducing medication errors.		

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

	Course Intended Learning Outcomes	Teaching Strategies	Assessment Strategies
b1	Differentiate between acts, regulations and rules.	- Dialogue and discussion - solving Problem	- Quizzes, Homework

(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	Analyze drugs according to restrict regulations and ethically use marketing skills for promoting.	- Lectures - Simulation & presentations	▪ Performance, Report
c2	Dispense the narcotics drug ethically according to the		

	regulation.		

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

	Course Intended Learning Outcomes	Teaching Strategies	Assessment Strategies
d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team	- Self – learning - Cooperative learning	- Homework's evaluation. ▪ Evaluation of Research reports

V. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1	**Law of pharmacy practice**	• Definitions, Introduction to Laws governing the practice of Pharmacy and sources of the Patrice of Pharm. • Registration of a controlled substances • Legal sanitary requirements for pharm. organizations • establishment	3	6	a1, a2, c1, c2, d1
2	**Drug abuse and Misuse of drug Act**	• Drug Abuse prevention and controlled Act (The misuse of drug Act): -Introduction and important definitions, types. -Schedules: introduction and	2	4	a1, a2, c1, c2, d1

		types			
3	**Poisons Act and Dangerous substances**	• Poisons: Definition and poisons list, • Dangerous substances and consumer Protection: ○ Definitions • list of dangerous substances Regulation	1	2	a1, a2, c1, c2, d1
4	Ministerial (National and Arabic) regulations	Types, definitions, differences	1	2	a2, c1, c2, d1
5	Mid Exam		1	2	a1, a2, b1, c1,
6	Syndicate of pharmacists and Other medical organizations	WHO and FIP and others	1	2	a1, a2, c1, c2, d1
7	Code of ethics	Professional Registration and • Regulation	1	2	a1, a2, c1, c2, d1
8	Ethics and professionalism	Prescription vs. OTC drugs, Generic substitution, and filling Prescriptions, Pharmacy practice problems, Local legal and professional to pharmacy practice regulation, new legal and professional to pharmacy practice, Applying Ethical Principles and Rules • regulation	5	10	a1, a2, c1, c2, d1
10	**Final exam**		**1**	2	a1, a2,

				b1, c1, d1
Number of Weeks /and Units Per Semester		**16**	**32**	

VI. Assignments:

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)
1	**Assignment 1: Attendance**	1-14	10	a1, a2, b1, c1, c2, d1
2	**Assignment 2: Homework, Research & Quizzes.**	6&12	10	a1, a2, b1, c1, c2, d1
Total			**20**	

VII. 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**	1-14	20	20%	a1, a2, b1, c1, c2, d1
2	**Mid-Term Theoretical Exam**	8	30	30%	a1, a2, b1, c1
5	**Final Theoretical Exam**	16	50	50%	a1, a2, b1, c1, c2, d1
Total			**100**	**100%**	

VIII. Learning Resources:

- *Written in the following order:* Author, Year of publication, Title, Edition, Place of publication, Publisher.

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

1. Abood RR. Pharmacy Practice and the Law, 6th Edition. Sudbury, MA: Jones and Bartlett Publishers5,; 2010. (ISBN-13: 978-0-7637-8129-3).
2. Veatch RM & Haddad A. Case Studies in Pharmacy Ethics, 2nd Edition. New York, NY: Oxford University Press; 2008. (ISBN-13: 978-0-19-530812-9).

2- Essential References.

1. Reiss BS & Hall GD. Guide to Federal Pharmacy Law, 7th Edition. Delmar, NY: Apothecary Press; 2010. (ISBN-13: 978-0967633268).
2. Garner BA, ed. Black's Law Dictionary, 3rd Pocket Edition. St. Paul, MN: West Group; 2001. (ISBN-10: 0314158626; ISBN-13: 978-0314158628)

3- Electronic Materials and Web Sites *etc.*

1. http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.

IX. 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 Medical Science

Department of Pharmacy

Program of B. Pharmacy

Course Plan (Syllabus) of

Pharmacy Legislation and Ethics

Course Code. PH1123263

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	

2024

II. Course Identification and General Information:

1.	**Course Title:**	Pharmacy **Legislation and Ethics**				
2.	**Course Code:**	PH1123263				
3.	**Course Type:**	Compulsory **course**				
4.	**Credit Hours:**	**Credit Hours**	**Theory Contact Hours**		**Practical Contact Hours**	
			Lecture	**Tutorial/ Seminar**	**Lab**	**Clinical**
		2	2	--		--
5.	**Level/ Semester at which this Course is offered:**	Fifth Level / First Semester				
6.	**Pre –Requisite (if any):**	Pharmaceutics III, Pharmacology IV amd Toxicology				
7.	**Co –Requisite (if any):**	------				
8.	**Program (s) in which the Course is Offered:**	Bachelor of pharmacy				
9.	**Language of Teaching the Course:**	English				
10.	**Location of Teaching the Course:**	Faculty of Medical Science, Thamar University				
11.	**Prepared by:**	Dr. Abdulkarim K. Alzomor				
12.	**Reviewed By:**					
13.	**Date and Number of Approval by Council:**					

III. Course Description:

This course will give students a general understanding of the laws and regulations that govern pharmacy practice. This course will also cover the ethical principles governing the pharmacy technician and the roles they play in a practice setting.

IV. Course Intended Learning Outcomes (CILOs) :

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

A. Knowledge and Understanding:	
a1	Illustrate the law and code of ethics for pharmacists.
a2	Explain the dispense of drugs and narcotics ethically and importance of the pharmacist's final check in reducing medication errors.
B. Intellectual Skills:	
b1	Differentiate between acts, regulations and rules.
C. Professional and Practical Skills:	
c1	Analyze drugs according to restrict regulations and ethically use marketing skills for promoting.
c2	Dispense the narcotics drug ethically according to the regulation.
D. Transferable Skills:	
d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team

V. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
1	**Law of pharmacy practice**	• Definitions, Introduction to Laws governing the practice of Pharmacy and sources of the Patrice of Pharm. • Registration of a controlled substances • Legal sanitary requirements for pharm. organizations • establishment	3	6
2	**Drug abuse and Misuse of drug Act**	Drug Abuse prevention and controlled Act (The misuse of drug Act): -Introduction and important definitions, types. -Schedules: introduction and types	2	4
3	**Poisons Act and Dangerous substances**	• Poisons: Definition and poisons list, • Dangerous substances and consumer Protection: o Definitions • list of dangerous substances Regulation	1	2
4	Ministerial (National and Arabic) regulations	Types, definitions, differences	1	2
5	Mid Exam		1	2
6	Syndicate of pharmacists and	WHO and FIP and others	1	2

	Other medical organizations			
7	Code of ethics	• **Professional** Registration and • Regulation	1	2
8	Ethics and professionalism	• **Prescription** vs. OTC drugs, Generic substitution, and filling Prescriptions, Pharmacy practice problems, Local legal and professional to pharmacy practice regulation, new legal and professional to pharmacy practice, Applying Ethical Principles and Rules • regulation	5	10
10	Final exam		**1**	2
Number of Weeks /and Units Per Semester			16	32

VI. : Teaching Strategies of the Course:

(A) (Knowledge and Understanding)

- Lectures and Groups discussion.
- Self – learning

(B) (Intellectual Skills)

- Dialogue and discussion
- solving Problem

(C) (Professional and Practical Skills)

- Lectures
- Simulation & presentations

(D) (Transferable Skills)

- Self – learning

- Cooperative learning

VII. Assessment Methods of the Course:

(A) (Knowledge and Understanding)

- Quizzes, Presentation and Written exam.

(B) (Intellectual Skills)

- Quizzes, Homework

(C) (Professional and Practical Skills)

- Performance, Report

(D) (Transferable Skills)

- Homework's evaluation.
- Evaluation of Research reports

VIII. Assignments:

No.	Assignments	Week Due	Mark
1	**Assignment 1:** Attendance	1-14	10
2	**Assignment 2:** Homework**, Research & Quizzes.**	6&12	10
Total			**20**

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

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment
1	**Assignments**	1-14	20	20%
2	**Mid-Term Theoretical Exam**	8	30	30%

5	**Final Theoretical Exam**	16	50	50%
Total				

X. Learning Resources:

- *Written in the following order: Author, Year of publication, Title, Edition, Place of publication, Publisher.*

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

Abood RR. Pharmacy Practice and the Law, 6th Edition. Sudbury, MA: Jones and Bartlett Publishers5,; 2010. (ISBN-13: 978-0-7637-8129-3).

Veatch RM & Haddad A. Case Studies in Pharmacy Ethics, 2nd Edition. New York, NY: Oxford University Press; 2008. (ISBN-13: 978-0-19-530812-9).

2- Essential References.

1- Reiss BS & Hall GD. Guide to Federal Pharmacy Law, 7th Edition. Delmar, NY: Apothecary Press; 2010. (ISBN-13: 978-0967633268).

2- Garner BA, ed. Black's Law Dictionary, 3rd Pocket Edition. St. Paul, MN: West Group; 2001. (ISBN- 10: 0314158626; ISBN-13: 978-0314158628)

3- Electronic Materials and Web Sites etc.

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.

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

Course Specification Community Pharmacy

I. Course Identification and General Information:

1	**Course Title:**	Community Pharmacy				
2	**Course Code &Number:**	PH1125167				
3	**Credit hours:**	C.H				TOTAL
		Th.	Seminar	Pr.	Tr.	
		2				2
4	**Study level/ semester at which this course is offered:**	5th Level / 1st semester				
5	**Pre –requisite (if any):**					
6	**Co –requisite (if any):**					
7	**Program (s) in which the course is offered:**	Bachelor of Pharmacy				
8	**Language of teaching the course:**	English				
9	**Location of teaching the course:**	Faculty of Medical Sciences, Themar University				
10	**Prepared By:**	Dr. Abdulkarim Kassem Alzomor				
11	**Date of Approval**	**2021**				

II. Course Description:

This course is covers the basic knowledge and skills that are required to practice pharmacy in community settings. It provides well-structured guide to making differential diagnosis for different body system carried out by the community pharmacist..

III. Course Objectives

1. To understand the organizational structure and management of community pharmacy
2. To learn the student the various roles of pharmacists in the delivery of health care services in community pharmacy practice settings .
3. To provide the student with the methods of patient assessment and care as they relate specifically to the drug and non -drug management of minor ailments

IV. Course Intended Learning Outcomes (CILOs):

Knowledge and Understanding:

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

After completing the course, the student will be able to:

Knowledge and Understanding PILOs		**Knowledge and Understanding CILOs**	
After completing this program, students would be able to:		**After completing this course, students would be able to:**	
A1	Explain the fundamentals of general sciences, the basic and biomedical sciences, and their relations to pharmacy profession.	a1	Explain the roles of community pharmacist at the community setting..
A4	Define basic principles of drug: target identification, design, informatics, and mechanisms of action.	a2	Recognize signs and symptoms of simple illness, as well as, differentiate between the simple aliments and major diseases

Intellectual Skills :

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

After completing the course, the student will be able to:

Intellectual Skills PILOs		Intellectual Skills CILOs	
After completing this program, students would be able to:		After completing this course, students would be able to:	
B1	Classify the synthetic and natural drugs according to their mechanism of action, systemic effect, therapeutic uses, contraindication and toxicity	b1	Identify between simple and severe illness, in order to treat the patient with suitable OTC drugs; or make referral for the physician when needed.
B4	Select drug therapy regimen using mathematical, genomic, clinical pharmacokinetic and pharmacodynamics principles for optimizing the patient therapy and medication safety	b2	Recall methods of patients assessment for symptoms in the Community Pharmacy to verify the degree of illness and hence treatment by non-prescription or prescription medications

Professional and Practical Skills

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

After completing the course, the student will be able to:

Professional and Practical Skills PILOs		Professional and Practical Skills CILOs	
After completing this program, students would be able to:		After completing this course, students would be able to:	
C1	Handle the chemical, biological, and pharmaceutical materials safely	c1	Apply the most effective, safe and economic non-prescription medications based on best data to ensure patient's drug related needs

Transferable (General) Skills :

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

After completing the course, the student will be able to:

d1 Communicate effectively and behave in discipline with colleagues.
d2 Develop his skills in the field of pharmacokinetics by using new technology in this field.
d3 Participate efficiently with colleagues in a team work

Transferable (General) Skills PILOs		Transferable (General) Skills CILOs	
After completing this program, students would be able to:		After completing this course, students would be able to:	
D1	Communicate effectively and behave in discipline with colleagues.	d1	Communicate effectively and behave in discipline with colleagues.
D2	Develop his skills in the field of pharmacokinetics by using new technology in this field.	d2	Develop his skills in the field of pharmacokinetics by using new technology in this field.
D3	Work effectively individually and in a team	d3	Participate efficiently with colleagues in a team work

V. Alignment Course Intended Learning Outcomes

(A) Alignment Course Intended Learning Outcomes of Knowledge and Understanding to Teaching Strategies and Assessment Strategies:

Course Intended Learning Outcomes		Teaching strategies	Assessment Strategies
a1	Explain the roles of community pharmacist at the community setting..	- Lectures, Discussions - Self - learning	- Quizzes, Written exam

a2	Recognize signs and symptoms of simple illness, as well as, differentiate between the simple aliments and major diseases		

(B) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and Assessment Strategies:

Course Intended Learning Outcomes		Teaching strategies	Assessment Strategies
b1	Identify between simple and severe illness, in order to treat the patient with suitable OTC drugs; or make referral for the physician when needed.	- Discussions and - Training - Problem solving	- Quizzes, Homework - Observation - Task's Evaluates
b2	Recall methods of patients assessment for symptoms in the Community Pharmacy to verify the degree of illness and hence treatment by non-prescription or prescription medications.		

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

Course Intended Learning Outcomes		Teaching strategies	Assessment Strategies
c1	Apply the most effective, safe and economic non-prescription medications based on best data to ensure patient's drug related needs	- Discussions and Training	- Quizzes, Homework - Observation

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

Course Intended Learning Outcomes		Teaching strategies	Assessment Strategies
d1	Communicate effectively and behave in discipline with colleagues.	- Group discussions - Cooperative learning. - Self – learning - Inductive and deductive	- Homework -Evaluates of Oral Presentation
d2	Participate efficiently with colleagues in a team work.		

I. Course Content**:**

A. Theoretical Aspect:

Order	Topic List / Units	Sub Topics List	Week Due	Contact Hours	ILOs
1	• Introduction to community pharmacy practice	- Definition - Roles of community pharmacist - Adverse drug effects - Drug –drug interaction	**2**	**4**	a1 ,a2**,b1**
2	• Over the counter drugs (OTC)	- Introduction - Types	**1**	**2**	a1, a2, b1, b2, c1, d1, d2
3	• Respiratory system	- Common cold & Influenza - Cough - Sore throat - Allergic Rhinitis	**2**	**4**	a1, a2, b1, b2, c1, d1, d2
4	• **Gastroenterology**	- Mouth ulcers - Heart burn - Nausea and vomiting - Diarrhoea	**1**	**2**	a1, a2, b1, b2, c1, d1, d2
5	• **Gastroenterology**	- Constipation - Irritable bowel syndrome (IBS) - Haemorrhoids	**1**	**2**	a1, a2, b1, b2, c1, d1, d2
6	• Worm infections	- Giardiasis, and amoebiasis, - Roundworm, and pinworm	**1**	**2**	a1, a2, b1, b2, c1, d1, d2
7	• Dermatology	- Scabies and head lice - Fungal infections and athlete’s foot	**1**	**2**	a1, a2, b1, b2, c1, d1, d2
8	• Dermatology	- Nappy rash - Hair loss and Dandruff	**1**	**2**	a1, a2, b1, b2, c1, d1, d2
9	• Central nervous system • Musculoskeletal conditions	- Pain (headache and migraine) - Insomnia - Acute low back pain	**1**	**2**	a1, a2, b1, b2, c1, d1, d2
10	• Women’s health	- Cystitis - Vaginal thrush - Dysmenorrhoea - Oral contraceptive	**1**	**2**	a1, a2, b1, b2, c1, d1, d2
11	• Ear problems	- Earache, Ear wax, Otitis externa	**1**	**2**	a1, a2, b1, b2, c1, d1, d2

12	• Eye conditions	- Red eye, Eyelid disorders	**1**	**2**	a1, a2, b1, b2, c1, d1, d2
	Number of Weeks /and Units Per Semester		**14**	**28**	

V. Teaching strategies of the course:

- Lectures, Discussions and Exercises.
- Group discussions
- Field visits
- Problem solving
- Simulation & Practical presentations
- Self-learning
- Cooperative learning, Training

VI. Assignments:

No	Assignments	Aligned CILOs(symbols)	Week Due	Mark
1	Class attendance and participation	a1, a2,b1, c1, d1, d2,	weekly	5
2	Reports on kinetics some drugs	a2, b2, c1, d1,d2	12	5
3	Exercises and home work	a1, b1, b2, c1, c2, d1, d2	weekly	5

I.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	1-13	15	15%	a1, a2,b1, b2, c1, d1, d2,
2	Quizzes 1	5	2.5	2.5%	a1, b1

3	Mid-semester exam of theoretical part (written exam	8	20	20%	a1, a2, b1
6	Quizzes 2	11	2.5	2.5%	a2, b2, c1
7	Final exam of theoretical part (written exam)	16	60	60%	a1, a2, b1, b2, c1, d1, d2
Total			100	100%	

VII. Learning Resources:

- *Written in the following order: (Author - Year of publication – Title – Edition – Place of publication – Publisher).*

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

2.Paul Rutter. Community pharmacy, symptoms, diagnosis, and treatment &pharmacy practice . 4th edition, 017 Elsevier Ltd.

3.Jon Waterfield, Community Pharmacy Handbook , London & Chicago, pharmaceutical press , latest edition

2- Essential References.

1. A. BLENKINSOPP, P. PAXTON, J. BLENKINSOPP. Symptoms in the Pharmacy, A Guide the Management of Common Illness. 7 edition, 2014 John Wiley & Sons Ltd, Aptara Inc., New Delhi, India.

3- Electronic Materials and Web Sites *etc.*

- www.sciencedirect.com
- www.pubmed.com

Council of Academic Accreditation & Quality Assurance of Higher Education (CAQA)

مركز التطوير الأكاديمي وضمان الجودة
Center of Academic Development and Quality Assurance

Faculty of Medical Sciences

Department of Pharmacy

Program of Bachelors Pharmacy

Course Specification of

Pharmaceutical Biotechnology

Course Code. (PH1125128)

2024

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

I. General Information:

1.	Course Title:	Pharmaceutical Biotechnology				
2.	Course Code:	PH1125128				
3.	Course Type:					
4.	Credit Hours:	Credit Hours	Theory Contact Hours		Practical Contact Hours	
			Lecture	Tutorial/ Seminar	Lab	Clinical
		2	2	--		--
5.	Level/ Semester at which this Course is offered:	Fifth Level / First Semester				
6.	Pre –Requisite (if any):	Pharmaceutics III, Microbiology II and Pharmacology IV				
7.	Co –Requisite (if any):	------				
8.	Program (s) in which the Course is Offered:	Bachelor of pharmacy				
9.	Language of Teaching the Course:	English				
10.	Location of Teaching the Course:	Faculty of Medical Science				
11.	Prepared by:	Dr. Abdulkarim K. Alzomor				
12.	Reviewed By:					
13.	Date and Number of Approval by Council:					

II. Course Description:

This course aim to covers various techniques in biotechnology and their applications in the manufacturing of biopharmaceuticals and biomedical research, major biotechnology products and bioconversion processes, biodegradation and bioremediation, principle of gene therapy, genetic engineering (applications; recombinant DNA technology; DNA cloning, hybridizations and sequencing).

III. Course Description:

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	Explain techniques and methodologies for the synthesis of pharmaceutical biotechnology.	**M**	**A4**	High accuracy identifies the physical & chemical properties & the toxic effects of various materials used in the preparation of medicines whether effective & ineffective.
a2	Recognize the biotechnology principles in development of new pharmaceutical biotechnology products.	**M**	**A5**	Enumerate correctly the principles of pharmacokinetics & biopharmaceutics & and their applications in pharmacological therapy.
B. Intellectual Skills:				
b1	Design different types of safe and effective pharmaceutical biotechnology drugs.	**M**	**B5**	Carefully analyzes, the doses & pharmacokinetics by using calculations & statistical methods &information techniques.
C. Professional and Practical Skills:				
c1	Search for information using electronic sources of information for pharmaceutical biotechnology	**M**	**C4**	Efficiently operates, the different technologies and equipment in the area of pharmacy.
D. Transferable Skills:				

d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team	**M**	**D1**	Works effectively in a unique team.
d2	Employ the technologies services to solve problems of pharmaceutical calculation and develop skills.	**M**	**D2**	Correctly uses, the means of the technology, information, programs of computer and the statistical programs, which contribute in raising the health level.
I= Introduced, P=Practiced or M/A= Mastered/Advanced				

IV. Alignment of Course Intended Learning Outcomes

(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	Explain techniques and methodologies for the synthesis of pharmaceutical biotechnology.	- Lectures and Groups discussion. - Self – learning	▪ Quizzes, and Written exam.
a2	Recognize the biotechnology principles in development of new pharmaceutical biotechnology products.		

(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 different types of safe and effective pharmaceutical biotechnology drugs.	- Dialogue and discussion - solving Problem	- Quizzes, Homework

(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 for information using electronic sources of information	- Lectures - Simulation & presentations	▪ Performance, Report

	for pharmaceutical biotechnology		

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

	Course Intended Learning Outcomes	Teaching Strategies	Assessment Strategies
d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team	- Self – learning - Cooperative learning	- Homework's evaluation. ▪ Evaluation of Research reports
d2	Employ the technologies services to solve problems of pharmaceutical calculation and develop skills.		

V. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1	Principles of Biotechnology	• Definition, History and Areas of Biotechnology	1	2	a1, a2
2	**Biocatalysts**	Biocatalysts, Bioreactors and Fermentation Technology	1	2	a1, b1, c1
3	Molecular Biotechnology	- Definition - Basics: Informational Bio-molecules - Gene Expression - DNA Extraction and Gel Electrophoresis - Cutting and Joining DNA Molecules - Gene Cloning and	2	4	a1, b1, c1, d1, d2

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
		Expression Systems • PCR and PCR-Applications			
4	Monoclonal Antibodies MAbs	- Immunoglobulin structure - Polyclonal and monoclonal antibodies - Production of monoclonal antibodies - Hybridoma technology - MAbs applications	1	2	a1, a2, b1, c1,
5	Vaccine technology	- Traditional vaccine preparations - The development of vaccines - The impact of genetic engineering on vaccine technology - Vaccine vectors - Vaccine clinical trial process Liposome and virosome technology	2	4	a1, a2, c1and d2
6	- Mid Exam		1	2	a1, a2, b1, c1
7	Process Economics, Optimization and Downstream Processing	- Optimization In Biotechnology Applications - Environmental factors affecting the response Optimization of the factors affecting the response	1	2	a1, a2, c1and d1
8	Antibiotics, Hormones and cytokines production	1- Production of antibiotics 2- Cytokines families - Interferons - Interleukins 3- Manufacturing steps of	3	6	a1, b1, c1

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
		interferons 4- Applications of intereferons 5- Interleukins production 6- Large scale drug production • 7- Production of Insulin and Growth hormones			
9	Bio Informatics	• Definition, Aims and Components • Biological Databases • Molecular Bioinformatics - Public organizations - Gateways to databases - Applications • Pharmaceutical Bioinformatics Drug Databases • Applications	2	4	a2, c1
10	Common industrial microbial products	1- Products of direct microbial fermentation • 2- Products from recombinant proteins.	1	2	a2, c1
11	**Final exam**		**1**	2	a1, a2, b1, c1, d1, d2
Number of Weeks /and Units Per Semester			**16**	**32**	

VI. Assignments:

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)
1	**Assignment 1: Attendance**	1-14	10	a1, a2, b1, c1, d1, d2
2	**Assignment 2: Homework, Research & Quizzes.**	6&12	10	a1, a2, b1, c1, d1, d2
Total			**20**	

VII. 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**	1-14	20	20%	a1, a2, b1, c1, d1, d2
2	**Mid-Term Theoretical Exam**	8	30	30%	a1, a2, b1.
5	**Final Theoretical Exam**	16	50	50%	a1, a2, b1, c1, d1, d2
Total			**100**	**100%**	

VIII. Learning Resources:

- *Written in the following order:* Author, Year of publication, Title, Edition, Place of publication, Publisher.

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

1. Gary Walsh, John Wiley and Sons Ltd, (2007). Pharmaceutical Biotechnology: Concepts and Applications, England.
2. James Swarbrick, (2006). Encyclopedia of Pharmaceutical Technology, Volume 1, edited by Pharmaceu Tech, Inc. Pinehurst, USA.

2- Essential References.

1. Williams and Wilkins, (2005). Remington; the Science and Practice of Pharmacy, first edition.
2. Patrick J. Sinko (2006). Martin's Physical Pharmacy and Pharmaceutical Sciences.

3- Electronic Materials and Web Sites *etc.*

1. www. Pharmaceutical manufacturing process.com

IX. 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 Medical Sciences

Department of Pharmacy

Program of Bachelors Pharmacy

Course Plan (Syllabus) of

Pharmaceutical Biotechnology

Course Code. PH 1125128

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	

2024

II. Course Identification and General Information:

1.	**Course Title:**	Pharmaceutical Biotechnology				
2.	**Course Code:**	PH1125128				
3.	**Course Type:**					
4.	**Credit Hours:**	**Credit Hours**	**Theory Contact Hours**		**Practical Contact Hours**	
			Lecture	**Tutorial/ Seminar**	**Lab**	**Clinical**
		2	2	--		--
5.	**Level/ Semester at which this Course is offered:**	Fifth Level / First Semester				
6.	**Pre –Requisite (if any):**	Pharmaceutics III, Microbiology II and Pharmacology IV				
7.	**Co –Requisite (if any):**	------				
8.	**Program (s) in which the Course is Offered:**	Bachelor of pharmacy				
9.	**Language of Teaching the Course:**	English				
10.	**Location of Teaching the Course:**	Faculty of Medical Science				
11.	**Prepared by:**	Dr. Abdulkarim K. Alzomor				
12.	**Reviewed By:**					
13.	**Date and Number of Approval by Council:**					

III. Course Description:

This course aim to covers various techniques in biotechnology and their applications in the manufacturing of biopharmaceuticals and biomedical research, major biotechnology products and bioconversion processes, biodegradation and bioremediation, principle of gene therapy, genetic engineering (applications; recombinant DNA technology; DNA cloning, hybridizations and sequencing).

IV. Course Intended Learning Outcomes (CILOs) :

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

	A. **Knowledge and Understanding:**
a1	Explain techniques and methodologies for the synthesis of pharmaceutical biotechnology.
a2	Recognize the biotechnology principles in development of new pharmaceutical biotechnology products.
	B. **Intellectual Skills:**
b1	Design different types of safe and effective pharmaceutical biotechnology drugs.
	C. **Professional and Practical Skills:**
c1	Search for information using electronic sources of information for pharmaceutical biotechnology
	D. **Transferable Skills:**
d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team
d2	Employ the technologies services to solve problems of pharmaceutical calculation and develop skills.

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

V. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
1	**Principles of Biotechnology**	• Definition, History and Areas of Biotechnology	1	2
2	**Biocatalysts**	Biocatalysts, Bioreactors and Fermentation Technology	1	2
3	**Molecular Biotechnology**	• Definition • Basics: Informational Bio-molecules • Gene Expression • DNA Extraction and Gel Electrophoresis • Cutting and Joining DNA Molecules • Gene Cloning and Expression Systems • PCR and PCR-Applications	2	4
4	Monoclonal Antibodies MAbs	- Immunoglobulin structure • - Polyclonal and monoclonal antibodies • - Production of monoclonal antibodies ○ - Hybridoma technology ○ - MAbs applications	1	2
5	Vaccine technology	Traditional vaccine preparations - The development of vaccines - The impact of genetic engineering on vaccine technology - Vaccine vectors - Vaccine clinical trial process Liposome and virosome technology	2	4
6	Mid Exam		1	2
7	Process Economics, Optimization and Downstream Processing	Optimization In Biotechnology Applications • Environmental factors affecting the response • Optimization of the factors affecting the	1	2

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
		response		
8	Antibiotics, Hormones and cytokines production	1- Production of antibiotics • 2- Cytokines families • - Interferons • - Interleukins • 3- Manufacturing steps of interferons o 4- Applications of intereferons o 5- Interleukins production ▪ 6- Large scale drug production ▪ 7- Production of Insulin and Growth hormones	3	6
9	Bio Informatics	Definition, Aims and Components • Biological Databases • Molecular Bioinformatics • Public organizations • Gateways to databases • Applications • Pharmaceutical Bioinformatics • Drug Databases • Applications	2	4
10	Common industrial microbial products	1- Products of direct microbial fermentation • 2- Products from recombinant proteins.	1	2
11	Final exam		1	2
Number of Weeks /and Units Per Semester			16	32

VI. : Teaching Strategies of the Course:

(A) (Knowledge and Understanding)

- Lectures and Groups discussion.
- Self – learning

(B) (Intellectual Skills)

- Dialogue and discussion

▪ solving Problem
(C) (Professional and Practical Skills)
▪ Lectures ▪ Simulation & presentations
(D) (Transferable Skills)
▪ Self – learning ▪ Cooperative learning

VII. Assessment Methods of the Course:

(A) (Knowledge and Understanding)
▪ Quizzes, Presentation and Written exam.
(B) (Intellectual Skills)
▪ Quizzes, Homework
(C) (Professional and Practical Skills)
▪ Performance, Report
(D) (Transferable Skills)
▪ Homework's evaluation. ▪ Evaluation of Research reports

VIII. Assignments:

No.	Assignments	Week Due	Mark
1	**Assignment 1:** Attendance	1-14	10
2	**Assignment 2:** Homework**, Research & Quizzes.**	6&12	10
Total			**20**

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

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment
1	**Assignments**	1-14	20	20%
2	**Mid-Term Theoretical Exam**	8	30	30%
5	**Final Theoretical Exam**	16	50	50%
Total			100	100%

X. Learning Resources:

- *Written in the following order: Author, Year of publication, Title, Edition, Place of publication, Publisher.*

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

Gary Walsh, John Wiley and Sons Ltd, (2007). Pharmaceutical Biotechnology: Concepts and Applications, England.

James Swarbrick, (2006). Encyclopedia of Pharmaceutical Technology, Volume 1, edited by Pharmaceu Tech, Inc. Pinehurst, USA.

2- Essential References.

1- Williams and Wilkins, (2005). Remington; the Science and Practice of Pharmacy, first edition.

2- Patrick J. Sinko (2006). Martin's Physical Pharmacy and Pharmaceutical Sciences.

3- Electronic Materials and Web Sites *etc.*

www. Pharmaceutical manufacturing process.com

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

Republic of Yemen

Ministry of Higher Education & Scientific Research

Council of Academic Accreditation & Quality Assurance of Higher Education (CAQA)

Faculty of Medical Sciences

Department of Pharmacy

Program of Pharmacy

Course Specification of

Pharmacogenomics

Course Code PH1125229

2023

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

I. General Information:

1.	**Course Title:**	Pharmacogenomics				
2.	**Course Code:**	PH1125229				
3.	**Course Type:**					
4.	**Credit Hours:**	**Credit Hours**	**Theory Contact Hours**		**Practical Contact Hours**	
			Lecture	**Tutorial/ Seminar**	**Lab**	**Clinical**
		1	1	--	--	--
5.	**Level/ Semester at which this Course is offered:**	5th Level / 2nd Semester				
6.	**Pre –Requisite (if any):**	None				
7.	**Co –Requisite (if any):**	None				
8.	**Program (s) in which the Course is Offered:**	Bachelor of pharmacy				
9.	**Language of Teaching the Course:**	English				
10.	**Location of Teaching the Course:**	Faculty of Medical Sciences – Thamar University				
11.	**Prepared by:**	Dr. Abdurrahman Alhaifi				
12.	**Date and Number of Approval by Council:**					

II. Course Description:

This course provides the knowledge needed to interpret a patient's genetic data and prescribe medications and dosages based on their unique genetic makeup. The course will cover topics in genetics, cell biology, molecular biology, and biochemistry relevant to the field of pharmacogenomics. In addition, some of the common laboratory techniques used in pharmacogenomics research laboratories will be introduced and pharmacogenomics literature and databases will be searched.

III. Course Intended Learning Outcomes

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 basic principles of genetics, such as single gene inheritance, independent assortment, linkage, and genetic variation.		**A1**	Show understanding of the fundamentals of the basic and biomedical sciences including physics, mathematics,

a2	Explain how the genome conveys information to the rest of the body (the central dogma of molecular biology).			chemistry, structure of human body, normal and abnormal body functions, basis of genomes and different biochemical pathways and their relations to different diseases.
a3	Explain scientific procedures and techniques frequently performed in Pharmacogenomic research.			
	B. Intellectual Skills:			
b1	Relate genetic polymorphisms to the function of various types of proteins, their role in disease development and therapeutics		**B1**	Collect, interpret and asses relevant pharmaceutical and biomedical sciences to construct the pharmacophores of the structure and their effect on the stability, pharmacokinetic and pharmacodynamics profile of the drug.
	C. Professional and Practical Skills:			
c1	Identify economic and policy considerations relevant to pharmacogenomics.		**C1**	Apply administrative and pharmacoeconomic rules in pharmacy and ethically use marketing skills for promoting the pharmaceutical and cosmetic products.
	D. Transferable Skills:			
d1	Research and interpret scientific literature and online databases to obtain and provide pertinent pharmacogenomics information.		**D1**	Retrieve the essential references of evidence-based practice to achieve maximum clinical effectiveness.
I= Introduced, P=Practiced or M/A= Mastered/Advanced				

IV. Alignment of Course Intended Learning Outcomes

(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 basic principles of genetics, such as single gene inheritance, independent assortment, linkage, and genetic variation	▪ Lectures ▪ Discussion Sessions	▪ Periodic exam (Quizzes) ▪ Evaluate assignments ▪ Mid & final exam
a2	Explain how the genome conveys information to the rest of the body (the central dogma of molecular biology).		

a3	Explain scientific procedures and techniques frequently performed in Pharmacogenomic research.		

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

Course Intended Learning Outcomes		Teaching Strategies	Assessment Strategies
b1	Relate genetic polymorphisms to the function of various types of proteins, their role in disease development and therapeutics.	▪ Problem solving ▪ Group discussion	▪ Oral presentations ▪ Evaluate assignments ▪ Mid & final exam

(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	Identify economic and policy considerations relevant to pharmacogenomics	▪ Discussion sessions ▪ Assignments	▪ Evaluate assignments ▪ Mid & final exam

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

Course Intended Learning Outcomes		Teaching Strategies	Assessment Strategies
d1	Research and interpret scientific literature and online databases to obtain and provide pertinent pharmacogenomics information.	▪ Discussion Sessions ▪ Assignments that require collecting information from the internet	▪ Evaluate assignments ▪ Mid & final exam

V. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1	**Human Genetics**	• Single Gene Inheritance • Pedigree Analysis • Independent Assortment • Linkage and Genetic	4	4	a1-a3,b1, c1, d1

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
		• Interactions • Genomes, Variation and Population Genetics • Structural Genetic Variation			
2	**Pharmacogenetics**	• Elements of Drug Disposition • Pharmacogenetics of Receptors • Pharmacogenetics of Enzymes • Pharmacogenetics of Signaling • Pharmacogenetics of Channels • Pharmacogenetics of Transporters	6	6	a1-a3, b1, c1, d1
	Med term Exam		1	1	a1-a3, b1, c1, d1
3	**Pharmacogenetics and Disease**	• Pharmacogenetics Haplotype Identification • Genomics of Cancer • Personalized Medicine and Genetic Testing • Genome Wide Association Studies • Pharmacogenomics in Drug Development	4	4	a1-a3, b1, c1, d1
4	**Final Theoretical Exam**		1	1	a1-a3, b1, c1, d1
Number of Weeks /and Units Per Semester			**16**	**16**	

VI. Assignments:

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)
1	**Assignment 1:**	4	5	a1-a3,b1, c1, d1
2	**Assignment 2:**	10	5	a1-a3,b1, c1, d1
Total			**10**	

VII. 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**	4,10	10	10%	a1-a3,b1, c1, d1
3	**Mid-Term Theoretical Exam**	6	20	20%	a1-a3,b1, c1, d1
6	**Final Theoretical Exam**	16	70	70%	a1-a3,b1, c1, d1
Total					

VIII. Learning Resources:

- *Written in the following order:* Author, Year of publication, Title, Edition, Place of publication, Publisher.

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

1- Griffiths, et al. Introduction to Genetic Analysis. Freeman/Worth. (most recent edition)

2- Alberts, et al. Molecular Biology of the Cell, 6th edition. Garland Science. (most recent edition) •

2- Essential References:

1- Bertino, et al. Pharmacogenomics: An Introduction and Clinical Perspective. McGraw-Hill Education LLC. (most recent edition)

3- Electronic Materials and Web Sites etc.:

Websites:

1. https://precision-medicine-academy.thinkific.com/courses/pgx-in-practice
2. https://www.newcastle.edu.au/course/PHAR4201

IX.	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.

Council of Academic Accreditation & Quality Assurance of Higher Education (CAQA)

مركز التطوير الأكاديمي وضمان الجودة
Center of Academic Development and Quality Assurance

Faculty of Medical sciences

Department of Pharmacy

Program of B. Pharmacy

Course Specification of

Industrial Pharmacy II

Course Code. (PH1125279)

2024

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

I. General Information:

1.	**Course Title:**	**Industrial Pharmacy II**				
2.	**Course Code:**	**PH1125279**				
3.	**Course Type:**	**Compulsory course**				
4.	**Credit Hours:**	**Credit Hours**	**Theory Contact Hours**		**Practical Contact Hours**	
			Lecture	**Tutorial/ Seminar**	**Lab**	**Clinical**
		2	2	--		--
5.	**Level/ Semester at which this Course is offered:**	Fifth Level / Second Semester				
6.	**Pre –Requisite (if any):**	Industrial pharmacy I				
7.	**Co –Requisite (if any):**	------				
8.	**Program (s) in which the Course is Offered:**	Bachelor of pharmacy				
9.	**Language of Teaching the Course:**	English				
10.	**Location of Teaching the Course:**	Faculty of Medical Science				
11.	**Prepared by:**	Dr. Abdulkarim K. Alzomor				
12.	**Reviewed By:**					
13.	**Date and Number of Approval by Council:**					

II. Course Description:

Students are to be introduced to the basic concepts involved in the manufacture of various drug dosage forms on large scale efficiently and economically. Moreover, they will be provided with the essential unit operation involved in the production of pharmaceuticals such as heat transfer, evaporation, drying, size reduction and separation, extraction, filtration, centrifugation, size enlargement and mixing process.

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**	Referenced PILOs	
a1	Explain the principles of the operation methods of various equipment which used for manufacturing pharmaceutical product.	**A**	**A3**	Clearly distinguishes the foundations of the design of medicines & their development, using the various equipment and techniques, as well as, the tests that use in the pharmaceutical industry.
B. Intellectual Skills:				
b1	Select suitable equipment required for operation process during pharmaceutical manufacturing.	**A**	**B1**	Correctly choose of the appropriate methods to isolate & purification and titration accurately of active substances from different sources according to the standards and policy of medicines
C. Professional and Practical Skills:				
c1	Apply developing equipment required for pharmaceutical operation process	**A**	**C3**	Extract the active substances from their various sources by correct scientific methods whether in their isolation , purification, titration and preparation.
D. Transferable Skills:				
d1	Perform tasks and costs of the course	**A**	**D1**	Works effectively in a unique

	independently and be able to work as an effective member in a team			team.
d2	Employ the technologies services to solve problems of pharmaceuticals and develop his skills.	**A**	**D2**	Correctly uses, the means of the technology, information, programs of computer and the statistical programs, which contribute in raising the health level.
I= Introduced, P=Practiced or M/A= Mastered/Advanced				

IV. Alignment of Course Intended Learning Outcomes

(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	Explain the principles of the operation methods of various equipment which used for manufacturing pharmaceutical product.	- Lectures and Groups discussion. - Self – learning	▪ Quizzes, Presentation and Written exam.

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

	Course Intended Learning Outcomes	Teaching Strategies	Assessment Strategies
b1	Select suitable equipment required for operation process during pharmaceutical manufacturing.	- Discussions and Training - Field visits - Problem solving	- Quizzes, Homework - Observation - Task's Evaluates

(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 developing equipment required for pharmaceutical operation process	- Lectures - Simulation & presentations	▪ Performance, Report

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

	Course Intended Learning Outcomes	Teaching Strategies	Assessment Strategies
d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team	- Group discussions - Cooperative learning. - Self – learning	- Homework - Evaluates of oral Presentation
d2	Employ the technologies services to solve problems of pharmaceuticals and develop his skills.		

V. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1	Heat transfer and Flow of heat	-Classification of heat flow process. -Overall coefficient of heat transfer. - Mechanisms of heat transfer, conduction, convection and radiation. -Steam and steam driers -Design of heating equipment (Heat exchanger): -Tubular heaters - Finely tube heat exchanger. -Plate heat exchanger -Spiral heat exchanger • -Fouling: define, causes. overcome	1	2	a1, b1, c1, d1, d2
2	Drying	• Introduction, - Terminologies, - Theory of drying loss on drying and moisture content, equilibrium moisture content. - Mechanism of drying and Factors effecting drying	2	4	a1, b1, c1, d1, d2

		- Classification of dryers • Dryers for solid materials. 1- Convectional dryers (Tray dryer and Fluid bed dryer) 2- Conduction dryers (Vacuum oven dryer and Vacuum Tumbler oven dryer). 3- Radiation dryers (IR dryer and Microwave radiation dryer) • Dryers for dilute solutions and suspensions. Examples: - Drum dryer - Spray dryer - Principles of freeze drying, freeze dryers.			
3	Evaporation	❖ General principals of evaporation. ❖ Factor affecting evaporation ❖ Classification of Evaporators: - jacketed kettles - tube evaporators, ❖ Forced circulation evaporator. ❖ Multiple effect evaporation. ❖ Evaporator accessories- Trap and cyclone. • Evaporation problems	1	2	a1, b1, c1, d1, d2
4	Mixing process	Introduction to mixing - Factors effecting mixing, - Fundamentals and mechanism. Classification of mixture ❖ Solid mixers 1- Tumbler mixer examples (Drum, cube, double cone, Slant and V-shaped mixer) 2- Agitator mixer examples (Horizontal Ribbon and Vertical Ribbon) 3- Special mixer (Disona,	3	6	a1, b1, c1, d1, d2

		pneumatic and zenkheta mixer) ❖ Semisolid mixer • Beater mixers • Kneaders • Triple roll • Extruders ❖ Liquid mixers, ❖ Type of liquid ❖ Factor effect on liquid mixing ❖ Vortex ❖ Type of impellers 1- Paddles 2- Turbines 3- Propellers 4- Special mixer for liqued			
5	Mid Exam		1	2	a1, b1, c1, d1, d2
6	Size enlargement	❖ Methods and mechanisms of granule formation. ❖ Reasons for size enlargement. ❖ Pharmaceutical granulation equipment: ❖ High speed mixer granulator, Oscillating granulator. Extruder.	1	2	a1, b1, c1, d1, d2
7	Size reduction	❖ Definitions, Important of milling, ❖ Factors effecting size reduction ❖ Advantage and disadvantage of milling. ❖ Theory and mechanisms of size reduction. ❖ Classification of size reduction equipment: ❖ Intermediate size reduction: • Hammer mill	2	4	a1, b1, c1

		• Cuter mill • Edge end mill ❖ Fine size reduction: • Fluid energy mill • Ball mill • Oscillator mill - Colloidal mill			
8	Filtration	❖ Definitions, Important of filtration ❖ Factors effecting filtration ❖ Advantage and disadvantage of filtration ❖ Methods of filtration: ❖ Gravity filter ❖ Pressure filter ❖ Drum filter ❖ Paper Filter ❖ Select suitable filter ❖ Filter Aids: Define, Important ❖ Types of filter aid: ❖ Cotton ❖ Nylon ❖ Synthetic filter aid	1	2	a1, b1, c1, d1, d2
9	Distillation	❖ Definition, Important of distillation in pharmacy ❖ Type of distillation: (a) Destructive distillation, (b) Vacuum distillation, (c) Steam distillation - d) Fractional distillation.	1	2	a1, b1, c1, d1, d2
10	Extraction process	❖ Extraction: definition, uses, factor affecting extraction ❖ Type of extraction: - Liquid/ solid extraction • Percolation • Maceration	1	2	a1, b1, c1, d2

		- Liquid/ liquid extraction • Plate baffle column • Backed column • Spray column • Schiable column			
11	Crystallization	- Definition, uses, factor affecting crystallization. - Classification, batch crystallizers, simple vacuum crystallizers. - Nucleation and crystal growth critical humidity prevention of caking, material and energy balances	1	2	a1, c1, d2
12	**Final exam**		**1**	2	a1, b1, c1, d1, d2
Number of Weeks /and Units Per Semester			**16**	**32**	

VI. Assignments:

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)
1	**Assignment 1: Attendance**	1-14	10	a1, b1, c1, d1, d2
2	**Assignment 2: Homework, Research & Quizzes.**	6&12	10	a1, b1, c1, d1, d2
Total			**20**	

VII. 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**	1-14	20	20%	a1, b1, c1, d1, d2
2	**Mid-Term Theoretical Exam**	8	30	30%	a1, b1, c1, d1, d2

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes
5	**Final Theoretical Exam**	16	50	50%	a1, b1, c1, d1, d2
Total			**100**	**100%**	

VIII. Learning Resources:

- *Written in the following order:* Author, Year of publication, Title, Edition, Place of publication, Publisher.

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

1- Badger, WL. and Banchero, J.T., (1995). Introduction to chemical engineering, McGRAW-HILL book publishing company INC., KOGAKUSHA company, LTD Tokyo.
2- Warren McCabe. Julian Smith, Peter Harriot (2000). Unit Operations, McGraw-Hill Publishing science. New Delhi, sixth edition.

Essential References:

1- Williams and Wilkins (2005). Remington; the Science and Practice of Pharmacy (2first edition). Publisher: Lippincott.
2- Bhatt NB, Panchal VM, Panchal VM, (2005). Machine Drawing. Charotar Publishing House PVT Ltd.

Electronic Materials and Web Sites *etc.*

IX. 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 Medical Science

Department of Pharmacy

Program of B. Pharmacy

Course Plan (Syllabus) of

Industrial Pharmacy II

Course Code. PH1125279

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	

2024

II. Course Identification and General Information:

1.	**Course Title:**	Industrial **Pharmacy II**				
2.	**Course Code:**	PH1125279				
3.	**Course Type:**	Compulsory **course**				
4.	**Credit Hours:**	**Credit Hours**	**Theory Contact Hours**		**Practical Contact Hours**	
			Lecture	**Tutorial/ Seminar**	**Lab**	**Clinical**
		2	2	--		--
5.	**Level/ Semester at which this Course is offered:**	Fifth Level / Second Semester				
6.	**Pre –Requisite (if any):**	Industrial pharmacy I				
7.	**Co –Requisite (if any):**	------				
8.	**Program (s) in which the Course is Offered:**	Bachelor of pharmacy				
9.	**Language of Teaching the Course:**	English				
10.	**Location of Teaching the Course:**	Faculty of Medical Science				
11.	**Prepared by:**	Dr. Abdulkarim K. Alzomor				
12.	**Reviewed By:**					
13.	**Date and Number of Approval by Council:**					

III. Course Description:

Students are to be introduced to the basic concepts involved in the manufacture of various drug dosage forms on large scale efficiently and economically. Moreover, they will be provided with the essential unit operation involved in the production of pharmaceuticals such as heat transfer, evaporation, drying, size reduction and separation, extraction, filtration, centrifugation, size enlargement and mixing process.

IV. Course Intended Learning Outcomes (CILOs):

Upon successful completion of the Course, student will be able to:	
A. Knowledge and Understanding:	
a1	Explain the principles of the operation methods of various equipment which used for manufacturing pharmaceutical product.
B. Intellectual Skills:	
b1	Select suitable equipment required for operation process during pharmaceutical manufacturing.
C. Professional and Practical Skills:	
c1	Apply developing equipment required for pharmaceutical operation process.
D. Transferable Skills:	
d1	Perform tasks and costs of the course independently and be able to work as an effective member in a team
d2	Employ the technologies services to solve problems of pharmaceuticals and develop his skills.

V. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
1	**Heat transfer and** Flow of heat	• Classification of heat flow process. -Overall coefficient of heat transfer. - Mechanisms of heat transfer, conduction, convection and radiation. -Steam and steam driers -Design of heating equipment (Heat exchanger): -Tubular heaters - Finely tube heat exchanger. -Plate heat exchanger -Spiral heat exchanger • -Fouling: define, causes. overcome	1	2
2	**Drying**	- Introduction, - Terminologies, - Theory of drying loss on drying and moisture content, equilibrium moisture content. - Mechanism of drying and Factors effecting drying - Classification of dryers • Dryers for solid materials. 4- Convectional dryers (Tray dryer and Fluid bed dryer) 5- Conduction dryers (Vacuum oven dryer and Vacuum Tumbler oven dryer). 6- Radiation dryers (IR dryer and Microwave radiation dryer) • Dryers for dilute solutions and suspensions. Examples: - Drum dryer - Spray dryer	2	4

		- Principles of freeze drying, freeze dryers.		
3	**Evaporation**	• General principals of evaporation. ❖ Factor affecting evaporation ❖ Classification of Evaporators: - jacketed kettles - tube evaporators, ❖ Forced circulation evaporator. ❖ Multiple effect evaporation. ❖ Evaporator accessories- Trap and cyclone. • Evaporation problems	1	2
4	Mixing process	Introduction to mixing - Factors effecting mixing, - Fundamentals and mechanism. Classification of mixture ❖ Solid mixers 4- Tumbler mixer examples (Drum, cube, double cone, Slant and V-shaped mixer) 5- Agitator mixer examples (Horizontal Ribbon and Vertical Ribbon) 6- Special mixer (Disona, pneumatic and zenkheta mixer) ❖ Semisolid mixer • Beater mixers • Kneaders • Triple roll • Extruders ❖ Liquid mixers, ❖ Type of liquid ❖ Factor effect on liquid mixing ❖ Vortex ❖ Type of impellers 5- Paddles 6- Turbines 7- Propellers 8- Special mixer for liqued	3	6

5	Mid Exam		1	2
6	Size enlargement	Methods and mechanisms of granule formation. ❖ Reasons for size enlargement. ❖ Pharmaceutical granulation equipment: ❖ High speed mixer granulator, Oscillating granulator. Extruder.	1	2
7	Size reduction	❖ Definitions, Important of milling, ❖ Factors effecting size reduction ❖ Advantage and disadvantage of milling. ❖ Theory and mechanisms of size reduction. ❖ Classification of size reduction equipment: ❖ Intermediate size reduction: • Hammer mill • Cuter mill • Edge end mill ❖ Fine size reduction: • Fluid energy mill • Ball mill • Oscillator mill - Colloidal mill	2	4
8	Filtration	- **Definitions**, Important of filtration ❖ Factors effecting filtration ❖ Advantage and disadvantage of filtration ❖ Methods of filtration: ❖ Gravity filter ❖ Pressure filter ❖ Drum filter	1	2

		❖ Paper Filter ❖ Select suitable filter ❖ Filter Aids: Define, Important ❖ Types of filter aid: ❖ Cotton ❖ Nylon ❖ Synthetic filter aid		
9	Distillation	• **Definition**, Important of distillation in pharmacy ❖ Type of distillation: (a) Destructive distillation, (b) Vacuum distillation, (c) Steam distillation - d) Fractional distillation.	1	2
10	Extraction process	Extraction: definition, uses, factor affecting extraction ❖ Type of extraction: - Liquid/ solid extraction • Percolation • Maceration - Liquid/ liquid extraction • Plate baffle column • Backed column • Spray column • Schiable column	1	2
11	Crystallization	- Definition, uses, factor affecting crystallization. - Classification, batch crystallizers, simple vacuum crystallizers. - Nucleation and crystal growth critical humidity prevention of caking, material and energy balances	1	2
12	Final exam		1	2
Number of Weeks /and Units Per Semester			16	32

VI. : Teaching Strategies of the Course:

(A) (Knowledge and Understanding)

- Lectures and Groups discussion.
- Self – learning

(B) (Intellectual Skills)

- Dialogue and discussion
- solving Problem

(C) (Professional and Practical Skills)

- Lectures
- Simulation & presentations

(D) (Transferable Skills)

- Self – learning
- Cooperative learning

VII. Assessment Methods of the Course:

(A) (Knowledge and Understanding)

- Quizzes, Presentation and Written exam.

(B) (Intellectual Skills)

- Quizzes, Homework

(C) (Professional and Practical Skills)

- Performance, Report

(D) (Transferable Skills)

- Homework's evaluation.
- Evaluation of Research reports

VIII. Assignments:

No.	Assignments	Week Due	Mark
1	**Assignment 1:** Attendance	1-14	10
2	**Assignment 2:** Homework**, Research & Quizzes.**	6&12	10
Total			**20**

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

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment
1	**Assignments**	1-14	20	20%
2	**Mid-Term Theoretical Exam**	8	30	30%
5	**Final Theoretical Exam**	16	50	50%
Total			**100**	**100%**

X. Learning Resources:

- *Written in the following order: Author, Year of publication, Title, Edition, Place of publication, Publisher.*

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

Badger, WL. and Banchero, J.T., (1995). Introduction to chemical engineering, McGRAW-HILL book publishing company INC., KOGAKUSHA company, LTD Tokyo.

Warren McCabe. Julian Smith, Peter Harriot (2000). Unit Operations, McGraw-Hill Publishing science. New Delhi, sixth edition.

Essential References:

1- Williams and Wilkins (2005). Remington; the Science and Practice of Pharmacy (2first edition). Publisher: Lippincott.

2- Bhatt NB, Panchal VM, Panchal VM, (2005). Machine Drawing. Charotar Publishing House

PVT Ltd.
Electronic Materials and Web Sites etc.

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

Course Specifications of Pharmaceutical Quality Control

I. Course Identification and General Information:						
1	**Course Title:**	**Pharmaceutical Quality Control**				
2	**Course Code &Number:**	**PH1125269**				
3	**Credit hours:**	C.H				TOTAL Credit Hours
		Th.	Seminar	Pr	Tr.	
		2		1		3
4	**Study level/ semester at which this course is offered:**	Level 5 / 2nd Semester				
5	**Pre –requisite (if any):**					
6	**Co –requisite (if any):**					
7	**Program (s) in which the course is offered:**	Bachelor of Pharmacy				
8	**Language of teaching the course:**	English				
9	**Location of teaching the course:**	Faculty of Medical Sciences				
10	**Prepared By:**	Assistant Prof. Dr. Sam Dawbaa				
11	**Date of Approval**					

II. Course Description:

This course deals with the various aspects of quality control and quality assurance in pharmaceutical industries. It provide details regarding GMP, QC tests, documentation, quality certifications, validation, calibration, stability studies, and regulatory affairs..

III. Course Objectives:

1. To explain the importance of quality and methods of evaluation of quality of pharmaceutical products.
2. Understanding the concepts and procedures involved in quality assurance, GMP, validation, calibration, drug stability, and drug registration and approval.
3. Understanding of Records and Data management.

IV. Course Intended Learning Outcomes (CILOs) :

Knowledge and Understanding:

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

Knowledge and Understanding PILOs	Knowledge and Understanding CILOs	Teaching Strategies
After completing this program, students would be able to:	**After completing this course, students would be able to:**	**Lectures, Discussions, Self-learning.**
A1: Understand the principles of pharmaceutical quality control	a1: Details the principle of QC, QA, GMP.	Lectures, Discussions, Self-learning.
A2: Explain the general principles of validation and calibration.	a2: • Understand the types, principles, characteristics, and methods of validation and calibration.	Lectures, Discussions, Self-learning.
A3: Explain the principles of stability studies and types of tests used in QC.	a3: • Explain the principles and types of stability studies of drugs and detail the required physicochemical quality control tests respective to each pharmaceutical dosage form..	Lectures, Discussions, Self-learning.

Intellectual Skills :

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

Intellectual Skills PILOs	Intellectual Skills CILOs	Teaching Strategies
After completing this program, students would be able to:	**After completing this course, students would be able to:**	**The following strategies should be used:**
B1: Understand the principles of pharmaceutical quality control	b1: Compare between QC and QA.	Lectures, Discussions, Seminars, Self-learning.
B2: Explain the general principles of validation and calibration.	b2: • Determine which method to and what characteristics of validation to measure..	Lectures, Discussions, Seminars, Self-learning.
B3: Explain the principles of stability studies and types of tests used in QC.	b3: Determine the type of	Lectures, Discussions, Seminars,

	stability study suitable to achieve and determine the required QC tests for each dosage form..	Self-learning.

Professional and Practical Skills		
Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)		
Professional and Practical Skills PILOs	**Professional and Practical Skills CILOs**	**Teaching Strategies**
After completing this program, students would be able to:	**After completing this course, students would be able to:**	**The following strategies should be used:**
C1. Use efficiently equipment and suitable methods for determination of physicochemical properties and assay of drugs to evaluate their quality.	c1: Achieve QC tests for selected pharmaceutical dosage forms based on pharmacopeial methods.	Lectures, Lab. experiments, Presentations, Brain-storming.
	c2: Perform stability studies for selected dosage form.	Lectures, Lab. experiments, Presentations, Brain-storming.

Transferable (General) Skills :		
Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)		
Transferable (General) Skills PILOs	**Transferable (General) Skills CILOs**	**Teaching Strategies**
After completing this program, students would be able to:	**After completing this course, students would be able to:**	**The following strategies should be used:**
D1 Use statistical software to achieve calculation related to QC evaluation.	d1: To use MS Excel in the determination of validation characteristics and calculations of stability studies.	Discussions, Presentations, Self-learning.

V. Course Content:

A – Theoretical Aspect:

Order	Units/Topics List	Sub Topics List	Number of Weeks	contact hours	Learning Outcomes (CILOs)
1	Introduction	• Definition of Quality Control (QC) and related terms. • Steps, objectives, benefits, and requirements of QC. • Quality systems	1	2	a1, a2, a3, b1, b2
		• Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance, Good laboratory practice (GLP), and GMP.	1	2	a1, a2, a3, b1, b2
	GMP	• Definition and objectives of GMP • GMP requirements for: o Personnel o Premises and equipment	1	2	a1, a2, a3, b1, b2
		• GMP requirements for: o Documentation and types of documentation. o Sanitation o Manufacturing operations o Warehousing: Good warehousing practice, materials management, complaints and evaluation of complaints, handling of returned goods, recalling and waste disposal.	1	2	a1, a2, a3, b1, b2
	Validation	• Definition and principles of validation • Related statistics	1	2	a1, a2, a3, b1, b2
		• Types of validation in pharmaceutical industries. • Production processes validation and their protocols. • Cleaning validation, and general	1	2	a1, a2, a3, b1, b2

		revalidation procedures.			
		• Analytical methods validation: General principles and importance. • Types of analytical methods requiring validation. • Validation characteristics. • Case study: example for an analytical method validation.	1	2	a1, a2, a3, b1, b2
	Mid-term	Mid-term exam	1	2	
	Calibration	• Introduction, definition, and general principles of calibration. • Case study: Calibration of pH meter, Qualification of UV-Visible spectrophotometer, calibration of analytical balance.	1	2	a1, a2, a3, b1, b2
	Shelf-life control: Drug stability studies	• Modes of drug degradation	1	2	a1, a2, a3, b1, b2
		• Regulatory requirements for stability studies. • Types of stability studies. • Types of stability tests.	1	2	a1, a2, a3, b1, b2
	Quality control tests	• General principles • Types of QC tests • Control tests of raw materials • Control tests of packaging materials	1	2	a1, a2, a3, b1, b2

		• Control tests of finished products
		  ○ In-process quality control
		  ○ Finished product quality control
		• In-process quality control and finished products quality control for following dosage forms: tablets, capsules, and syrups.
			1	2	a1, a2, a3, b1, b2

		• In-process quality control and finished products quality control for:
		  ○ Suspensions
		  ○ Ointments
			1	2	a1, a2, a3, b1, b2

		○ Suppositories ○ Creams ○ Parenterals ○ Ophthalmic products ○ Surgical products			
	Drug approval and registration	• New Drug Approval Process. • Technical requirements for registration of biopharmaceuticals for human use (according to ICH).	1	2	a1, a2, a3, b1, b2
	Final	Final Exam	1	2	
Number of Weeks /and Units Per Semester		**16**		**32**	

B – Case Studies and Practical Aspect: (if any)

Order	Tasks/ Experiments	Number of Weeks	contact hours	Learning Outcomes (CILOs)
1	Evaluation of a selected drug tablets using physicochemical quality tests	1	2	c1, c2, d1
2	Evaluation of a selected drug capsule using physicochemical quality tests	1	2	c1, c2, d1
3	Evaluation of a selected drug syrup using physicochemical quality tests	1	2	c1, c2, d1
4	Evaluation of a selected drug suspension using physicochemical quality tests	1	2	c1, c2, d1
5	Evaluation of a selected drug ointment using physicochemical quality tests	1	2	c1, c2, d1
6	Evaluation of a selected drug cream using physicochemical quality tests	1	2	c1, c2, d1
7	Evaluation of a selected drug ampule using physicochemical quality tests	1	2	c1, c2, d1
8	Evaluation of a selected drug vial using physicochemical quality tests	1	2	c1, c2, d1
9	Evaluation of a selected drug eye drops using physicochemical quality tests	1	2	c1, c2, d1
10	Stability study for a selected drug	1	2	c1, c2, d1
11	Stability study for a selected drug	1	2	c1, c2, d1
12	Stability study for a selected drug	1	2	c1, c2, d1
13	Stability study for a selected drug	1	2	c1, c2, d1

14	A visit to a pharmaceutical company	1	2	c1, c2, d1
15	Final Exam	1	2	
Number of Weeks /and Units Per Semester		**15**	**30**	

VI. Teaching strategies of the course:

Lectures, Discussions, Simulated software program, Self-learning, Seminars, Lab Experiments

VII. 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 (Homework and class discussion activity)		1-12	5	5%	a1,a2,
2	Quiz 1		4	2.5	2.5%	a1,a2, ,b1,b2
3	Mid-semester exam of theoretical part (written exam)		8	10	10%	c1,c2,
4	Quiz 2		12	2.5	2.5%	c1,c2,
5	Lab. Term works	Attitude	1-14	5	5%	c1, c2,d1,d2
6		Accomplishments		5	5%	
7	Final exam (practical)		15	20	20%	c1, c2,d1,d2
8	Final exam of theoretical part		16	50	50%	a1,a2,b1,b2,c1, d1,d2
Total				100	100%	

VIII. Learning Resources:

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

1. Shayne Cox Gad - Pharmaceutical Manufacturing Handbook Regulations and Quality
2. Kate McCormick, Quality

2- Essential References.

1. Ermer & Miller, Method Validation in Pharmaceutical Analysis A Guide to Best Practice
2. Carstensen & Rhodes, Drug Stability: Principles & Practices.
3. Mekasha et. Al., Important terminology in pharmaceutical quality assurance: Literature review.

3- Electronic Materials and Web Sites *etc*.

https://scholar.google.com/

https://www.sciencedirect.com/

Course Specification

Clinical Pharmacy II

I. ourse Identification and **General Information**:						
1	**Course Title:**	**Clinical Pharmacy II**				
2	**Course Number & Code:**	**PH1125259**				
3	**Credit hours:**	C.H				TOTAL
		Th.	Seminar	Pr	Tr.	
		2		1		3
4	**Study Level/ Semester at which this Course is offered:**	**Level 5/ semester 2**				
5	**Pre –Requisite (if any):**	Physiology, Pharmacology1,2 & 3				
6	**Co –Requisite (if any):**					
7	**Program (s) in which the Course is Offered:**	Bachelor of Pharmacy				
8	**Language of Teaching the Course:**	English				
9	**Study System:**	semester				
10	**Mode of Delivery:**	Full Time				
11	**Location of Teaching the Course:**	Faculty of Medical Science				
12	**Prepared by:**					
13	**Date of Approval:**					

II. Course **Description**:

This course is a continuation of clinical pharmacy -1. It will help the student to Describe and define the disease pathophysiology and the appropriate therapeutic interventions and information required to treat different disease status ((thiroid diseases, Diabetes Militates, renal failure , Osteoarthritis, Alzheimer's disease and Parkinsonism). Students will be exposed to patients and patient medical records, drug formulary, therapy choice, drug monitoring and concepts and practical experience (problem-based) sessions on poisoning and toxicity. The course reviews the behavioral aspects of working as a member of complementary health team.

Practical : The course also train the student to solve clinical cases and prevent drug-related problems. Student will visit hospital during the course to interact with other health professionals in relation to clinical case selection, discussion, presentation and reflection in an inter professional environment..

III. Aims and Intended learning outcomes (ILOs) of **the course**:

1. Aims of The Course:

The overall aims of the course are:

1. To inform the pharmacy students about their contemporary role in the hospital settings.
1. To enable the student to assimilate and apply her/his previously acquired pharmaceutical knowledge in a patient care environment.

2. Intended learning outcomes (ILOs) of the course:

(A) Alignment Course Intended Learning Outcomes of Knowledge and Understanding to Teaching Strategies and Assessment Strategies:

Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
a1- Define the etiology, epidemiology, clinical features and laboratory diagnosis of different diseases (endocrine, liver, kidney) .	• Lectures • Discussion Sessions • Assignments	• Periodic exam (Quizzes) • Home Assignments • Exams
a2- identify the principles of therapeutic plan and the proper selection of the drug according to its rational use.		

a3- Identify the mechanism of action, side effects, drug interactions of the drugs used in the treatment of the condition under study		
a4- Describe the principles of clinical pharmacy practice, including maintenance of patient profiles, proper documentation and drug filing systems		

(B) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and Assessment Strategies:

Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
b1- Select proper drug for various disease condition. .	• Discussion Sessions • Problem solving • Group Discussion	• Oral presentations • Home assignments
b2- Interpret of clinical laboratory data with the impact of clinical symptoms.		
b3- Integrate a suitable therapeutic plan for a patient.		
b4- Design and discuss of the monitoring assessment and intervention in drug therapy to obtain the most effective, most safe, and economic drug regimen.		

©Alignment Course Intended Learning Outcomes of Professional and Practical Skills to Teaching Strategies and Assessment Strategies:

Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
c1- Apply proper salvation to any problem regarding patient`s compliance to medications.	• Discussion Sessions • Assignments	• Oral presentations • Exams • LAB report
c2- Change the patient therapeutic regimen according to his state		
c3- Create the concepts of pharmaceutical care in different diseases		
c4- Use properly the pharmaceutical and medical terms, abbreviations and symbols in pharmacy practice		
c5- Employ proper documentation and drug filing system		

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

Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
d1- Effectively, communicate with health care providers and sharing in designing the patient therapeutic plan.	• iscussion Sessions • ssignments that require collecting information from	• ral presentations • riting
d2- Deal to any alterations in the cases at hand.		

d3- Effectively, interact with patient and his relatives using verbal and non-verbal communications.	the internet.	
d4- Generate effective and reasonable solutions for solving patient problems.		

IV. Course **Content**:

A. Theoretical Aspect:

Order	Units/Topics List	Sub Topics List	Number of Week	contact hours	ILOs
1	• **Renal failure**	- Acute Kidney injury (AKI) - Chronic and End-Stage Renal Disease (CKD and ESRD)	2	4	a1,a2, a3, b2, b3, c5, d1,d2,d4
2	• **Diabetes mellitus (DM)** - **DM Type 1** - DM **type** 2	- Physiological principles of glucose and insulin metabolism - Epidemiology and classification - Aetiology and pathogenesis - Natural history - Clinical features - Complications - Management - Monitoring	2	4	a1, a2,a3, a4 b1,b2,b3,d1,d2,d 3
3	• **Thyroid disease**	- Physiological principles - Hypothyroidism - Hyperthyroidism	2	4	a1, a2, a3,b1, b3, b4, c1
4	• **Parathyroid disorders**	- Hypoparathyroidism - Hyperparathyroidism	1	2	a1, a2, a3,b1, b3, b4, c1,d4
5	• **Mid exam**		1	2	a1.a2,a3, b1,b2, c4
5	• **Osteoarthritis**		1	2	a1, a2, b23,b4, c4,d4
6	• **Gout and Hyperuricemia**		1	2	a1, a2, b23,b4, c4,d4
7	• **Liver disease**	- Clinical physiology of the liver - Clinical features of hepatic disease - Gallstones (cholelithiasis) - Viral and other infective hepatitis - Drugs and the liver - Liver cirrhosis - Liver failure	3	6	a1, a2, a3, b3, b4, c2, d1, d2
8	**CNS disorders**	○ Parkinsonism ○ Alzheimer's disease	2	4	a1.a2, a4,b1, b3, c5,
9	**Dyslipidaemia**		1	2	a1,a2, a4, b3, c2, d1
Number of Weeks /and Units Per Semester			**16**	**32**	

B. Practical Aspect: (if any)				
Order	**Tasks/ Experiments**	**Number of Weeks**	**contact hours**	**ILOs**
1	- **Fluid and Electrolyte Disorders** ○ Electrolytes ○ Sodium Water Balance ○ SODIUM, POTASSIUM , CALCIUM	1	**2**	c2,c4, c5
2	Cases in renal diseases Acute and chronic	1	**2**	c1, c2,c4 c5
3	Case in DM (type 1 and type 3)	3	**6**	c1, c2,c3,c4
4	Case in thyroids diseases(hyper –hypothyroidism)	**3**	**6**	c2,c3,c4
5	Case in liver diseases	**3**	**6**	c2,c3,c4,c5
6	Case in osteoarthritis , gout , hyperlipidemia	**1**	**2**	c1,c2,c3,c4
7	Review	**1**	**2**	C1,c2,c3,c4
Number of Weeks /and Units Per Semester		**13**	**26**	

V. Teaching strategies of the **course**:
• Lectures
• Search topic and discussion sessions
• LAB Class
• Media Presentations: Power Point, Video
• Assignments

VI. Assignments:

no	Assessment Tasks	Week Due	Mark	Proportion of Final Assessment	Aligned CILOs(symbols)
1	**Participation, quizzes**	Each week	5	5%	a1, a2, a4, b1,b2, c5
2	**Research, assignments**	6th week	5	5%	a1, a3, b1, b2, c1, c5, d2
3	**Mid – Exam (theoretical)**	7th week	20	20%	a1.a2,a3, b1,b2, c4
4	**Final Exam (practical)**	15th week	30	30%	a1.a2,a3, b1,b3, c4, d1,d2
5	**Final Exam (theoretical)**	16th week	40	40%	a1.a2,a3, b1,b2, c1, c4
	Total		100	100%	

VII. Learning Resources:	
1. Required Textbook(s) (maximum two).	
	○ Clinical pharmacy and therapeutics by: Roger Walker.
2. Recommended Readings and Reference Materials.	
	1. Pharmacotherapeutics (a primary care guide) by: Eills Quinn Youngkin 2. pharmacotherapeutics for advanced practice a practical approach by: Virginia Poole Arcangelo. 3. Clinical pharmacy and hospital drug management by:Lawson.
3. Essential References.	
	1. A HF S, Drug Information Essentials (American Society of Health-system Pharmacists) 2. Drug Information Handbook. Charles Lacy, Lora Armstrong and Orton 3. Goldman (11th edition, 2003).
4. Electronic Materials and Web Sites *etc*.	
	○ www.PubMed.com ○ www.uptodate.com (for drug-drug interactions) ○ www.guideline.gov ○ http://www.medscape.com/druginfo/druginterchecker?src=ads
5. Other Learning Material.	
	○ Data show projector

	I. Course **Policies**:
1	**Class Attendance:** □ Absence from lectures and/or tutorials shall not exceed 25%. Students who exceed the 25% limit without a medical or emergency excuse acceptable to and approved by the Dean of the relevant college shall not be allowed to take the final examination and shall receive a mark of zero for the course.
2	**Tardy:** □ Students should be attending the classes as its required for the assessments if the student is 15 minutes late in attending to the class for more than two classes he will loss 50% of quizzes mark.
3	**Exam Attendance/Punctuality:** □ All examination and their roles will be according to Students affairs regulations
4	**Assignments & Projects:** - Student who is submitting the assignments or the projects on time, will be awarded good percentage in grading of participation.
5	**Cheating**: - All students must be an ideal behavior and respect each other, their teachers and respect the roles of the colleague. In addition, students should follow safety roles while working in the lab. Those who has been caught in any cheating case will be punished according to the Students affairs regulations
6	**Plagiarism**: □ Student will be punished depend upon gravity of the action and according to Students affairs regulations which might be ranged from rewriting the homework to suspension or dismissal
7	**Other policies:** - Using mobile or another electronic device capable to store or transfer data in class during the lecture or the exam is forbidden.

Course Specification of

Hospital pharmacy

I. Course Identification and General Information:							
1	**Course Title:**	Hospital pharmacy					
2	**Course Code &Number:**	PH1125268					
3	**Credit hours:**	C.H				TOTAL	
		Th.	Seminar	Pr	Tr.		
		2				2	
4	**Study level/ semester at which this course is offered:**	*Level* **5**/ *semester 2*					
5	**Pre –requisite (if any):**	Community Pharmacy					
6	**Co –requisite (if any):**						
7	**Program (s) in which the course is offered:**	Bachelor of Pharmacy					
8	**Language of teaching the course:**	English					
9	**Location of teaching the course:**	Thamar University - Faculty of Medical Sciences					
10	**Prepared By:**	**Dr. Ahmed G. Al- Akydy – Dr. Ahmed Al-Washli**					
11	**Date of Approval**	2021					

II. Course Description:

This course provides the student with knowledge the basic principles related to development, functions, organization and administration of pharmaceutical services within a hospital. Methods of drug distribution, I.V. admixture unit, pharmacy and therapeutic committee, hospital formulary, purchasing and inventory control, determining actual needs of the inquirer, in-patients, outpatients and ambulatory patients with respect to filling prescriptions, counseling and rational patient-oriented drug use are involved.

III. Course Objectives:

1. To Know the different pharmacy services within the hospital and the methods of and methods of drug distribution, patient counseling I.V. admixture unit.
2. To Illustrate the importance of pharmaceutical skills to the pharmacy profession such as, drug information, drug therapy monitoring.
3. To perform calculations, compounding preparations, manipulation of IV admixtures, total parenteral nutrition (TPN), and preventing incompatibilities during therapy.

I. Course Intended Learning Outcomes (CILOs) :

Knowledge and Understanding:

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

After completing the course, the student will be able to:

a1. Understand the principles of organization hospital pharmacy departments, and the different services of hospital pharmacy, such as, IV admixture preparation, awareness about drug in-compatibilities, TPN preparation and drug distribution.

a2, Describe the role of the pharmacist in the hospital setting, the rule of pharmacy and therapeutic committee and drug formulary

a3. Explain the different in and out -patient pharmacy services

Knowledge and Understanding PILOs		Knowledge and Understanding CILOs	
After completing this program, students would be able to:		**After completing this course, students would be able to:**	
A1	Explain the fundamentals of general sciences and the basic and biomedical sciences and their relations to pharmacy profession.	a2	**Describe** the role of the pharmacist in the hospital setting, the rule of pharmacy and therapeutic committee and drug formulary
A2	Illustrate the fundamentals of social and behavioral sciences relevant to pharmacy, ethics of health care and its impact on their relationship with patients and other healthcare professionals.		
A3	Describe relationships between chemical structure of compounds of pharmaceutical and medicinal interest and biological activities	a1	**Understand** the principles of organization hospital pharmacy departments, and the different

			services of hospital pharmacy, such as, IV admixture preparation, awareness about drug in-compatibilities, TPN preparation and drug distribution.
A4	Define basic principles of drug: target identification, design, informatics, and mechanisms of action		
A5	Outline principles of clinical pharmacology, therapeutics and Pharmacovigilance.	a3	**Explain** the different in and out - patient pharmacy services

Intellectual Skills :

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

b1. Predict possible incompatibilities during IV admixture and other prescription related problems

b2. Recognize and select guide lines in preparing hospital formulary.

b3. Interpret patient profile and medication histories for in-patients and out-patients.

Intellectual Skills PILOs		**Intellectual Skills CILOs**	
After completing this program, students would be able to:		**After completing this course, students would be able to:**	
B1	Classify the synthetic and natural drugs according to their mechanism of action, systemic effect, therapeutic uses, contraindication and toxicity		
B2	Design risk reduction strategies to ensure patient safety and prevent medication errors, drug interaction, and adverse drug effects,	b1	**Predict** possible incompatibilities during IV admixture and other prescription related problems
B3	Solve problems to reduce drug therapy problems		
B4	Select drug therapy regimen using mathematical, genomic, clinical pharmacokinetic and pharmacodynamics principles for optimizing the patient therapy	b2	**Recognize** and **select** guide lines in preparing hospital formulary.

	and medication safety	b3	**Interpret** patient profile and medication histories for in-patients and out-patients.

Professional and Practical Skills

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

c1. Apply the proper pharmacy services related to drug distribution systems, IV admixture preparation, awareness about drug in-compatibilities, and TPN preparation.
c2. Employ proper and safe dispensing, labeling, storing, and, conduct the procurement and inventory control systems utilized by the hospital.

c3- Analyze the rationale and patient-oriented drug use.

Professional and Practical Skills PILOs		**Professional and Practical Skills CILOs**	
After completing this program, students would be able to:		**After completing this course, students would be able to:**	
C1	Handle the chemical, biological, and pharmaceutical materials safely	c2	**Employ** proper and safe dispensing, labeling, storing, and, conduct the procurement and inventory control systems utilized by the hospital.
C2	Operate different pharmaceutical equipment and instruments		
C3	Extract active substances from different sources.		
C4	Carry outpatient physical assessment.		
C5	Advise the patients and health care professionals for optimizing medicines use.	c1	**Apply** the proper pharmacy services related to drug distribution systems, IV admixture preparation, awareness about drug in-compatibilities, and TPN preparation.

		c3	**Analyze** the rationale and patient-oriented drug use.

Transferable (General) Skills :

Alignment of CILOs (Course Intended Learning Outcomes) to PILOs (Program Intended Learning Outcomes)

d1. Interact effectively with patients, the public and health care professionals; including communication, interpretation and presentation of pharmaceutical information and data both written and oral

d2. Advice the patients and other health care professionals about safe and proper use of medicines

d3, Work effectively in a team in a variety of health care settings.

Transferable (General) Skills PILOs		**Transferable (General) Skills CILOs**	
After completing this program, students would be able to:		**After completing this course, students would be able to:**	
D1	Communicate effectively and ethically with patients, public, and health care professionals.	d1	**Interact** effectively with patients, the public and health care professionals; including communication, interpretation and presentation of pharmaceutical information and data both written and oral
D2	Use information systems and computer softwares in order to enhance the delivery of pharmaceutical care,	**d2**	**Advice** the patients and other health care professionals about safe and proper use of medicines
D3	Work effectively individually and in a team	**d3**	**Work** effectively in a team in a variety of health care settings.
D4	Have the skills of decision-making and time management and lifelong learning		

II. Alignment Course Intended Learning Outcomes

(A) Alignment Course Intended Learning Outcomes of Knowledge and Understanding to Teaching Strategies and Assessment Strategies:

Course Intended Learning Outcomes		Teaching strategies	Assessment Strategies
a1	**Understand** the principles of organization hospital pharmacy departments, and the different services of hospital pharmacy, such as, IV admixture preparation, awareness about drug in-compatibilities, TPN preparation and drug distribution.	• Lectures • Discussion Sessions • Assignments	• Periodic exam (Quizzes) • Evaluate assignments • Mid & final exam
a2	**Describe** the role of the pharmacist in the hospital setting, the rule of pharmacy and therapeutic committee and drug formulary		
a3	**Explain** the different in and out - patient pharmacy services		

(B) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and Assessment Strategies:

Course Intended Learning Outcomes		Teaching strategies	Assessment Strategies
b1	**Predict** possible incompatibilities during IV admixture and other prescription related problems	• Discussion Sessions • Problem solving • Group discussion • Assignments	• Oral presentations • Evaluate assignments • Mid & final exam
b2	**Recognize** and select guide lines in preparing hospital formulary.		
b3	**Interpret** patient profile and medication histories for in-patients and out-patients.		

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

Course Intended Learning Outcomes		Teaching strategies	Assessment Strategies
c1	**Apply** the proper pharmacy services related to drug distribution systems, IV admixture preparation, awareness about drug in-compatibilities, and TPN preparation.	• Discussion sessions • Assignments	• Oral presentations • Theory & Practical exams • LAB report • Evaluate assignments
c2	**Employ** proper and safe dispensing, labeling, storing, and, conduct the procurement and inventory control systems utilized by the hospital.		
c3	**Analyze** the rationale and patient-oriented drug use.		

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

Course Intended Learning Outcomes		Teaching strategies	Assessment Strategies
d1	**Interact** effectively with patients, the public and health care professionals; including communication, interpretation and presentation of pharmaceutical information and data both written and oral	• Discussion Sessions • Assignments that require collecting information from the internet.	• Oral presentations • Writing
d2	**Advice** the patients and other health care professionals about safe and proper use of medicines		
d3	**Work** effectively in a team in a variety of health care settings.		

V. Course Content:

A – Theoretical Aspect:

Order	Units/Topics List	Sub Topics List	Number of Weeks	contact hours	Learning Outcomes (CILOs)
1	General Introduction to hospital pharmacy		1w	2	a1;
2	Function of hospital	- Hospital organization - Hospital pharmacy - Departments	1w	2	a1;
3	Pharmacy and therapeutics committee		1w	2	a2; d3;
4	The abilities and responsibilities of hospital pharmacists	- Roles of pharmacists in the hospital - Educational activities and training services	1w	2	a2; d1;
5	**Drug Store Management and Inventory Control**	- Organization and Structure - Organization of hospital pharmacy - Storage conditions.	1w	2	a1;
		- Purchase and Inventory - Control Procurement and stocking	1w	2	a1; c2
6	Drug distribution services	- Complete floor stock system - Individual or patient	1w	2	a1;
		- Prescription order system - Combination of system - Unit dose system	1w	2	a1; c1;
		- Dispensing of drugs to ambulatory patients. - Drug information services - Drug formulary	1w	2	a1; a2; a3; b2; c1; c3; d2;
7	Out -patient pharmacy		1w	2	a1; a3; b3; d1;
8	**Inpatient pharmacy service**	- I.V. admixtures and TPN\ - Parenteral and sterile products admixture - Drug in-compatabilies in infusion solutions, Patient counseling	1w	2	a1; a3; b1; b3; c1; d1;
		- Practice the appropriate aseptic technique used in the preparation of IV admixture	1w	2	a1; a3; b1; b3; c1;

		- Total Parenteral Nutrition - Drug therapy monitoring	1W	2	a1; a3;b1; b3; c1; d2;
		- Rational use of drugs - Essential drug list - Patient-data base.	1W	2	a1; a2; a3; b1; b2; b3;c3; d2;
Number of Weeks /and Units Per Semester			**14**	**24**	

VI. Teaching strategies of the course:

- Lectures
- Discussion sessions
- Media Presentations: Power Point, Video
- Assignments
- Solving of problems

V. Assignments:

No	Assignments	Aligned CILOs(symbols)	Week Due	Mark
1	Participation	5	Weekly	a1; a2; a3; b2; c1
2	Quizzes	5	Weekly	a1; a2; a3; b1; c1
3	Research	5	6th W	a2; b2; b3; c2; c3; ; d2
4	Assignments	5	6th W	a2; a3; b2; b3; c1; c2
	Mid – Exam (theoretical)	20	7th W	a1; a2; a3; b1
	Total score	**40%**		

V. 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 & Homework, Tasks & Presentation	Fortnightly	10	10%	a2; a3; b2; b3; c1; c2
2	Quizzes	W6	5	5%	a1; a2; a3; b1; c1
3	Mid-Term exam	W8	20	20%	a1; a2; a3; b1
4	Practical reports	W12	5	5%	a1; a2; a3; b1; c1
6	Final Exam theory	W16	60	60%	a1; a2; a3; b1
Total			**100**	**100%**	

VI. Learning Resources:

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

1. Introduction to hospital and health system, pharmacy practice by: David Hold ford, Thomas Brown. 2010
2. Hospital Pharmacy by: Stephens, Martin, Second edition (Mar 2011)

2- Essential References.

1. Hand book of Hospital pharmacy
2. Pharmacy Practice Manual: A Guide to the Clinical Experience by: Larry E. Boh, Lippincott Willia Wilkins; Second edition (March 15, 2001)
3. A practical Guide to pharmaceutical care by John P. Rovers, Jay D. Currie, Harry P. Hagel, Randy P. McDonough, Jenelle L. Sobotka. APhA Publications; 2nd edition (2003).

3- Electronic Materials and Web Sites *etc.*	
	www.pharmaceuticalpractice . http://www.ashp.org/ http://www.ahfsdruginformation.com/