

Kafr el-Sheikh University
Faculty of Pharmacy
Pharm-D program
Course Specification
2025/2026



Pharm-D program Course Specification 2025/2026 Fifth Level Second Semester

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Course Specification

(2025)

1. Basic Information

Course Title (according to the bylaw)	Quality control of pharmaceuticals			
Course Code (according to the bylaw)	PA 005			
Department/s participating in delivery of the course	Pharmaceutical Analytical Chemistry			
Number of credit hours/points of the course (according to the bylaw)	Theoretical 2	Practical 1	Other (specify) -	Total 3
Course Type	Compulsory			
Academic level at which the course is taught	Level (5)			
Academic Program	Bachelor in pharmacy (Pharm D)			
Faculty/Institute	Faculty of Pharmacy			
University/Academy	Kafrelsheikh University			
Name of Course Coordinator	Prof.Dr.Fathalla Belal			
Course Specification Approval Date	9/2025			
Course Specification Approval (Attach the decision/minutes of the department /committee/council)	Department council			

2. Course Overview (Brief summary of scientific content)

This course covers quality control and quality assurance of pharmaceuticals, good analytical practice and sampling: Introduction, sampling of pharmaceuticals and related materials, type of sampling tools, sampling plans, documentation, validation of analytical methods according to ICH guidelines Q2 R1, drug stability, stability studies and stability indicating methods, and official methods of analysis applied to raw materials and end products.

3. Course Learning Outcomes CLOs

Matrix of course learning outcomes CLOs with program outcomes POs (NARS/ARS)

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
DOMAIN 1- FUNDAMENTAL KNOWLEDGE 1.1. Competency		<p>Graduates will be able to integrate knowledge from basic analytical techniques to identify as well as quantify different active pharmaceutical ingredients either authentic or in different pharmaceutical formulations in addition to biological samples.</p> <p>This competency will be developed via the following key elements:</p>	
1.1.1	Demonstrate understanding of knowledge of pharmaceutical, biomedical, social, behavioral, administrative, and clinical sciences .	1.1.1	Define the basic analytical chemistry techniques and their applications.
		1.1.2	Identify the official methods of analysis applied to raw materials and end products.
1.1.3	Integrate knowledge from fundamental sciences to handle, identify, extract, design, prepare, analyze, and assure quality of synthetic/natural pharmaceutical materials/products.	1.1.3	Explain different analytical techniques under good laboratory practice to validate and assure quality of pharmaceutical material and products.
		1.1.4	Perform qualitative and quantitative analysis of pharmaceutical materials.
1.1.6	Utilize scientific literature and collect and interpret information to enhance professional decisions .	1.1.5	Identify active pharmaceutical ingredients using compendial and instrumental methods.
		1.1.6	Integrate information from different scientific resources on recent technologies that contribute to pharmaceutical analytical chemistry in quality control labs.
		1.1.7	Locate and summarize primary and secondary scientific sources relevant to pharmaceutical quality control.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
1.1.7	Identify and critically analyze newly emerging issues influencing pharmaceutical industry and patient health care.	1.1.8	Critically analyze scientific literature and case studies on quality- related issues and assess the impact of such issues on product quality and patient safety and propose evidence-based quality control strategies.
DOMAIN 2: PROFESSIONAL AND ETHICAL PRACTICE 2.2. Competency		<p>Graduates will be able to determine pharmaceutical active ingredients and their stability in formulations as well as inspection of their shelf lives in addition to calibration of instrumentations.</p> <p>This competency will be developed via the following key elements:</p>	
2.2.2	Apply the basic requirements of quality management system in developing, manufacturing, analyzing, storing, and distributing pharmaceutical materials/ products considering various incompatibilities.	2.2.1	Describe the official methods to control quality specifications of dosage forms.
		2.2.2	Isolate active ingredients by solid phase or liquid-liquid extraction, inspection of its purity by different spectroscopic analytical techniques and finally, subjected to analytical quantification.
		2.2.3	Apply the compendial methods for QC/QA of bulk drugs and drug products
		2.2.4	Employ international guidelines concerning QC and QA in sampling, stability indicating assays on storage and incompatibility problems.
2.2.3	Recognize the principles of various tools and instruments and select the proper techniques for synthesis and analysis of different materials and production of pharmaceuticals.	2.2.5	Explain the principles of operation and components of the analytical instruments used in pharmaceutical quality control as UV-Vis and HPLC.
		2.2.6	Select and develop analytical methodologies to ensure that the results obtained comply with the pharmacopeial international specifications of both synthetic or natural authentic samples in addition to pharmaceuticals.
		2.2.7	Recognize different sampling techniques, different types of error and validation parameters.
2.3. Competency		<p>Proper dealing with samples containing active pharmaceutical ingredients either biological, pharmaceutical product or even authentic without deterioration in a manner keeping their physical and chemical characteristics in accordance to national and international regulations.</p> <p>This competency will be developed via the following key elements:</p>	

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
2.3.1	Handle, identify, and dispose biologicals, synthetic/natural materials, biotechnology-based and radio-labeled products, and other materials/products used in pharmaceutical fields.	2.3.1	Identify the proper treatment of different samples of pharmaceutical interest like those are natural, authentic, nano-formulated, radioactive and pharmaceutical products as well as their characterization.
		2.3.2	Apply the appropriate analytical and quality control techniques to assess the purity, quality, and safety of these materials.
		2.3.3	Handle pharmaceutical materials following official methods to control quality specifications of dosage forms
2.3.2	Recognize and adopt ethical, legal, and safety guidelines for handling and disposal of biologicals, and pharmaceutical materials/products.	2.3.4	Recognize the regulations for safe dealing with active pharmaceutical ingredients.
		2.3.5	Apply standard operating procedures (SOPs) to ensure compliance with GMP and GLP during handling.
2.5. Competency		<p>Participation in optimizing as well as validation of newly developed analytical methods for accurate determination of pharmaceutical products in addition to clinical applications either in volunteers or laboratory animals required for approval.</p> <p>This competency will be developed via the following key elements:</p>	
2.5.1	Fulfill the requirements of the regulatory framework to authorize a medicinal product including quality, safety, and efficacy requirements.	2.5.1	Perform analytical identification of analytes as raw material, in dosage forms or in biological fluids as well as determination of their concentration in accordance to ethical research regulations.
		2.5.2	Apply relevant guidelines (ICH, WHO, FDA) in quality control process.
DOMAIN 4: PERSONAL PRACTICE 4.1 .Competency		<p>Express leadership, time management, critical thinking, problem solving, independent and team working, creativity and entrepreneurial skills.</p> <p>This competency will be developed via the following key elements:</p>	
4.1.1	Demonstrate responsibility for team performance and peer evaluation of other team	4.1.1	Interact as a part of team to plan, conduct, and report pharmaceutical quality control experiments.
		4.1.2	Provide peer evaluation of the performance of team members.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	members, and express time management skills.	4.1.3	Adhere to a timeline for completion of the tasks.
4.1.2	Retrieve and critically analyze information, identify and solve problems, and work autonomously and effectively in a team.	4.1.4	Retrieve information from a variety of sources, including libraries, databases and internet.
		4.1.5	Analyze data and solve scientific problems and use effectively computer programs (EXCEL) to determine the validation parameters.
		4.1.6	Work autonomously to complete analytical QC tasks.
4.1.3	Demonstrate creativity and apply entrepreneurial skills within a simulated entrepreneurial activity.	4.1.7	Work in teams to identify a real challenge in pharmaceutical quality control and develop a creative solution.
		4.1.8	Plan appropriate experiments in the laboratory bearing in mind technical availability and time limitations.
4.2 .Competency		<p>Effectively communicate verbally, non-verbally and in writing with individuals and communities.</p> <p>This competency will be developed via the following key elements:</p>	
4.2.2	Use contemporary technologies and media to demonstrate effective presentation skills.	4.2.1	Show the ability to effectively present a topic of interest using recent technologies.
		4.2.2	Use of digital tools to create formative presentations and incorporation of visual aids as charts and images.
4.3. Competency		<p>Express self-awareness and be a life-long learner for continuous professional improvement.</p> <p>This competency will be developed via the following key elements:</p>	
4.3.1	Perform self-assessment to enhance professional and personal competencies.	4.3.1	Perform self-improvements on both academic and research professional levels at all aspects of pharmaceutical analytical chemistry.
		4.3.2	Perform self-assessment of their own practical work by comparing their results with standards to enhance professional competencies and self-estimation.
4.3.2	Practice independent learning is needed for continuous professional development.	4.3.3	Practice independent learning by giving the opportunity to perform internet search and literature survey so as to find out answers to tutorial questions throughout the course.
		4.3.4	Identify learning needs to enhance expertise in pharmaceutical quality control.

4. Teaching and Learning Methods

1. Lectures
2. Practical training / laboratory
3. E- Learning
4. Class Activity
5. Discussion
6. Brain storming
7. Assignment
8. Presentation
9. Case study



Course Schedule

Number of the Week	Scientific content of the course (Course Topics)	Total Weekly Hours	Expected number of the Learning Hours			
			Theoretical teaching (lectures/discussion groups/.....)	Training (Practical/ Clinical/.....)	Self-learning (Tasks/ Assignments/	Other (to be determined)
1	Quality control (QC): general introduction and background	4	2	2	-	-
2	Chemical purity of drugs	4	2	2	-	-
3	Impurities in official articles; USP	4	2	2	-	-
4	Official methods to control quality specifications of dosage forms (DF)	4	2	2	-	-
5	Quality standards	4	2	2	-	-
6	Sampling	4	2	2	-	-
7	Periodical exam					
8	Documentation	4	2	2	-	-
9	Assay methods of drugs	4	2	2	-	-
10	Compendial methods for QC/QA of bulk drugs and drug products	4	2	2	-	-
11	Applications of spectrophotometric methods in analysis and QC of drugs	4	2	2	-	-
12	Atomic spectroscopy	4	2	2	-	-
13	Validation of analytical procedures	4	2	2	-	-
14	Stability of drugs in their dosage forms	2	2	Practical exam	-	-
15	Stability Indicating Assay Methods (SIAMs)	2	2	Practical exam	-	-

1. Methods of students' assessment

No.	Assessment Methods	Assessment Timing (Week Number)	Marks/ Scores	Percentage of total course Marks
1.	Periodical exam	Week7	15	15%
2.	Final written exam	Week 16,17	50	50%
3.	Final practical exam	Week14,15	20	20%
4.	Final oral exam	Week 16,17	10	10%
5.	Assignments / Project /Portfolio/ Logbook	Week 9	5	5 %

2. Learning Resources and Supportive Facilities

Learning resources (books, scientific references, etc.)	The main (essential) reference for the course (must be written in full according to the scientific documentation method)	<ul style="list-style-type: none"> Mitra, A. (2021). Fundamentals of quality control and improvement (5th ed.). Wiley.
	Other References	<ul style="list-style-type: none"> Shukla, S. S., Pandey, R. K., Gidwani, B., & Kalyani, G. (2023). Pharmaceutical Calibration, Validation and Qualification: A Comprehensive Approach. World Health Organization. (2024). Quality assurance of pharmaceuticals: a compendium of guidelines and related materials, Volume 1. Good practices and related regulatory guidance.
	Electronic Sources (Links must be added)	www.pubmed.com www.sciencedirect.com
	Learning Platforms (Links must be added)	https://lms3.kfs.edu.eg/pharm/login/index.php
	Other (to be mentioned)	-
Supportive facilities &	Devices/Instruments	Laboratory facilities like pH meters, UV/Vis spectrophotometer, and HPLC

equipment for teaching and learning	Supplies	Chemicals as reagents and indicators for proper lab work and analytical tools as burettes, pipettes, stands, funnels, and flasks.
	Electronic Programs	--
	Skill Labs/ Simulators	--
	Virtual Labs	--
	Other (to be mentioned)	Data show, smart board, unit for distance learning, computers, internet and library

Course Plan
Matrix of course learning outcomes CLOs- teaching and learning strategy and student assessment

Week	Topic	Key elements	Teaching and Learning Methods	Student Assessment Methods
1	Quality control (QC): general introduction and background	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 2.2.1, 2.2.4, 2.3.4, 2.3.5, 2.5.1, 2.5.2	Lectures, E-learning, and class activity	Written and oral exams
2	Chemical purity of drugs	1.1.1, 1.1.2, 1.1.3, 2.2.1, 2.3.1, 2.3.2, 4.1.1, 4.1.2, 4.2.1, 4.2.2	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams
3	Impurities in official articles; USP	1.1.2, 1.1.3, 1.1.6, 1.1.7, 2.2.1, 2.2.2, 2.3.1, 2.3.2, 4.1.1, 4.1.2, 4.2.1, 4.2.2	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams
4	Official methods to control quality specifications of dosage forms (DF)	1.1.2, 1.1.3, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.3, 2.3.4, 2.3.5, 4.1.3, 4.1.4, 4.1.7, 4.1.8	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams
5	Quality standards	2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.3.1, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.5.1, 2.5.2, 4.2.1, 4.2.2	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams
6	Sampling	2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.3.1, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.5.1, 2.5.2, 4.2.1, 4.2.2	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams
7	Periodical exam			
8	Documentation	1.1.2, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.3.1, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.5.1, 2.5.2, 4.2.1, 4.2.2, 4.3.1, 4.3.2	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams

9	Assay methods of drugs	1.1.2, 1.1.3, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 2.2.1, 2.2.2, 2.2.3, 2.2.3, 2.2.4, 2.3.4, 2.3.5, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams
10	Compendial methods for QC/QA of bulk drugs and drug products	1.1.2, 1.1.3, 1.1.5, 1.1.6, 1.1.8, 2.2.1, 2.2.2, 2.2.3, 2.2.3, 2.2.4, 2.3.4, 2.3.5, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams
11	Applications of spectrophotometric methods in analysis and QC of drugs	1.1.2, 1.1.3, 1.1.5, 1.1.6, 1.1.8, 2.2.1, 2.2.2, 2.2.3, 2.2.3, 2.2.4, 2.3.4, 2.3.5, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams
12	Atomic spectroscopy	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 2.2.1, 2.2.5, 2.2.6, 2.3.3, 4.3.1, 4.3.2	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams
13	Validation of analytical procedures	1.1.2, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.3.1, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.5.1, 2.5.2, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.3.1, 4.3.2	Lectures, practical training, E-learning, and class activity	Written, practical and oral exams
14	Stability of drugs in their dosage forms	1.1.2, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.3.1, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.5.1, 2.5.2, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.3.1, 4.3.2	Lectures, E-learning, and class activity	Written and oral exams
15	Stability Indicating Assay Methods (SIAMs)	1.1.2, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.3.1, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.5.1, 2.5.2, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.3.1, 4.3.2	Lectures, E-learning, and class activity	Written and oral exams

Name and Signature
Course Coordinator
Prof. Dr. Fathalla Belal

Name and Signature
Program Coordinator
Prof. Dr. Abdelaziz Elashmawy

Course Specification

2025

Basic Information

Course Title (according to the bylaw)	Drug interaction			
Course Code (according to the bylaw)	PP005			
Department/s participating in delivery of the course	Pharmacology & Toxicology			
Number of credit hours/points of the course (according to the bylaw)	Theoretical	Practical	Other (specify)	Total
	1	1		2
Course Type	Compulsory			
Academic level at which the course is taught	Fifth Level			
Academic Program	Bachelor of Pharmacy (Pharm D)			
Faculty/Institute	Faculty of Pharmacy			
University/Academy	Kafrelsheikh University			
Name of Course Coordinator	Dr. Samar Elsbaay			
Course Specification Approval Date	9/2025			
Course Specification Approval	Department of Pharmacology and Toxicology Council			

1. Course Overview (Brief summary of scientific content)

This course provides the knowledge and skills enabling them to develop professional competencies in the recognition and discussion of the pharmacological aspects of drug-drug, drug-chemical, drug herb or drug-food interactions and their clinical significance as well as the application of that knowledge to minimize the risk and outcome of interactions. It covers different types of drug interaction including pharmaceutical interactions, pharmacokinetic interactions, pharmacodynamic interactions, herbal & food drug interactions, alcohol and smoking drug interactions, interactions of cardiovascular acting drugs, interactions of anticoagulants and interactions of antibiotics. The course is designed to familiarize students with the major types of drug interactions (Pharmacokinetic, pharmacodynamic and pharmacogenetic interactions) in the clinical setting, in addition to drug food and drug herbal interactions. The course compromises digitalis drug interactions, anticoagulants, hypoglycemic interactions and antihypertensive interactions. Students will be expected to determine whether a given interaction is clinically significant or require pharmacist intervention and make rational, scientific recommendations for management of drug interaction.

2. Course Learning Outcomes CLOs

Matrix of course learning outcomes CLOs with program outcomes POs (NARS/ARS)

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
Domain 1 (FUNDAMENTAL KNOWLEDGE) 1-1- COMPETENCY		Integrate knowledge from basic and clinical sciences to explain the principles, mechanisms, and types of drug interactions. Apply scientific understanding of drug interactions to optimize patient-centered therapeutic care. This competency will be developed via the following key elements:	
1.1.1	Demonstrate understanding of knowledge of pharmaceutical, biomedical, social, behavioral, administrative, and clinical sciences.	1.1.1	Demonstrate understanding of pharmaceutical, biomedical, social, behavioral, administrative, and clinical sciences relevant to drug interaction ,mechanisms and effects.
		1.1.2	Identify and describe the types of drug interactions, including pharmacokinetic, pharmacodynamic interactions, and their relevance in clinical practice.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
		1.1.3	Explain the influence of patient-specific factors such as genetics, age, comorbidities, and lifestyle (e.g., smoking, alcohol, herbal use) on drug interaction occurrence and severity.
1.1.4	Articulate knowledge from fundamental sciences to explain drugs' actions and evaluate their appropriateness, effectiveness, and safety in individuals and populations .	1.1.4	Apply knowledge from fundamental sciences to evaluate the appropriateness, effectiveness, and safety of drug therapy, considering potential interactions.
		1.1.5	Retrieve, interpret, and integrate scientific information to identify, prevent, and solve therapeutic problems related to drug interactions.
		1.1.6	Articulate knowledge from fundamental sciences to explain how drug actions can be altered by various interactions, and evaluate the appropriateness, effectiveness, and safety of drug use in individuals and populations, considering pharmaceutical, pharmacokinetic, pharmacodynamic, and drug-food/herbal interactions.
DOMAIN 2: PROFESSIONAL AND ETHICAL PRACTICE 2-2- COMPETENCY		<p>Apply knowledge of drug interactions when dispensing, storing, and distributing medicines to ensure compatibility and stability.</p> <p>Participate in establishing safe dispensing systems that prevent harmful drug-drug, drug-food, and drug-herbal interactions.</p> <p>This competency will be developed via the following key elements:</p>	
2.2.2	Apply the basic requirements of quality management system in developing, manufacturing,	2.2.1	Recognize and prevent clinically significant drug interactions during dispensing and patient counseling.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	analyzing, storing, and distributing pharmaceutical materials/ products considering various incompatibilities.	2.2.2	Apply knowledge of drug compatibility and stability to avoid harmful interactions.
		2.2.3	Identify and minimize risks of drug interactions through quality assurance in pharmacy practice.
		2.2.4	Utilize pharmacokinetic, biopharmaceutic, and statistical principles to adjust therapy and prevent adverse outcomes.
2.2.4	Adopt the principles of pharmaceutical calculations, biostatistical analysis, bioinformatics, pharmacokinetics, and biopharmaceutics and their applications in new drug delivery systems, dose modification, bioequivalence studies, and pharmacy practice	2.2.5	Monitor and document interaction risks during dispensing and clinical review.
		2.2.6	Apply evidence-based strategies to manage complex patient medication regimens.
		2.2.7	Collaborate with healthcare teams to prevent and manage drug interactions in clinical settings.
2-4- COMPETENCY		<p>Take prompt professional action in emergency situations caused by severe or life-threatening drug interactions.</p> <p>Contribute to the clinical management of patients experiencing adverse outcomes from drug</p> <p>This competency will be developed via the following key elements:</p>	
2.4.3	Take actions to solve any identified medicine-related and pharmaceutical care problems	2.4.1	Recognize adverse reaction (ADR) and toxicity of different pharmaceuticals; and manage such problems to improve individual health care
Domain 3: Pharmaceutical Care 3-2- Competency		<p>Educate patients and communities on how to prevent and manage drug-drug, drug-food, and drug-herbal interactions.</p> <p>Provide clear counseling on the safe and rational use of medicines, considering possible interactions and their</p>	

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
		impact on therapy This competency will be developed via the following key elements:	
3.2.1	Integrate the pharmacological properties of drugs including mechanisms of action, therapeutic uses, dosage, contraindications, adverse drug reactions and drug interactions	3.2.1	Integrate pharmacological properties, mechanisms, therapeutic uses, and interaction profiles of drugs into clinical decisions.
3.2.5	Educate and counsel patients, other health care professionals, and communities about safe and proper use of medicines including OTC preparations and medical devices	3.2.3	Design and implement care plans to prevent and manage drug interactions in various patient populations.
Domain 4: Personal Practice 4-1- Competency		Demonstrate leadership and teamwork when evaluating and resolving clinical cases involving drug interactions. Apply critical thinking and problem-solving skills to develop creative strategies for preventing and managing drug interactions in various healthcare settings. This competency will be developed via the following key elements:	
4.1.1	Demonstrate responsibility for team performance and peer evaluation of other team members, and express time management skills	4.1.1	Demonstrate critical thinking, problem-solving, creativity, time management and decision-making abilities to evaluate team performance as well as team members.
4.1.2	Retrieve and critically analyze information, identify and solve problems, and work autonomously and effectively in a team.	4.1.2	Adapt prevention and management strategies to different healthcare settings.
		4.1.3	Collaborate with interprofessional teams to improve medication safety.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
		4.1.4	Document and share best practices for interaction prevention and management.
4-2- Competency		<p>Communicate effectively with patients, healthcare professionals, and the public to explain the risks and management of drug interactions.</p> <p>Use clear verbal, non-verbal, and written communication to promote safe and rational medicine use, considering potential interactions.</p> <p>This competency will be developed via the following key elements:</p>	
4.2.1	Demonstrate effective communication skills verbally, non-verbally, and in writing with professional health care teams, patients, and communities.	4.2.1	Communicate clearly by verbal and written means with patients and members of healthcare society
4.2.2	Use contemporary technologies and media to demonstrate effective presentation skills	4.2.2	Prepare educational materials for professionals and the public.
		4.2.3	Use decision-support systems to detect and prevent drug interactions.
4-3- Competency		<p>Reflect on personal performance in identifying and managing drug interactions to enhance professional competence.</p> <p>Engage in continuous learning to stay updated on current evidence and best practices for preventing and managing drug interactions.</p> <p>This competency will be developed via the following key elements:</p>	
4.3.1	Perform self-assessment to enhance professional and personal	4.3.1	Perform self-assessment to identify learning needs in drug interaction management.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	competencies.	4.3.2	Engage in continuous professional development to update knowledge on interactions.
		4.3.3	Participate in professional training on interaction prevention and management.
4.3.2	Practice independent learning needed for continuous professional development	4.3.4	Apply reflective practice to improve decision-making in drug interaction cases.
		4.3.5	Contribute to research and quality improvement projects related to interactions.
		4.3.6	Demonstrate commitment to lifelong learning in drug interaction science.

3. Teaching and Learning Methods

1. Lectures
2. E-learning
3. Practical
4. Discussion
5. Brainstorming
6. Assignment
7. Presentation
8. Case study

Course Schedule

Number of the Week	Scientific content of the course (Course Topics)	Total Weekly Hours	Expected number of the Learning Hours			
			Theoretical teaching (lectures/discussion groups/)	Training (Practical/Clinical/.....)	Self-learning (Tasks/Assignments/Projects/ ...)	Other (to be determined)
1	-General introductions to drug interactions -Pharmacokinetic D.I	2	1	1		
2	Pharmacokinetic D.I (cont.)	2	1	1		
3	Pharmacokinetic D.I (cont.)	2	1	1		
4	Pharmacodynamic D.I	2	1	1		
5	Antibiotics-drug interactions	2	1	1		
6	C V S drug – drug interactions	2	1	1		
7	Periodical exam					
8	C V S drug – drug interactions (cont.)	2	1	1		
9	C V S drug – drug interactions (cont.)	2	1	1		
10	Anti-coagulant drug interactions	2	1	1		
11	Drug-Food interactions	2	1	1		
12	Food -Drug interactions	2	1	1		
13	Drug-Herbal interactions	2	1	1		
14	Antidiabetic drug-drug interactions	2	1	1		
15	revision	1	1	Practical exam		

4. Methods of students' assessment

No.	Assessment Methods *	Assessment Timing (Week Number)	Marks/ Scores	Percentage of total course Marks
1	Formative exam	4	5	5%
2	Periodical exam	7	10	10%
3	Final Practical/Clinical/... Exam	14,15	25	25%
4	Final Written Exam	16,17	50	50%
5	Final Oral Exam	16,17	10	10%

5. Learning Resources and Supportive Facilities *

Learning resources (books, scientific references, etc.) *	The main (essential) reference for the course	- Stockley's Drug Interactions. Stockley HI(Ed). Pharmaceutical Press.12 th edition
	Other References	- Baxter K, Preston CL (eds.). Stockley's Drug Interactions. 12th ed. London: Pharmaceutical Press; 2022. - Koda-Kimble MA, Young LY, et al. Applied Therapeutics: The Clinical Use of Drugs. 11th ed. Wolters Kluwer; 2022. - Katzung BG, Vanderah TW. <i>Basic and Clinical Pharmacology</i> . 16th ed. McGraw-Hill; 2021.
	Electronic Sources	https://www.drugs.com/drug_interactions.html www.medscape.com https://go.drugbank.com www.ncbi.nlm.nih.gov/pmc/ www.ncbi.nlm.nih.gov/pmc/articles/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5355877/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5355877/
	Learning Platforms	https://lms3.kfs.edu.eg/pharm/login/index.php
	Other	

Supportive facilities & equipment for teaching and learning *	Devices/Instruments	Data show, smart board, Unit for distance learning, Computers and Internet
	Supplies	-Class rooms.
	Electronic Programs	----
	Skill Labs/ Simulators	----
	Virtual Labs	----
	Other (to be mentioned)	-Library

Course Plan

Matrix of course learning outcomes CLOs – Teaching and Learning Strategy and Student Assessment

Course title: Drug interaction

Course code: PP005

Course Contents		Key elements	Teaching and Learning Methods	Student Assessment Methods
Week 1	<ul style="list-style-type: none"> -General introductions to drug interactions -Pharmacokinetic D.I 	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E-learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams
Week # 2	Pharmacokinetic D.I (cont.)	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E-learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams
Week # 3	Pharmacokinetic D.I (cont.)	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E-learning, Practical, Discussion, Brainstorming	Written, practical and oral exams

			Assignment, Presentation and case study	
Week # 4	- Pharmacodynamic D.I	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E- learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams
Week # 5	Antibiotics-drug interactions	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E- learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams
Week # 6	C V S drug – drug interactions	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E- learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams
Week # 7	Periodical exam			
Week # 8	C V S drug – drug interactions (cont.)	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1,	Lectures, E- learning,	Written, practical and

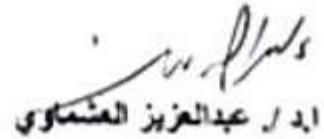
		3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Practical, Discussion, Brainstorming Assignment, Presentation and case study	oral exams
Week # 9	C V S drug – drug interactions (cont.)	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E-learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams
Week # 10	Anti-coagulant drug interactions	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E-learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams
Week # 11	Drug-Food interactions	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E-learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams

Week # 12	Food -Drug interactions	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E-learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams
Week # 13	Drug-Herbal interactions	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E-learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams
Week # 14	Antidiabetic drug-drug interactions	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	Lectures, E-learning, Practical, Discussion, Brainstorming Assignment, Presentation and case study	Written, practical and oral exams
Week # 15	revision	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.4.1, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 4.3.5, 4.3.6	, E-learning, Practical, Discussion, Brainstorming Assignment, Presentation and	Written, practical and oral exams

			case study	
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Name and Signature
Course Coordinator
Dr. Samar El-sebaey Ayoub

Name and Signature
Program Coordinator
Prof. Dr. Abdel Aziz El-Ashmawy



د. أ. عبد العزيز الشحاتي

Course Specification

2025

1. Basic Information

Course Title (according to the bylaw)	Advanced Drug Delivery Systems			
Course Code (according to the bylaw)	PT 011			
Department/s participating in delivery of the course	Pharmaceutics & Pharmaceutical Technology			
Number of credit hours/points of the course (according to the bylaw)	Theoretical	Practical	Other (specify)	Total
	1	1	----	2
Course Type	Compulsory			
Academic level at which the course is taught	Fifth level, semester (2)			
Academic Program	Bachelor of Pharmacy (PharmD)			
Faculty/Institute	Faculty of Pharmacy			
University/Academy	Kafrelsheikh university			
Name of Course Coordinator	Ass. Prof. Eman Mazyd Lecturer. Ahmed Adel			
Course Specification Approval Date	9/2025			
Course Specification Approval (Attach the decision/minutes of the department /committee/council)	Department council			

2. Course Overview (Brief summary of scientific content)

This course covers the different targeted drug delivery systems, novel formulations based on the physicochemical properties of the drug substance and the intended use of the drug product, the formulation aspects of different biotechnology-derived pharmaceuticals, the different nanotechnology-based drug delivery systems, the applications of polymers and different excipients in improving bioavailability, selective transport, targeting, and tailoring release profiles of the drugs.

3. Course Learning Outcomes CLOs

Matrix of course learning outcomes CLOs with program outcomes POs (NARS/ARS)

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
Domain 1 (FUNDAMENTAL KNOWLEDGE) 1-1- COMPETENCY		Upon finishing this course, students will be able to integrate knowledge from basic pharmaceutical science to formulate different classes of semisolid dosage forms as a preliminary step in the manufacture of therapeutic and cosmetic products. This competency will be developed via the following key elements:	
1.1.1	Demonstrate understanding of knowledge of pharmaceutical, biomedical, social, behavioral, administrative, and clinical sciences.	1.1.1	Understand the relationship between the physicochemical properties of the drug (active pharmaceutical ingredient) and the drug product and the biological performance of the drug.
		1.1.2	Integrate information from different scientific resources on recent technologies that contribute to pharmaceutical industries.
		1.1.3	Demonstrate a deep understanding of the molecular properties of drugs and how they

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
			affect the choice of drug delivery system and administration route
		1.1.4	Relate barrier properties (physiological, biochemical, chemical), proteins and enzymes transport to their importance for drug delivery via different routes of administration.
		1.1.5	Identify novel formulation principles for different routes of administration; nasal, parenteral, oral, dermal, and ocular.
		1.1.6	Identify the different types of controlled-release dosage forms.
1.1.3	Integrate knowledge from fundamental sciences to handle, identify, extract, design, prepare, analyze, and assure quality of synthetic/natural pharmaceutical materials/products.	1.1.7	Identify novel formulation principles for different routes of administration; nasal, parenteral, oral, dermal, and ocular.
DOMAIN 2: PROFESSIONAL AND ETHICAL PRACTICE 2-2- COMPETENCY		Upon finishing this course, students will be able to formulate and manufacture different semisolid dosage forms and participate in systems for dispensing, storage, and distribution of all semisolid dosage forms. This competency will be developed via the following key elements:	
2.2.2	Apply the basic requirements of quality management system in developing, manufacturing, analyzing, storing, and distributing pharmaceutical materials/products considering various incompatibilities.	2.2.1	Design, develop, and optimize new drug delivery systems to improve the efficacy of the conventional dosage forms.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
2.2.3	Recognize the principles of various tools and instruments and select the proper techniques for synthesis and analysis of different materials and production of pharmaceuticals.	2.2.2	Differentiate between the different techniques used to increase the absorbed drugs and its stability.
2.2.4	Adopt the principles of pharmaceutical calculations, biostatistical analysis, bioinformatics, pharmacokinetics, and biopharmaceutics and their applications in new drug delivery systems, dose modification, bioequivalence studies, and pharmacy practice	2.2.3	Tailor and adjust dosage regimens depending on the proposed drug delivery strategy.
2-3- COMPETENCY		<p>Upon finishing this course, students will be able to handle and dispose of synthetic/natural pharmaceutical materials used in preparation of semisolid pharmaceutical products effectively and safely with respect to relevant laws and legislations.</p> <p>This competency will be developed via the following key elements:</p>	
2.3.1	Handle, identify, and dispose biologicals, synthetic/natural materials, biotechnology-based and radio-labeled products, and other materials/products used in pharmaceutical fields.	2.3.1	Safely handle different chemicals to avoid harm to the students.
2.3.2	Recognize and adopt ethical, legal, and safety guidelines for handling and disposal of biological and pharmaceutical materials/products.	2.3.2	Recognize and adopt MSDS safety guidelines for safe and appropriate handling and disposal of pharmaceutical chemical materials.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
2-5- COMPETENCY		<p>Upon finishing this course, students will be able to contribute to pharmaceutical research studies and clinical trials needed to authorize medicinal products.</p> <p>This competency will be developed via the following key elements:</p>	
2.5.3	Contribute in planning and conducting research studies using appropriate methodologies	2.5.1	Search for new drug delivery platforms for better therapeutic outcomes.
		2.5.2	Develop critical thinking skills while addressing the drawbacks of conventional drug delivery systems.
Domain 4: Personal Practice 4-1- Competency		<p>Upon finishing this course, students will be able to express leadership, time management, critical thinking, problem solving, independent and teamwork, creativity and entrepreneurial skills.</p> <p>This competency will be developed via the following key elements:</p>	
4.1.1	Demonstrate responsibility for team performance and peer evaluation of other team members, and express time management skills	4.1.1	Support teamwork and time management skills through different activities
4.1.2	Retrieve and critically analyze information, identify and solve problems, and work autonomously and effectively in a team	4.1.2	Use recent technologies to effectively present a topic of interest.
4-2- Competency		<p>Upon finishing this course, students will be able to Effectively communicate verbally, non-verbally and in writing with individuals and communities.</p> <p>This competency will be developed via the following key elements:</p>	

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
4.2.2	Use contemporary technologies and media to demonstrate effective presentation skills.	4.2.1	Perform presentation on the different drug delivery systems
		4.2.2	Acquire effective presentation skills in the modern technology and media to create engaging and memorable experiences. This includes using interactive slides, incorporating multimedia (videos, images, audio), and employing tools for real-time feedback and collaboration. By integrating these elements, student can enhance audience engagement, clarify complex information, and leave a lasting impact.
4-3- Competency		<p>Upon finishing this course, students will be able to express self-awareness and be a life-long learner for continuous professional improvement.</p> <p>This competency will be developed via the following key elements:</p>	
4.3.1	Perform self-assessment to enhance professional and personal competencies.	4.3.1	Integrate students in many research techniques
4.3.2	Practice independent learning needed for continuous professional development	4.3.2	Depend on students in many research issues and the different methods needed to solve the problem and achieve more outcomes.

4. Teaching and Learning Methods

- 1- Lectures (✓)
- 2- E-learning (✓)
- 3- Practical training/ laboratory (✓)

4- Assignment (✓)

5- Presentation (✓)

Course Schedule

Number of the Week	Scientific content of the course (Course Topics)	Total Weekly Hours	Expected number of the Learning Hours			
			Theoretical teaching (lectures/ discussion groups/)	Training (Practical/ Clinical/)	Self-learning (Tasks/ Assignments/ Projects/ ...)	Other (to be determined)
1	Introduction	2	1	1	-----	-----
2	Liposomes, Niosomes, Ethosomes, and Transfersomes	2	1	1	-----	-----
3	Iontophoresis, Sonophoresis, Electroporation, Microneedles, and Jet injectors.	2	1	1	-----	-----
4	Vaccine Delivery	2	1	1	-----	-----
5	Challenges in Peptide & Protein Formulation and Delivery	2	1	1	-----	-----
6	Challenges in Peptide & Protein Formulation and Delivery	2	1	1	-----	-----
7	Periodical exam					
8	Hot Melt Extrusion Technology	2	1	1	-----	-----
9	Tablet Coating Approaches	2	1	1	-----	-----
10	Controlled Drug Delivery	2	1	1	-----	-----
11	Controlled Drug Delivery	2	1	1	-----	-----
12	Targeted Drug Delivery	2	1	1	-----	-----
13	Targeted Drug Delivery	2	1	1	-----	-----

14	Advanced Drug Delivery Systems Using Different Routes of Drug Administration	1	1	Practical exam	-----	-----
15	Advanced Drug Delivery Systems Using Different Routes of Drug Administration	1	1	Practical exam	-----	-----

5. Methods of students' assessment

No.	Assessment Methods	Assessment Timing (Week Number)	Marks/ Scores	Percentage of total course Marks
1	Periodical exam	7	15	15%
2	Final Practical/Clinical/... Exam	14, 15	15	15%
3	Final Written Exam	16,17	50	50%
4	Final Oral Exam	16,17	10	10%
5	Assignments / Project /Portfolio/ Logbook	14,15	10	10%
Total			100	100%

6. Learning Resources and Supportive Facilities

Learning resources (books, scientific references, etc.)	The main (essential) reference for the course (must be written in full according to the scientific documentation method)	Notes on Advanced Drug Delivery Systems prepared by the department staff.
	Other References	Advanced Drug Delivery Systems Principles and Practice by Rekha Rao, Sanju Nanda, and Sheefali Mahant.

		Advanced and Modern Approaches for Drug Delivery by Amit Kumar Nayak, Md Saquib Hasnain, Bibek Laha, and Sabyasachi Maiti.
	Electronic Sources (Links must be added)	https://www.fda.gov/ https://www.ich.org/
	Learning Platforms (Links must be added)	https://lms3.kfs.edu.eg/pharm/login/index.php
	Other (to be mentioned)	
Supportive facilities & equipment for teaching and learning	Devices/Instruments	Laboratory facilities (Equipment of factory).
	Supplies	Water bath, digital balances and other lab instruments
	Electronic Programs	----
	Skill Labs/ Simulators	----
	Virtual Labs	----
	Other (to be mentioned)	Data shows, smart boards, Unit for distance learning, Computers, Internet and Library.

Course Plan

Matrix of course learning outcomes CLOs – Teaching and Learning Strategy and Student Assessment

Course title: Advanced Drug Delivery Systems Course code: PT 011

Week	Course Contents	ILOs	Teaching and Learning Methods	Student Assessment Methods
1	Introduction	1.1.1, 1.1.2, 1.1.3, 2.2.1, 2.2.2, 2.2.3 2.5.1, 2.5.2, 4.2.1	Lectures and discussion.	Written, practical and oral exams.
2	Liposomes, Niosomes, Ethosomes, and Transfersomes	1.1.1, 1.1.2, 1.1.3, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.1.1, 4.1.2 4.2.1	Lectures and practical training.	Written, practical and oral exams.
3	Iontophoresis, Sonophoresis, Electroporation, Microneedles, and Jet injectors.	1.1.1, 1.1.2, 1.1.3, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.2.1, 4.3.2	Lectures and practical training.	Written, practical and oral exams.
4	Vaccine Delivery	1.1.1, 1.1.2, 1.1.3, 2.2.1, 2.2.2, 2.2.3, 2.5.1, 2.5.2, 4.3.1, 4.2.1	Lectures and practical training.	Written, practical and oral exams.
5	Challenges in Peptide & Protein Formulation and Delivery	1.1.1, 1.1.2, 1.1.3, 1.1.4, 2.2.1, 2.2.2, 2.3.1, 2.3.2, 2.5.1, 2.5.2, 4.2.1, 4.2.2	Lectures and practical training.	Written, practical and oral exams.
6	Challenges in Peptide & Protein Formulation and Delivery	1.1.1, 1.1.2, 1.1.3, 1.1.4, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.2.1	Lectures and practical training.	Written, practical and oral exams.
7	Semester works			
8	Hot Melt Extrusion Technology	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.2.1, 4.2.2.	Lectures and practical training.	Written, practical and oral exams.

9	Tablet Coating Approaches	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.2.1	Lectures and practical training.	Written, practical and oral exams.
10	Controlled Drug Delivery	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.2.1	Lectures and practical training.	Written, practical and oral exams.
11	Controlled Drug Delivery	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.2.1	Lectures and practical training.	Written, practical and oral exams.
12	Targeted Drug Delivery	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.2.1	Lectures and practical training.	Written, practical and oral exams.
13	Targeted Drug Delivery	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.2.1	Lectures and practical training.	Written, practical and oral exams.
14	Advanced Drug Delivery Systems Using Different Routes of Drug Administration	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.2.1, 4.3.1, 4.3.2	Lectures and discussion.	Written and oral exams.
15	Advanced Drug Delivery Systems Using Different Routes of Drug Administration	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 2.2.1, 2.2.2, 2.5.1, 2.5.2, 4.2.1, 4.3.1, 4.3.2	Lectures and discussion.	Written and oral exams.

Name and Signature

Course Coordinator

Ass. Prof. Eman Mazyd
Lecturer. Ahmed Adel

Name and Signature
Program Coordinator

Prof. Abdel Aziz ElSayed

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أحمد عادل

عبد العزيز إلسayed

Course Specification

(2025)

Course Title (according to the bylaw)	Clinical Pharmacy II & Pharmacotherapeutics			
Course Code (according to the bylaw)	PP 006			
Department/s participating in delivery of the course	Clinical Pharmacy Department			
Number of credit hours/points of the course (according to the bylaw)	Theoretic al	Practical	Other (specify)	Total
	1	1	----	2
Course Type	Compulsory			
Academic level at which the course is taught	Fifth level, second semester			
Academic Program	BSc in pharmacy (pharm-D)			
Faculty/Institute	Faculty of Pharmacy			
University/Academy	Kafrelsheikh University			
Name of Course Coordinator	Associate. Prof. Noha El-Khodary			
Course Specification Approval Date	31/8/2025			
Course Specification Approval (Attach the decision/minutes of the department /committee/council)	Department council			

2. Course Overview (Brief summary of scientific content)

This course covers major musculoskeletal and dermatological disorders including Gout & Hyperuricemia, Osteoporosis, Osteoarthritis, Rheumatoid Arthritis, and various skin infections such as viral, fungal, and parasitic infections. It also addresses chronic inflammatory skin diseases like Psoriasis and Atopic Dermatitis. The course integrates pathophysiology, etiology, epidemiology, clinical manifestations, diagnostics, and both pharmacological and non-pharmacological management strategies. Students will also develop skills in patient counseling, prevention, and monitoring treatment outcomes.

3. Course Learning Outcomes CLOs

Matrix of course learning outcomes CLOs with program outcomes POs (NARS/ARS)

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
Domain 1 (FUNDAMENTAL KNOWLEDGE) 1-1- COMPETENCY		Upon finishing this course, students will be able to recognize musculoskeletal and dermatological disorders including symptoms, signs, pathophysiology, risk factors and lab investigations that help them diagnosis patients and identify the non-pharmacological and pharmacological treatment for each musculoskeletal and dermatological disorder. This competency will be developed via the following key elements:	
1.1.1	Demonstrate understanding of knowledge of pharmaceutical, biomedical, social, behavioral, administrative, and clinical sciences.	1.1.1	Understand the main scientific terms in the science of dermatological and musculoskeletal diseases
		1.1.2	Describe the pathophysiology of common dermatologic and rheumatologic conditions including psoriasis, atopic dermatitis, and contact dermatitis, Osteoporosis, Osteoarthritis and Rheumatoid Arthritis
		1.1.3	Recognize social and behavioural risk factors for musculoskeletal diseases (e.g., diet, lifestyle, occupational hazards).

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
		1.1.4	Understand healthcare system and administrative aspects of chronic disease management in dermatology and rheumatology.
1.1.4	Articulate knowledge from fundamental sciences to explain drugs' actions and evaluate their appropriateness, effectiveness, and safety in individuals and populations.	1.1.5	Explain the mechanism of action of DMARDs, biologics, topical corticosteroids, and antifungal agents to their therapeutic effects.
		1.1.6	Compare the effectiveness of guideline recommended therapies for different rheumatologic and dermatologic conditions.
		1.1.7	Evaluate drug regimens for safety in patients with comorbidities such as liver disease or immunosuppression.
		1.1.8	Identify different safety aspects of the medications used in management of these disorders.
1.1.5	Retrieve information from fundamental sciences to solve therapeutic problems	1.1.9	Use knowledge of skin physiology and immune system to adjust topical and systemic therapy.
		1.1.10	State different mechanisms of immunosuppressants and use them for best selection according to specific autoimmune conditions.
1.1.6	Utilize scientific literature and collect and interpret information to enhance professional decisions.	1.1.11	Review and apply ACR and AAD treatment guidelines for rheumatologic and dermatologic conditions.
		1.1.12	Identify lab values (e.g., ESR and CRP) to support clinical decisions.
		1.1.13	Evaluate systematic reviews on management strategies of chronic inflammatory conditions.
1.1.7	Identify and critically analyze newly emerging issues influencing pharmaceutical industry and patient health care.	1.1.14	Discuss new drug classes in rheumatology and dermatology therapy (e.g., JAK inhibitors, IL-17 inhibitors).
		1.1.15	Evaluate novel drug delivery systems for topical and systemic therapy.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
DOMAIN 2: PROFESSIONAL AND ETHICAL PRACTICE 2-1- COMPETENCY		Upon finishing this course, students will be able to Work collaboratively as a member of an inter-professional health care team to improve the quality of life of individuals and communities and respect patients' rights. This competency will be developed via the following key elements:	
2.1.1	Perform responsibilities and authorities in compliance with the legal and professional structure and role of all members of the health care professional team.	1.1.1	Learn how to deal with the other members of the health care team for achieving the appropriate management of the rheumatological and dermatological conditions
2.1.2	Adopt ethics of health care and pharmacy profession respecting patients' rights and valuing people diversity.	2.1.2	Maintain patient confidentiality when discussing chronic inflammatory conditions and cosmetic concerns.
		2.1.3	Respect patient preferences in treatment plans (e.g., topical vs systemic therapy, lifestyle modifications).
2.1.3	Recognize your own personal and professional limitations and accept the conditions of referral to or guidance from other members of the health care team.	2.1.4	Refer patients with severe systemic inflammatory conditions (e.g., severe RA flare, systemic lupus) to specialist care.
		2.1.5	Collaborate with dermatologists, rheumatologists, and physical therapists for comprehensive management.
2-2- COMPETENCY		<p>In the Management of rheumatologic and dermatologic Diseases course, students gain the ability to apply scientific principles to ensure the quality and effectiveness of medications used in rheumatologic and dermatologic conditions. They learn:</p> <ul style="list-style-type: none"> • How liver and renal diseases affect drug metabolism, and how this influences drug formulation and dosing. • How to choose proper dosage forms. • How to ensure proper storage of the medications 	

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
		<ul style="list-style-type: none"> • How to participate in safe and accurate dispensing systems, especially for chronic treatments requiring long-term adherence. <p>This competency will be developed via the following key elements:</p>	
2.2.4	Adopt the principles of pharmaceutical calculations, biostatistical analysis, bioinformatics, pharmacokinetics, and biopharmaceutics and their applications in new drug delivery systems, dose modification, bioequivalence studies, and pharmacy practice	2.2.1	Apply PK/PD principles for drug dosing to optimize immunosuppressive therapy and calculate appropriate doses for biologics based on body weight and disease severity.
		2.2.2	Adjust drug doses in special populations (e.g., elderly, pediatric) and in case of renal or hepatic impairment for systemic therapies.
		2.2.3	Understand the impact of liver and renal disease on drug bioavailability and metabolism.
2-4- COMPETENCY		Students learn how to take professional and quick action in emergency situations that may affect the rheumatologic and dermatologic system or be life-threatening.	
2.4.3	Take actions to solve any identified medicine-related and pharmaceutical care problems.	2.4.1	Identify and resolve drug interactions in cases requiring combination therapy (e.g., between DMARDs and other immunosuppressants).

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
		2.4.2	Manage ADRs related to drugs.
		2.4.3	Address nonadherence in long-term immunosuppressive and topical therapy regimens.
2-5- COMPETENCY		Students are introduced to how pharmaceutical research and clinical trials and other resources are essential for developing and approving new treatments for rheumatologic and dermatologic conditions.	
2.5.2	Competency Contribute to pharmaceutical research studies and clinical trials needed to authorize medicinal products.	2.5.1	Students must be able to review evidence from Cochrane, NICE, or UpToDate for rheumatologic and dermatologic treatments.
		2.5.2	Participate in reviewing and discussing case studies or clinical trial examples relevant to rheumatologic and dermatologic disorders. complex information and leave a lasting impact.
3-2- Competency		Students are trained to educate patients and communities about how to use rheumatologic and dermatologic medications safely and effectively.	

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
3.2.1	Integrate the pharmacological properties of drugs including mechanisms of action, therapeutic uses, dosage, contra-indications, adverse drug reactions and drug interactions.	3.2.1	Describe MOA, indications, ADRs, and interactions of major dermatologic and rheumatologic drug classes.
		3.2.2	Identify contraindications and list drug-drug interactions in patients on multiple immunosuppressive agents.
3.2.2	Apply the principles of clinical pharmacology and pharmacovigilance for the rational use of medicines and medical devices.	3.2.3	Monitor ADRs and report side effects of long-term immunosuppressive therapy and detect drug-related adverse outcomes.
		3.2.4	Recommend safe medication use in pregnancy and lactation for chronic inflammatory conditions.
3.2.3	Provide evidence-based information about safe use of complementary medicine including phytotherapy, aromatherapy, and nutraceuticals.	3.2.5	Evaluate evidence for complementary medicine such as turmeric, omega-3 fatty acids in inflammatory conditions.
3.2.4	Provide information about toxic profiles of drugs and other xenobiotics including sources, identification, symptoms, and management control	3.2.6	Identify signs of drug toxicity (e.g., methotrexate toxicity, topical steroid adverse effects).
		3.2.7	Provide management steps for drug overuse/misuse (e.g., educate patients on safe topical steroid use).
3.2.5	Educate and counsel patients, other health care professionals, and communities about safe and proper use of medicines including OTC preparations and medical devices.	3.2.8	Teach correct application techniques for topical medications and use of medical devices.
		3.2.9	Counsel on adherence to chronic immunosuppressive therapy.
3.2.6	Maintain public awareness on social health hazards of drug misuse and abuse	3.2.10	Warn against misuse of topical steroids and unsupervised use of immunosuppressants.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
		3.2.11	Discuss the harm of unregulated "natural" anti-inflammatory products.
Domain 4: Personal Practice 4-1- Competency		From this competency, the student should learn how to: <ul style="list-style-type: none"> • Work well with others when preparing and presenting topics like rheumatologic and dermatologic diseases (e.g., OA, RA, atopic dermatitis). • Manage time to finish tasks on schedule. • Take responsibility and show leadership when needed. • Think clearly and solve problems — for example, how to explain treatment options or organize the content in a better way. • Be creative in making the presentation easy to understand and interesting. • Work independently but also support the team when needed. This competency will be developed via the following key elements: 	
4.1.1	Demonstrate responsibility for team performance and peer evaluation of other team members, and express time management skills.	4.1.1	Participate in interdisciplinary teams managing chronic inflammatory conditions and prioritizing patient cases with urgent concerns.
		4.1.2	Manage tasks in collaborative projects on chronic disease monitoring and evaluate peer contributions during group assignments.
		4.1.3	Manage time effectively by organizing tasks like researching drug therapies for

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
			OA, designing slides, and rehearsing together before the deadline
4.1.2	Retrieve and critically analyze information, identify and solve problems, and work autonomously and effectively in a team.	4.1.4	Research treatment guidelines for rare inflammatory disorders and independently assess medication plans.
		4.1.5	Solve therapeutic dilemmas in conflicting comorbidities and demonstrate initiative in tackling nonadherence issues
		4.1.6	collaborate and contribute meaningfully to team discussions about treatment strategies or patient care plans.
4-2- Competency		Upon finishing this course, students will be able to Effectively communicate verbally, non-verbally and in writing with individuals and communities. This competency will be developed via the following key elements:	
4.2.1	Show the ability to effectively present a topic of interest using recent technology.	4.2.1	Communicate counseling information clearly to patients and discuss chronic treatment plans with empathy and in patient-friendly terms
		4.2.2	Provide community education on prevention of inflammatory and infectious skin conditions.
4.2.2	Communicate clearly by verbal and written means with patients and members of healthcare society	4.2.3	Prepare multimedia case presentations on different dermatologic and rheumatologic conditions.
		4.2.4	Employ tele-pharmacy for follow-up in chronic patients and create

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
			infographic summaries of treatment guidelines.
4-3- Competency		<p>The student should learn how to reflect on their own performance when working on rheumatologic and dermatologic -related tasks (such as presenting a case on Osteoporosis or designing a care plan for Psoriasis).</p> <p>They should identify their strengths and weaknesses This competency will be developed via the following key elements:</p>	
4.3.1	Perform self-assessment to enhance professional and personal competencies.	4.3.1	Reflect on patient counselling effectiveness in managing chronic conditions.
		4.3.2	Develop a personal improvement plan for dermatology and rheumatology knowledge
4.3.2	Practice independent learning is needed for continuous professional development.	4.3.3	Seek new research on emerging therapies and track continuous updates with respect to new regulations and guidelines.
		4.3.4	Maintain a learning portfolio on dermatologic and rheumatologic conditions and learn independently to develop professional skills.

4. Teaching and Learning Methods

- 1- Lectures (✓)
- 2- E-learning (✓)
- 3- Practical training/ laboratory (✓)
- 4- Discussion (✓)
- 5- Brainstorming (✓)
- 6- Class activity (✓)
- 7- Seminars (✓)

Course Schedule

Number of the Week	Scientific content of the course (Course Topics)	Total Weekly Hours	Expected number of the Learning Hours			
			Theoretical teaching (lectures/discussion groups/	Training (Practical/Clinical/	Self-learning (Tasks/ Assignments/ Projects/ ...)	Other (to be determined)
1	Gout & Hyperuricemia	4	2	2	---	---
2	Osteoporosis	4	2	2	---	---
3	Osteoarthritis	4	2	2	---	---
4	Rheumatoid Arthritis	4	2	2	---	---
5	Rheumatoid Arthritis (Cont.)	4	2	2	---	---
6	Viral infections of the skin	4	2	2	---	---
7	Periodical exam					

8	Fungal infections of the skin	4	2	2	---	---
9	Bacterial infection of skin	4	2	2	---	---
10	Parasitic infections of the skin	4	2	2	---	---
11	Psoriasis	4	2	2	---	---
12	Atopic Dermatitis	4	2	2	---	---
13	Atopic Dermatitis (Cont.)	4	2	2	---	---
14	Contact Dermatitis	4	2	Practical exam		
15	Scaly Dermatoses	4	2	Practical exam		

5. Methods of students' assessment

No.	Assessment Methods *	Assessment Timing (Week Number)	Marks/ Scores	Percentage of total course Marks
1	Periodical exam	Week 7	10 marks	10%
3	Final Written Exam	Week 16,17	50 marks	50%
4	Final Practical/Clinical/... Exam	Week 14,15	15 marks	15%
5	Final Oral Exam	Week 16,17	10 marks	10%
6	Assignments / Project /Rubric/ Logbook	All semester long	10 marks	10%
7	Quizzes	Week 4, 8, 12	5 marks	5%

6. Learning Resources and Supportive Facilities *

Learning resources (books, scientific references, etc.) *	The main (essential) reference for the course (must be written in full according to the scientific documentation method)	<ul style="list-style-type: none"> • Pharmacotherapy: A Pathophysiologic Approach, DiPiro JT, 12th Edition, McGraw-Hill • Applied Therapeutics: The Clinical Use of Drugs, 12th Edition, 2024. • Pharmacotherapy: Principles & Practice, 7th Edition, latest release. • Clinical Pharmacy and Therapeutics, 7th Edition, 2025.
	Other References	Theoretical Notes and Lab manual prepared by the department staff.
	Electronic Sources (Links must be added)	http://www.pubmed.com http://www.sciencedirect.com/ http://www.FDA.gov
	Learning Platforms (Links must be added)	https://lms3.kfs.edu.eg/pharm/login/index.php
	Other (to be mentioned)	Pharmacotherapy handbook, 12th (2023)
Supportive facilities & equipment for teaching and learning *	Devices/Instruments	Data show. - Computers. -Library. -Internet. -Interactive boards and distant learning unit
	Supplies	Classrooms. -Educational pharmacy
	Electronic Programs	https://www.mdcalc.com
	Skill Labs/ Simulators	Educational pharmacy

Course Plan

Matrix of course learning outcomes CLOs – Teaching and Learning Strategy and Student Assessment

Course title: Clinical Pharmacy II & Pharmacotherapeutics
Course code: P006

Course Contents		Key elements	Teaching and Learning Methods	Student Assessment Methods
Week # 1	Gout & Hyperuricemia	1.1.1 , 1.1.2 , 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11. 1.1.12, 1.1.13 ,1.1.14, 1.1.15 2.1.1 , 2.1.2 , 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning	Written, practical and oral exams
Week # 2	Osteoporosis	1.1.1 , 1.1.2 , 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11. 1.1.12, 1.1.13 ,1.1.14, 1.1.15 2.1.1 , 2.1.2 , 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 3	Osteoarthritis	1.1.1 , 1.1.2 , 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11. 1.1.12, 1.1.13 ,1.1.14, 1.1.15 2.1.1 , 2.1.2 , 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 4	Rheumatoid Arthritis	1.1.1 , 1.1.2 , 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11. 1.1.12, 1.1.13 ,1.1.14, 1.1.15 2.1.1 , 2.1.2 , 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1,	Lectures, E-learning, practical training and class activities	Written, practical and oral exams

		2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4		
Week # 5	Rheumatoid Arthritis (Cont.)	1.1.1 , 1.1.2 , 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13 ,1.1.14, 1.1.15 2.1.1 , 2.1.2 , 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 6	Viral infections of the skin	1.1.1 , 1.1.2 , 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13 ,1.1.14, 1.1.15 2.1.1 , 2.1.2 , 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 7	Periodical exam			
Week # 8	Fungal infections of the skin	1.1.1 , 1.1.2 , 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13 ,1.1.14, 1.1.15 2.1.1 , 2.1.2 , 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 9	Bacterial infection of skin	1.1.1 , 1.1.2 , 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10,	Lectures, E-learning, practical	Written, practical and oral exams

		1.1.11, 1.1.12, 1.1.13, 1.1.14, 1.1.15 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	training and class activities	
Week # 10	Parasitic infections of the skin	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13, 1.1.14, 1.1.15 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 11	Psoriasis	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13, 1.1.14, 1.1.15 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning, practical training, seminars and class activities	Written, practical and oral exams
Week # 12	Atopic Dermatitis	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13, 1.1.14, 1.1.15 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning, seminars and practical training	Written, practical and oral exams
Week # 13	Atopic Dermatitis (Cont.)	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13, 1.1.14,	Lectures, E-learning, seminars	Written, practical and oral exams

		1.1.15 2.1.1 , 2.1.2 , 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	and practical training	
Week # 14	Contact Dermatitis	1.1.1 , 1.1.2 , 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13 ,1.1.14, 1.1.15 2.1.1 , 2.1.2 , 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning, and practical training	Written, practical and oral exams
Week # 15	Scaly Dermatoses	1.1.1 , 1.1.2 , 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13 ,1.1.14, 1.1.15 2.1.1 , 2.1.2 , 2.1.3, 2.1.4, 2.1.5, 2.2.1, 2.2.2, 2.2.3, 2.4.1, 2.4.2, 2.4.3, 2.5.1, 2.5.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6, 3.2.7, 3.2.8, 3.2.9, 3.2.10, 3.2.11, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4	Lectures, E-learning, and practical training	Written, practical and oral exams

Name and Signature

Course Coordinator

**Associate. Prof. Noha
Mahmoud El-Khodary**

Name and Signature

Program Coordinator

Prof. Abdelaziz Elashmawy



Course Specification

1. Basic Information

Course Title (according to the bylaw)	Entrepreneurship			
Course Code (according to the bylaw)	NP 006			
Department/s participating in delivery of the course	Department of Business Administration Faculty of Commerce - Kafrelsheikh University			
Number of credit hours/points of the course (according to the bylaw)	Theoretical 1	Practical 1	Other (specify)	Total 2
Course Type	Compulsory			
Academic level at which the course is taught	Level (5)			
Academic Program	Bachelor in pharmacy (Pharm D)			
Faculty/Institute	Faculty of Pharmacy			
University/Academy	Kafrelsheikh University			
Name of Course Coordinator	Dr. Waleed Hemdan			
Course Specification Approval Date	9/2025			
Course Specification Approval (Attach the decision/minutes of the department /committee/council)	Head of department			

2. Course Overview (Brief summary of scientific content)

This course is designed to enhance a student's knowledge in leadership, business, and financial skills in pharmacy practice while learning the traits of an entrepreneur, current topics in entrepreneurship with a specific focus on pharmacy practice and patient care programs. This course will teach the participants a comprehensive set of critical skills needed to develop a profitable business project. This course is designed to provide the students the personal and business tools including risk-taking, strategic planning, marketing, competitiveness, and social responsibility to make the transition from the academic environment to the daily practice of pharmacy now and in the future, with an emphasis on entrepreneurship.

3- Course Learning Outcomes CLOs

Matrix of course learning outcomes CLOs with program outcomes POs (NARS/ARS)

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
Domain 1 (FUNDAMENTAL KNOWLEDGE) 1-1- COMPETENCY		Upon finishing this course, Graduates will be able to integrate knowledge in leadership, business, and financial skills in pharmacy practice. This competency will be developed through understanding the following key elements:	
1.1.1	Demonstrate understanding of knowledge of pharmaceutical, biomedical, social, behavioral, administrative, and clinical sciences.	1.1.1	Enhance a student's knowledge in leadership, business, and financial skills in pharmacy practice.
		1.1.2	Learn the traits of an entrepreneur and current topics in entrepreneurship with a specific focus on pharmacy practice.
		1.1.3	Define the participants a comprehensive set of critical skills needed to develop a profitable business project.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
			1.1.4 Teach the participants the business tools including risk-taking, strategic planning, marketing, competitiveness, and social responsibility.
DOMAIN 2: PROFESSIONAL AND ETHICAL PRACTICE 2-1- COMPETENCY		<p>Upon finishing this course, Graduates will be able to work as a collaborative member of an inter-professional health care team to improve the quality of life of patients and communities, and respect human rights.</p> <p>This competency will be developed via the following key elements:</p>	
2.1.3	Recognize own personal and professional limitations and accept the conditions of referral to or guidance from other members of the health care team.	2.1.1	Understand that Innovation Isn't Easy Managing Innovation and Entrepreneurship
		2.1.2	Recognize Dimensions of Innovation: What Can We Change?
2-6- COMPETENCY		<p>Upon finishing this course, Graduates will be able to perform pharmacoeconomic analysis and develop promotion, sales, marketing, and business administration skills.</p> <p>This competency will be developed via the following key elements:</p>	
2.6.1	Apply the principles of business administration and management to ensure rational use of financial and human resources.	2.6.1	What Is 'Social Innovation'? A Process Model for Innovation and Entrepreneurship
2.6.2	Utilize the principles of drug promotion, sales, marketing,	2.6.2	Recognize Sustainability-led Innovation.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	accounting, and pharmacoeconomic analysis	2.6.3	Learn Motivation: Why Do It?
Domain 4: Personal Practice 4-1- Competency		Upon finishing this course, students will be able to Effectively communicate verbally, non-verbally and in writing with individuals and communities. This competency will be developed via the following key elements:	
4.1.1	Demonstrate responsibility for team performance and peer evaluation of other team members, and express time management skills .	4.1.1	Demonstrate critical thinking, problem-solving, creativity, time management and decision-making abilities to evaluate team performance as well as team members. .
4.1.2	Retrieve and critically analyze information, identify and solve problems, and work autonomously and effectively in a team.	4.1.2	Apply skills of Interact independently or as a part of team in different pharmaceutical field
4.1.3	Demonstrate creativity and apply entrepreneurial skills within a simulated entrepreneurial activity	4.1.3	Retrieve information; and set realistic targets and time plan to accomplish a required mission in deadlines

Domain 4: Personal Practice 4-2- Competency	Upon finishing this course, Graduates will be able to effectively communicate verbally, non-verbally and in writing with individuals and communities. This competency will be developed via the following key elements:
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4.2.2	Use contemporary technologies and media to demonstrate effective presentation skills.	4.2.1	<p>Show the ability to effectively present a topic of interest using recent technologies.</p> <p>.</p>
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Domain 4: Personal Practice 4-3- Competency		Upon finishing this course, Graduates will be able to Express self-awareness and be a life-long learner for continuous professional improvement. This competency will be developed via the following key elements:	
4.3.1	Perform self-assessment to enhance professional and personal competencies.	4.3.1	Collect and analyze information from different sources to determine self-merits/ limitations and improve professional and personal skills.
4.3.2	Practice independent learning needed for continuous professional development.	4.3.2	Learn independently to develop professional skills.

3. Teaching and Learning Methods

- 1- Lectures
- 2- E-learning
- 3- Practical training/ laboratory
- 4- Class activity
- 5- Seminars
- 6- Assignment
- 7- Case study

Course Schedule						
mber of the Week	Scientific content of the course (Course Topics)	Total Weekly Hours	Expected number of the Learning Hours			
			Theoretical teaching (lectures/discussion groups/)	Training (Practical/ Clinical/)	Self-learning (Tasks/ Assignments / Projects/ ...)	Other (to be determined)
1	Chapter 1: The Innovation Imperative Innovation Matters Innovation and Entrepreneurship	3	1	2		
2	Innovation Isn't Easy! Managing Innovation and Entrepreneurship	3	1	2		
3	Dimensions of Innovation: What Can We Change?	3	1	2		
4	A Process Model for Innovation and Entrepreneurship	3	1	2		
5	How Can We Make Change Happen?	3	1	2		
6	What, Why and When: The Challenge of Innovation Strategy Chapter Summary Key Terms Defined	3	1	2		
7	Periodical exam					
8	Chapter 2: Social Innovation What Is 'Social Innovation'?	3	1	2		
9	Different Players Motivation: Why Do It?	3	1	2		
10	Enabling Social Innovation	3	1	2		
11	The Challenges of Social Entrepreneurship Chapter Summary	3				

	References.		1	2		
12	Chapter 3: Sustainability-led Innovation The Challenge of Sustainability-led Innovation	3	1	2		
13	We've Seen This Before Sustainability-led Innovation	3	1	2		
14	Different Players Motivation: Why Do It?	1	1	Practical exam		
15	A Framework Model for Sustainability-led Innovation Responsible Innovation References	1	1	Practical exam		

4. Methods of students' assessment

No.	Assessment Methods *	Assessment Timing (Week Number)	Marks/ Scores	Percentage of total course Marks
1	Periodical exam	Week 7	15	15%
2	Final Written Exam	Week 16, 17	50	50%
3	Final Practical/Clinical/... Exam	Week 14, 15	20	20%
4	Final Oral Exam	Week 16, 17	10	10%
5	Assignments / Project /Portfolio/ Logbook	Week 14,15	5	5%

5. Learning Resources and Supportive Facilities *

Learning resources (books, scientific references, etc.) *	The main (essential) reference for the course (must be written in full according to the scientific documentation method)	1. DOLLINGER, Marc J. <i>Entrepreneurship</i> . Marsh Publications, 2008. 2. HISRICH, Robert D.; PETERS, Michael P.; SHEPHERD, Dean A. <i>Entrepreneurship</i> . McGraw-Hill Education, 2017.
	Other References	Notes prepared by the department staff.

	Electronic Sources (Links must be added)	www.pubmed.com www.sciencedirect.com
	Learning Platforms (Links must be added)	<u>https://lms3.kfs.edu.eg/pharm/login/index.php</u>
	Other (to be mentioned)	
Supportive facilities & equipment for teaching and learning *	Devices/Instruments	----
	Supplies	-----
	Electronic Programs	----
	Skill Labs/ Simulators	----
	Virtual Labs	----
	Other (to be mentioned)	▪ Data show, smart board, Unit for distance learning, Computers, Internet and Library.

Course Plan

Matrix of course learning outcomes CLOs – Teaching and Learning Strategy and Student Assessment

Course title Entrepreneurship

Course code: NP 006

Course Contents		Key elements	Teaching and Learning Methods	Student Assessment Methods
Week # 1	Chapter 1: The Innovation Imperative Innovation Matters Innovation and Entrepreneurship	1.1.1, 1.1.2, 1.1.3, 1.1.4	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 2	Innovation Isn't Easy! Managing Innovation and Entrepreneurship	1.1.1, 1.1.2, 1.1.3, 2.1.1	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 3	Dimensions of Innovation: What Can We Change?	1.1.1, 1.1.2, 1.1.3, 1.1.4, 2.1.2	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 4	A Process Model for Innovation and Entrepreneurship	1.1.2, 1.1.3, 1.1.4, 2.6.1	Lectures, E-learning, practical training and class activities	Written, practical and oral exams

Week # 5	How Can We Make Change Happen?	1.1.1, 1.1.3, 1.1.4, 2.1.1, 2.1.2	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 6	What, Why and When: The Challenge of Innovation Strategy Chapter Summary Key Terms Defined	. 1.1.1, 1.1.2, 1.1.4, 2.1.1, 2.1.2	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 7	Periodical exam			
Week # 8	Chapter 2: Social Innovation What Is 'Social Innovation'?	1.1.1, 1.1.2, 1.1.4, 2.6.1, 2.6.2, 2.6.3	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 9	Different Players Motivation: Why Do It?	1.1.1, 1.1.2, 1.1.3, 1.1.4, 2.6.1, 2.6.2, 2.6.3	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 10	Enabling Social Innovation	1.1.1, 1.1.3, 1.1.4, 2.6.1, 2.6.2	Lectures, E-learning, practical training and class activities	Written, practical and oral exams
Week # 11	The Challenges of Social Entrepreneurship Chapter Summary References	1.1.1, 1.1.3, 1.1.4, 2.6.1, 2.6.2, 4.1.1, 4.1.3	Lectures, E-learning, practical training, seminars and class activities	Written, practical and oral exams
Week # 12	Chapter 3: Sustainability-led Innovation The Challenge of Sustainability-led Innovation	1.1.1, 1.1.2, 1.1.3, 2.6.2	Lectures, E-learning, seminars and practical training	Written, practical and oral exams
Week # 13	We've Seen This Before Sustainability-led Innovation	1.1.1, 1.1.2, 1.1.3, 2.6.2	Lectures and E-learning	Written, practical and oral exams
Week # 14	Different Players Motivation: Why Do It?	1.1.1, 1.1.2, 1.1.3, 2.6.2, 2.6.3, 4.1.1	Lectures and E-learning	Written and oral exams

		4.2.1,4.3.1, 4.3.2		
Week # 15	A Framework Model for Sustainability-led Innovation Responsible Innovation References	1.1.1,1.1.2 1.1.3 ,1.1.4, 2.6.2 ,2.6.3 ,4.1.1, 4.2.1 , 4.3.1, 4.3.	Lectures and E-learning	Written and oral exams

**Name and Signature
Course Coordinator**

Dr. Waleed Hemdan



**Name and Signature
Program Coordinator**

Prof. Dr. Abdelaziz Elashmawy



Course Specification

(2025)

Course Title (according to the bylaw)	Clinical Research, pharmacoepidemiology and Pharmacovigilance			
Course Code (according to the bylaw)	PP 007			
Department/s participating in the delivery of the course	Clinical pharmacy department			
Number of credit hours/points of the course (according to the bylaw)	Theoretical	Practical	Other (specify)	Total
	1	1	----	2
Course Type	Compulsory			
Academic level at which the course is taught	Fifth level			
Academic Program	BSc in pharmacy (Pharm-D)			
Faculty/Institute	Faculty of Pharmacy			
University/Academy	Kafrelsheikh University			
Name of Course Coordinator	Associate. Prof. Ahmed Amin			
Course Specification Approval Date	31/8/2025			
Course Specification Approval	Department Council			

2. Course Overview (Brief summary of scientific content)

This course introduces the student to the basic principles of clinical research, design of research studies, types of research studies, clinical trials, statistical presentation of research data and ethical guidelines in drug research. This course also provides the students with understanding of pharmacovigilance importance, concept, processes, systems, global safety standards and regulations and reporting systems.

3. Course Learning Outcomes CLOs

Matrix of course learning outcomes CLOs with program outcomes POs (NARS/ARS)

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
Domain 1 (FUNDAMENTAL KNOWLEDGE) 1-1- COMPETENCY		Upon completion of the course, the student will be able to: Integrate knowledge from pharmaceutical, biomedical, and clinical sciences to design and evaluate clinical research, apply pharmacoepidemiologic methods, and perform pharmacovigilance activities to ensure the safe, effective, and ethical use of medicines in populations and patients. This competency will be developed via the following key elements:	
1.1.1	Demonstrate understanding of knowledge of pharmaceutical, biomedical, social, behavioral, administrative, and clinical sciences.	1.1.1	Define and describe fundamental concepts in epidemiology, pharmacovigilance, and clinical research relevant to medicine development and safety.
		1.1.2	List and outline the major steps in the drug life cycle, from discovery to post-marketing surveillance.
		1.1.3	Recognize the interrelationship between biomedical, clinical, and administrative sciences in ensuring medicine quality and patient safety.
1.1.4	Articulate knowledge from fundamental sciences to explain drugs' actions and evaluate their appropriateness,	1.1.4	Identify and state the pharmacological mechanisms of drug action and their clinical relevance.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	effectiveness, and safety in individuals and populations.	1.1.5	Recall and describe evidence-based criteria for determining drug appropriateness and benefit-risk balance.
		1.1.6	Point out and recognize examples of drug safety and effectiveness evaluation at the individual and population levels.
1.1.5	Retrieve information from fundamental sciences to solve therapeutic problems.	1.1.7	Recognize and select appropriate pharmacoepidemiologic and clinical trial data sources.
		1.1.8	Retrieve and record information relevant to drug safety, effectiveness, or utilization issues.
		1.1.9	Write and outline evidence-based solutions to clinical and safety-related therapeutic problems.
1.1.6	Utilize scientific literature and collect and interpret information to enhance professional decisions.	1.1.10	Read and recall key findings from clinical research, safety reports, and pharmacoepidemiologic studies.
		1.1.11	Match and describe research evidence to appropriate public health or therapeutic interventions.
1.1.7	Identify and critically analyze newly emerging issues influencing pharmaceutical industry and patient health care.	1.1.12	Identify, describe, and critically analyze newly emerging drug safety signals, therapeutic trends, and regulatory developments that may influence pharmaceutical research, industry practices, and patient health care outcomes.
		1.1.13	Monitor and evaluate emerging drug safety signals, regulatory alerts, and trends in medicine utilization impacting healthcare practice and policy.
DOMAIN 2: PROFESSIONAL AND ETHICAL PRACTICE 2-1- COMPETENCY		<u>Upon finishing this course, students will be able to:</u> Work collaboratively as a member of multidisciplinary research, regulatory, and public health teams to design, conduct, and evaluate clinical research; perform pharmacoepidemiologic analyses; and implement pharmacovigilance activities that protect public health, improve patient outcomes, and respect ethical principles, regulatory requirements, and the rights,	

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
		safety, and confidentiality of research participants and patients. This competency will be developed via the following key elements:	
2.1.1	Perform responsibilities and authorities in compliance with the legal and professional structure and role of all members of the health care professional team.	2.1.1	Identify national and international regulations, guidelines, and good practice standards (ICH-GCP, WHO, EMA, FDA) governing clinical research, pharmacoepidemiology, and pharmacovigilance.
2.1.2	Adopt ethics of health care and pharmacy profession respecting patients' rights and valuing people diversity.	2.1.2	State and explain ethical principles in clinical research, including informed consent, confidentiality, and equitable participant selection.
		2.1.3	Apply patient rights protection measures in data collection, analysis, and reporting of safety and efficacy outcomes.
		2.1.4	Identify situations in clinical research, safety assessment, or pharmacoepidemiologic work that require input from other experts.
2.1.3	Recognize your own personal and professional limitations and accept the conditions of referral to or guidance from other members of the health care team.	2.1.5	Demonstrate a willingness to collaborate, share responsibilities, and incorporate feedback to ensure safe, ethical, and high-quality decision-making.
2-2- COMPETENCY		Upon finishing this course, students will be able to: Apply scientific principles and regulatory standards to ensure the quality, safety, and effectiveness of medicines by participating in clinical research, pharmacoepidemiologic evaluations, and pharmacovigilance systems; contribute to the monitoring of medicine utilization, benefit-risk assessment, and implementation of measures for the safe storage, distribution, and rational use of	

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
		<p>pharmaceutical products in both clinical and public health settings.</p> <p>This competence will be developed via the following key elements:</p>	
2.2.4	<p>Adopt the principles of pharmaceutical calculations, biostatistical analysis, bioinformatics, pharmacokinetics, and biopharmaceutics and their applications in new drug delivery systems, dose modification, bioequivalence studies, and pharmacy practice.</p> <p>2-4- COMPETENCY</p>	2.2.1	Define and describe core principles of pharmaceutical calculations, pharmacokinetics, biostatistics, bioinformatics, and biopharmaceutics, and recognize their relevance to clinical research, pharmacoepidemiology, and pharmacovigilance.
		2.2.2	Interpret and record results from bioinformatics platforms, safety databases, and statistical analyses to support regulatory submissions, safety evaluations, and evidence-based healthcare decisions.
		<p>Upon finishing this course, students will be able to:</p> <p>Actively contribute to evidence-based decision-making and timely interventions in emergency situations, including poisoning with various xenobiotics, by applying clinical research findings, pharmacoepidemiologic data, and pharmacovigilance reports; collaborate with healthcare and forensic teams to investigate, document, and prevent future incidents, ensuring patient safety and compliance with ethical and regulatory standards.</p> <p>This competency will be developed via the following key elements:</p>	
2.4.3	Take actions to solve any identified medicine-related and pharmaceutical care problems .	2.4.1	Identify and recognize medicine-related problems, including adverse drug reactions, drug interactions, medication errors, and inappropriate medicine use detected during

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
			clinical research, pharmacoepidemiologic studies, or pharmacovigilance activities.
		2.4.2	Retrieve, analyze, and interpret data from clinical records, safety databases, and epidemiological reports to determine the causes and implications of the identified problems.
		2.4.3	Select, apply, and record appropriate evidence-based corrective measures, ensuring that outcomes are monitored and communicated to improve patient safety and therapeutic effectiveness.
	2-5- COMPETENCY	Upon finishing this course, students will be able to: contribute to pharmaceutical research studies and clinical trials needed to authorize medicinal products This competency will be developed via the following key elements:	
2.5.2	Retrieve, interpret, and critically evaluate evidence-based information needed in pharmacy profession	2.5.1	Retrieve and recognize relevant scientific literature, clinical trial reports, pharmacoepidemiologic studies, and pharmacovigilance data from credible databases and information systems.
		2.5.2	Interpret and analyze study designs, statistical results, and safety reports to assess validity, reliability, and applicability to clinical or regulatory decisions.
		2.5.3	Record and summarize evidence in a clear and structured manner to support medicine safety assessments, public health recommendations, and policy development.
2.5.3		2.5.4	Identify and describe appropriate research questions, objectives, and hypotheses in the context of clinical research,

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	Contribute in planning and conducting research studies using appropriate methodologies.		pharmacoepidemiology, or pharmacovigilance.
		2.5.5	Select and apply suitable study designs, data collection tools, and analytical methods to address identified research objectives.
		2.5.6	Record, interpret, and report research findings in compliance with ethical guidelines, regulatory requirements, and good scientific practice.
DOMAIN 3: Pharmaceutical Care 3-1- COMPETENCY		<u>Upon finishing this course, students will be able to:</u> apply the principles of body functions to participate in improving health care services using evidence-based data. This competency will be developed via the following key elements:	
3.1.4	Relate etiology, epidemiology, pathophysiology, laboratory diagnosis, and clinical features of infections/diseases and their pharmacotherapeutic approaches	3.1.1	Identify and describe the etiology, epidemiology, and pathophysiology of diseases, and recognize their relevance to medicine use, safety, and effectiveness in clinical and population settings.
		3.1.2	Interpret and analyze laboratory results and diagnostic data in relation to disease state, treatment response, and detection of potential adverse drug reactions.
		3.1.3	Relate pharmacotherapeutic strategies to disease characteristics, integrating evidence from clinical research, pharmacoepidemiologic data, and pharmacovigilance reports to support optimal decision-making.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
3-2- COMPETENCY		<p>Upon finishing this course, students will be able to:</p> <p>Provide counselling and education services to patients and communities about safe and rational use of medicines and medical devices.</p> <p>This competency will be developed via the following key elements:</p>	
3.2.1	Integrate the pharmacological properties of drugs including mechanisms of action, therapeutic uses, dosage, contraindications, adverse drug reactions and drug interactions	3.2.1	Interpret and relate genomic data and physiological parameters to individualized pharmacotherapy, adverse drug reaction risk, and benefit-risk assessment.
		3.2.2	Apply pharmacogenomic principles in clinical research, pharmacoepidemiology, and pharmacovigilance to optimize therapeutic strategies for different patient populations.
3.2.2	Apply the principles of clinical pharmacology and pharmacovigilance for the rational use of medicines and medical devices.	3.2.3	Select and apply evidence-based infection control measures informed by epidemiological data, antimicrobial resistance trends, and clinical research findings.
		3.2.4	Assess and record the effectiveness of implemented infection control strategies, integrating results from pharmacoepidemiologic surveillance and pharmacovigilance activities.
3.2.5	Educate and counsel patients, other health care professionals, and communities about safe and proper use of medicines including OTC preparations and medical devices.	3.2.5	Select and implement awareness and prevention strategies based on public health data, pharmacoepidemiologic findings, and community needs.
3.2.6	Maintain public awareness on social health hazards of drug misuse and abuse.	3.2.6	Evaluate and record the impact of public awareness activities on reducing drug misuse and improving community health outcomes.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
DOMAIN 4: Personal Practice 4-1- COMPETENCY			Upon finishing this course, students will be able to: express leadership, time management, critical thinking, problem solving, independent and teamwork, creativity and entrepreneurial skills This competency will be developed via the following key elements:
4.1.1	Demonstrate responsibility for team performance and peer evaluation of other team members, and express time management skills.	4.1.1	Identify and describe individual and collective responsibilities in multidisciplinary clinical research, pharmacoepidemiology, and pharmacovigilance teams.
		4.1.2	Apply peer evaluation methods to provide constructive feedback on the performance of other team members in research and safety monitoring tasks.
4.1.2	Retrieve and critically analyze information, identify and solve problems, and work autonomously and effectively in a team.	4.1.3	Demonstrate effective time management by planning, prioritizing, and recording progress to meet project deadlines and quality standards.
		4.1.4	Retrieve and analyze relevant clinical, epidemiological, and safety data from credible sources to address research and pharmacovigilance questions.
4.1.3	Demonstrate creativity and apply entrepreneurial skills within a simulated entrepreneurial activity.	4.1.5	Present a simple project to classmates, showing creativity and good organization using tools like PowerPoint, Canva, or Prezi.
4-2- COMPETENCY			Upon finishing this course, students will be able to: Effectively communicate verbally, non-verbally and in writing with individuals and communities. This competency will be developed via the following key elements:
4.2.1	Demonstrate effective communication skills verbally, non-verbally, and in	4.2.1	Identify and apply principles of clear, accurate, and respectful communication when interacting with multidisciplinary research

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
4.2.2	writing with professional health care teams, patients, and communities		teams, regulatory authorities, and public health professionals.
		4.2.2	Demonstrate effective verbal and non-verbal communication strategies when counseling patients, explaining research processes, or delivering pharmacovigilance findings to stakeholders.
4.2.3	Use contemporary technologies and media to demonstrate effective presentation skills.	4.2.3	Prepare and write structured reports, summaries, and educational materials tailored to the needs of healthcare teams, patients, or community groups.
4-3- COMPETENCY		<p>Upon finishing this course, students will be able to express self-awareness and be a life-long learner for continuous professional improvement.</p> <p>This competency will be developed via the following key elements:</p>	
4.3.1	Perform self-assessment to enhance professional and personal competencies.	4.3.1	Identify strengths and areas for improvement in clinical research, pharmacoepidemiology, and pharmacovigilance knowledge and skills through structured self-assessment.
		4.3.2	Record and analyze feedback from peers, mentors, and performance evaluations to guide personal and professional growth.
4.3.2	Practice independent learning is needed for continuous professional development.	4.3.3	Select and apply targeted learning and skill-development activities to enhance competency in research, safety monitoring, and public health practice.

4. Teaching and Learning Methods

- 1- **Lectures** (✓)
- 2- **E-learning** (✓)
- 3- **Practical training** (✓)
- 4- **Discussion** (✓)
- 5- **Brainstorming** (✓)
- 6- **Assignments** (✓)
- 7- **Case study** (✓)
- 8- **Seminars** (✓)

Course Schedule

Number of the Week	Scientific content of the course (Course Topics)	Total Weekly Hours	Expected number of the Learning Hours			
			Theoretical teaching (lectures/discussion groups/)	Training (Practical/Clinical/)	Self-learning (Tasks/Assignments/Projects/ ...)	Other (to be determined)
1	Introduction to principal of clinical research	3	1	2	---	---
2	Types of clinical research studies and Evaluation of clinical trials	3	1	2	---	---
3	Introduction to principal of pharmacoepidemiology	3	1	2	---	---
4	Principle of pharmacoepidemiology applied to the study of medical use	3	1	2	---	---
5	Study design for pharmacoepidemiology	3	1	2	---	---
6	Evaluation of the pharmacoepidemiology literature	3	1	2	---	---
7	Periodical exam					
8	Introduction to Pharmacovigilance and adverse drug reactions (ADRs)	3	1	2	---	---
9	Classifications of ADRs	3	1	2	---	---
10	Case studies in pharmacovigilance	3	1	2	---	---
11	Causality and probability of ADRs	3	1	2	---	---
12	The process of Pharmacovigilance	3	1	2	---	---
13	Reporting ADRs	3	1	2	---	---

14	Reporting ADRs (cont.)	1	1	Practical exam		
15	Establishing pharmacovigilance center	1	1	Practical exam		

5. Methods of students' assessment

No.	Assessment Methods *	Assessment Timing (Week Number)	Marks/ Scores	Percentage of total course Marks
1	Periodical exam	Week 7	10 marks	10%
2	Quizzes / formative exam	Week 4. 8.12	5 marks	5%
3	Final Practical Exam	Week 14,15	15 marks	15%
4	Assignments / Project / Logbook	All semester long	10 marks	10%
5	Final Written Exam	Week 16,17	50 marks	50%
6	Final Oral Exam	Week 16,17	10 marks	10%

6. Learning Resources and Supportive Facilities *

Learning resources (books, scientific references, etc.) *	The main (essential) reference for the course	<ul style="list-style-type: none"> • Cobert, B., Gregory, W. W., Thomas, J.-L., & Baldridge, C. (2024). <i>Cobert's manual of drug safety and pharmacovigilance</i> (4th ed.). World Scientific Publishing. • DiPiro, J. T., Yee, G. C., Haines, S. T., Nolin, T. D., Ellingrod, V., & Posey, L. M. (Eds.). (2023). <i>Pharmacotherapy: A pathophysiologic approach</i> (12th ed.). McGraw-Hill Education.
	Other References	<ul style="list-style-type: none"> • <u>Lecture notes</u> on clinical research, pharmacoepidemiology, and Pharmacovigilance prepared by Department of Clinical Pharmacy.

		<ul style="list-style-type: none"> • Practical notes on clinical research, pharmacoepidemiology and Pharmacovigilance prepared by the Department of Clinical Pharmacy.
	Electronic Sources	<p>www.biomedcentral.com</p> <p>www.medscape.com</p> <p>http://www.sciencedirect.com/</p> <p>http://www.ncbi.nlm.nih.gov/</p> <p>http://www.FDA.gov</p>
	Learning Platforms	https://lms3.kfs.edu.eg/pharm/login/index.php
	Other	
Supportive facilities & equipment for teaching and learning *	Devices/Instruments	<ul style="list-style-type: none"> - Data show. - Computers. - Library. - Internet. - Interactive boards.
	Supplies	<p>Classrooms.</p> <p>Educational pharmacy</p> <p>Drug information center</p>
	Electronic Programs	
	Skill Labs/ Simulators	<p>Educational pharmacy</p> <p>Drug information center</p>

Course Plan

Matrix of course learning outcomes CLOs – Teaching and Learning Strategy and Student Assessment

Course title: Clinical Research, Pharmacoepidemiology and Pharmacovigilance
Course code: PP007

Course Contents		Key elements	Teaching and Learning Methods	Student Assessment Methods
Week 1	Introduction to the principles of clinical research	1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 2.1.1, 2.1.2, 4.1.1, 4.2.1, 4.3.1	Lectures ,(case study) , class activity (discussion, brain storm)	Written and oral exams
Week 2	Types of clinical research studies and Evaluation of clinical trials	1.1.4, 1.1.5, 1.1.6, 1.1.7, 1.1.8, 1.1.9, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.2, 4.2.1, 4.2.2, 4.3.2	Lectures and practical, (case study) , class activity (discussion, brainstorm)	Written , practical and oral exams
Week 3	Introduction to the principles of pharmacoepidemiology	1.1.7, 1.1.8, 1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13, 2.4.1, 2.4.2, 2.4.3, 3.1.1, 3.1.2, 4.1.3, 4.3.1, 4.3.2, 4.2.3	Lectures and practical, (case study) , class activity (discussion, brainstorm)	Written , practical and oral exams
Week 4	Principle of pharmacoepidemiology applied to the study of medical use	1.1.9, 1.1.10, 1.1.11, 1.1.12, 1.1.13, 2.4.1, 2.4.2, 2.4.3, 3.1.1, 3.1.3, 3.2.1, 3.2.2, 4.1.4, 4.2.2, 4.3.3, 4.3.1	Lectures and, practical ,(case study) , class activity (discussion, brainstorm)	Written , practical and oral exams
Week 5	Study design for pharmacoepidemiology	1.1.12, 1.1.13, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 3.1.2, 3.1.3, 3.2.3, 4.1.1, 4.1.3, 4.2.3, 4.3.3, 4.3.2	Lectures and practical ,(case study) , class activity (discussion, brainstorm)	Written , practical and oral exams

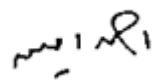
Week 6	Evaluation of the pharmacoepidemiology literature	1.1.10, 1.1.11, 1.1.12, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 3.2.1, 3.2.4, 4.1.2, 4.1.4, 4.2.1, 4.2.2, 4.3.1, 4.3.2	Lectures and practical ,(case study) , class activity (discussion, brain storm)	Written, practical and oral exams
Week 7				
Week 8	Introduction to Pharmacovigilance and adverse drug reactions (ADRs)	1.1.12, 1.1.13, 2.4.1, 2.4.2, 2.4.3, 2.1.1, 2.1.2, 2.1.3, 3.2.1, 3.2.3, 4.1.2, 4.1.3, 4.2.1, 4.2.3, 4.3.1, 4.3.2	Lectures and practical, (case study) , class activity (discussion, brainstorm)	Written , practical and oral exams
Week 9	Classifications of ADRs	2.4.1, 2.4.2, 2.4.3, 2.1.1, 2.1.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4, 4.1.4, 4.2.2, 4.3.2, 4.3.3, 2.5.4, 2.5.5	Lectures and practical ,(case study) , class activity (discussion, brainstorm)	Written , practical and oral exams
Week 10	Case studies in pharmacovigilance	2.4.2, 2.4.3, 2.1.1, 2.1.2, 3.1.1, 3.1.2, 3.1.3, 3.2.3, 4.1.1, 4.2.1, 4.2.2, 4.3.1, 4.3.2, 4.3.3, 2.5.6	Lectures and practical,(case study) , class activity (discussion, brainstorm)	Written , practical and oral exams
Week 11	Causality and probability of ADRs	2.4.3, 2.1.1, 2.1.2, 3.1.3, 3.2.3, 3.2.4, 4.1.2, 4.1.3, 4.2.1, 4.2.3, 4.3.1, 4.3.3, 2.5.1, 2.5.2, 2.5.3	Lectures and practical ,(case study) , class activity (discussion, brainstorm)	Written, practical and oral exams
Week 12	The process of Pharmacovigilance	2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 3.1.1, 3.1.2, 3.2.1, 4.1.1, 4.1.2, 4.1.4, 4.2.1, 4.2.2, 4.2.3, 4.3.2, 4.3.3	Lectures and practical,(case study) , class activity (discussion, brainstorm)	Written, practical and oral exams

Week 13	Reporting ADRs	2.1.3, 2.1.4, 2.5.3, 2.5.4, 3.2.2, 3.2.3, 3.2.4, 4.1.2, 4.1.3, 4.2.1, 4.2.2, 4.3.1, 4.3.2, 4.3.3, 1.1.13	Lectures and practical , (case study) , class activity (discussion, brain storm)	Written, practical and oral exams
Week 14	Reporting ADRs (cont.)	2.1.4, 2.1.5, 3.1.1, 3.1.3, 3.2.1, 3.2.4, 4.1.1, 4.1.3, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 1.1.12	Lectures ,(case study) , class activity (discussion, brainstorm)	Written and oral exams
Week 15	Establishing a pharmacovigilance center	2.2.1, 2.2.2, 2.5.1, 2.5.2, 3.1.2, 3.1.3, 3.2.2, 4.1.1, 4.1.2, 4.1.3, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.3, 1.1.10	Lectures (case study) , class activity (discussion, brainstorm)	Written and oral exams

Name and Signature

Course Coordinator

**Associate. Prof. Ahmed Amin
Ali**



Name and Signature

Program Coordinator

Prof. Dr. Abdel Aziz El-Ashmawy



Course Specification

(2025)

1. Basic Information

Course Title (according to the bylaw)	Professional Ethics			
Course Code (according to the bylaw)	NP 007			
Department/s participating in delivery of the course	Pharmaceutical Chemistry Department			
Number of credit hours/points of the course (according to the bylaw)	Theoretical	Practical	Other (specify)	Total
	1	----	----	1
Course Type	compulsory			
Academic level at which the course is taught	Fifth level, semester (2)			
Academic Program	Bachelor of Pharmacy (Pharm D)			
Faculty/Institute	Faculty of Pharmacy			
University/Academy	Kafrelsheikh University			
Name of Course Coordinator	Associate Prof. Rofida Salem			
Course Specification Approval Date	9/2025			
Course Specification Approval (Attach the decision/minutes of the department /committee/council)	Department council			

2. Course Overview (Brief summary of scientific content)

This course covers ethical principles and historical context that govern the practice of pharmacy, including medical ethics, pharmacist-patient relationships, and the management of conflicts of interest in various professional scenarios, such as disaster response, medication errors, research, and animal ethics.

3. Course Learning Outcomes CLOs

Matrix of course learning outcomes CLOs with program outcomes POs (NARS/ARS)

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
Domain 1 (FUNDAMENTAL KNOWLEDGE) 1-1- COMPETENCY		Upon completing this course, students will be able to integrate knowledge from basic and applied pharmaceutical and clinical sciences to standardize materials, formulate and manufacture products, and deliver population and patient-centered care. This competency will be developed via the following key elements:	
1.1.1	Demonstrate understanding of knowledge of pharmaceutical, biomedical, social, behavioral, administrative, and clinical sciences.	1.1.1	Explain the foundations of professional ethics and their applications in pharmaceutical and biomedical fields.
		1.1.2	Analyze the social and behavioral aspects of ethical decision-making in health care practice.
		1.1.3	Discuss the role of ethical codes in the administrative and clinical context of pharmacy.
DOMAIN 2: PROFESSIONAL AND ETHICAL PRACTICE 2-1- COMPETENCY		Upon completing this course, students will be able to work collaboratively as a member of an inter-professional health care team to improve the quality of life of individuals and communities, and respect patients' rights. This competency will be developed via the following key elements:	
2.1.1	Perform responsibilities and	2.1.1	Interpret the legal responsibilities of pharmacists

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
2.1.2	authorities in compliance with the legal and professional structure and role of all members of the health care professional team.		within the health care team.
		2.1.2	Apply ethical and legal guidelines to professional decision-making.
		2.1.3	Evaluate inter-professional collaboration through ethical practice.
2.1.2	Adopt ethics of health care and pharmacy profession respecting patients' rights and valuing people diversity.	2.1.4	Respect patient confidentiality, autonomy, and informed consent.
		2.1.5	Recognize and address ethical dilemmas related to cultural and social diversity.
		2.1.6	Promote fairness and justice in patient care and access to medicines.
2.1.3	Recognize own personal and professional limitations and accept the conditions of referral to or guidance from other members of the health care team.	2.1.7	Demonstrate self-awareness regarding professional boundaries.
		2.1.8	Apply ethical decision-making when referrals are needed.
2-5- COMPETENCY		<p>Upon completing this course, students will be able to contribute in pharmaceutical research studies and clinical trials needed to authorize medicinal products.</p> <p>This competency will be developed via the following key elements:</p>	
2.5.1	Fulfill the requirements of the regulatory framework to authorize a medicinal product including quality, safety, and efficacy requirements.	2.5.1	Identify the ethical aspects of regulatory approval processes.
		2.5.2	Discuss the balance between patient safety and market access.
		2.5.3	Evaluate ethical challenges in clinical trials and drug development.
2.5.3	Contribute in planning and conducting research studies using	2.5.4	Recognize ethical guidelines in pharmaceutical and clinical research.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	appropriate methodologies.	2.5.5	Apply principles of research integrity and responsible conduct.
		2.5.6	Evaluate the role of ethics committees in safeguarding research participants.
Domain 4: Personal Practice 4-1- Competency		<p>Upon completing this course, students will be able to express leadership, time management, critical thinking, problem solving, independent and teamwork, creativity and entrepreneurial skills.</p> <p>This competency will be developed via the following key elements:</p>	
4.1.1	Demonstrate responsibility for team performance and peer evaluation of other team members, and express time management skills.	4.1.1	Practice accountability and transparency in teamwork.
		4.1.2	Provide constructive peer evaluation with ethical consideration.
4.1.2	Retrieve and critically analyze information, identify and solve problems, and work autonomously and effectively in a team.	4.1.3	Apply ethical reasoning in solving professional dilemmas.
		4.1.4	Critically evaluate information sources with integrity.
		4.1.5	Balance autonomy and teamwork in ethical decision-making.
4.1.3	Demonstrate creativity and apply entrepreneurial skills within a simulated entrepreneurial activity.	4.1.6	Recognize ethical considerations in pharmaceutical business and entrepreneurship.
		4.1.7	Develop innovative solutions respecting professional codes of ethics.
4-2- Competency		<p>Upon completing this course, students will be able to effectively communicate verbally, non-verbally and in writing with individuals and communities.</p> <p>This competency will be developed via the following key elements:</p>	
4.2.1	Demonstrate communication skills effectively verbally,	4.2.1	Communicate ethical decisions clearly and respectfully.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	non-verbally, and in writing with professional health care teams, patients, and communities.	4.2.2	Apply empathy and professionalism in patient interactions.
4.2.2	Use contemporary technologies and media to demonstrate effective presentation skills.	4.2.3	Apply digital tools to present ethical cases and guidelines.
		4.2.4	Communicate ethical topics using professional media formats.
4-3- Competency		<p>Upon completing this course, students will be able to express self-awareness and be a life-long learner for continuous professional improvement.</p> <p>This competency will be developed via the following key elements:</p>	
4.3.1	Perform self-assessment to enhance professional and personal competencies.	4.3.1	Reflect on personal ethical strengths and weaknesses.
		4.3.2	Set professional goals for ethical growth.
4.3.2	Practice independent learning needed for continuous professional development.	4.3.3	Explore updated ethical guidelines in pharmacy and health care.
		4.3.4	Engage in lifelong learning to address new ethical challenges.

4. Teaching and Learning Methods

- 1- Lectures (✓)
- 2- E-learning (✓)
- 3- Practical training/ laboratory (X)
- 4- Class activity (✓)
- 5- Presentation (✓)

Course Schedule

Number of the Week	Scientific content of the course (Course Topics)	Total Weekly Hours	Expected number of the Learning Hours			
			Theoretical teaching (lectures/ discussion groups/)	Training (Practical/ Clinical/)	Self-learning (Tasks/ Assignments / Projects/ ...)	Other (to be determined)
1	Introduction to Pharmacy Ethics	1	1	-----	-----	-----
2	General Principles of Medical Ethics	1	1	-----	-----	-----
3	Conflicts of Interest in Pharmacy Practice	1	1	-----	-----	-----
4	Pharmacist-Patient Relationships	1	1	-----	-----	-----
5	Pharmacist's Role in Society	1	1	-----	-----	-----
6	Ethics in Disaster Response	1	1	-----	-----	-----
7	Semester works					
8	Medication Errors	1	1	-----	-----	-----
9	Informed Consent	1	1	-----	-----	-----
10	Research Ethics	1	1	-----	-----	-----
11	Animal Ethics	1	1	-----	-----	-----
12	Ethical Decision-Making Frameworks	1	1	-----	-----	-----
13	Cultural Competence and Ethics	1	1	-----	-----	-----
14	Legal Aspects of Pharmacy Ethics	1	1	-----	-----	-----

15	Emerging Ethical Issues in Pharmacy	1	1	-----	-----	-----
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5. Methods of students' assessment

No.	Assessment Methods	Assessment Timing (Week Number)	Marks/ Scores	Percentage of total course Marks
1	Periodical exam	7	15	15%
2	Final Written Exam	16,17	85	85%
	Total		100	100%

6. Learning Resources and Supportive Facilities

Learning resources (books, scientific references, etc.)	The main (essential) reference for the course	Notes on professional ethics by Dept. of Pharmaceutical Chemistry "Pharmaceutical Ethics" by Sam Salek and Andrew Edgar Bioethics: Principles, Issues, and Cases" by Lewis Vaughn
	Other References	"Medical Ethics: Accounts of Ground-Breaking Cases" by Gregory Pence
	Electronic Sources	www.fda.gov , www.mohp.gov , www.emea.org , www.who.int , www.pdb.org
	Learning Platforms	https://lms3.kfs.edu.eg/pharm/login/index.php
Supportive facilities & equipment for teaching and learning	Devices/Instruments	- Data shows, Computers, Library, Internet.
	Supplies	Classrooms.

Course Plan

Matrix of course learning outcomes CLOs – Teaching and Learning Strategy and Student Assessment

Course title: Professional Ethics

Course code: NP 007

Course Contents		Key elements	Teaching and Learning Methods	Student Assessment Methods
Week # 1	Introduction to Pharmacy Ethics	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 2	General Principles of Medical Ethics	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 3	Conflicts of Interest in Pharmacy Practice	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 4	Pharmacist-Patient Relationships	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 5	Pharmacist's Role in Society	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 6	Ethics in Disaster Response	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 7	Semester works			
Week # 8	Medication Errors	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7,	Lectures and class activities	Written exams

		4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.		
Week # 9	Informed Consent	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 10	Research Ethics	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 11	Animal Ethics	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 12	Ethical Decision-Making Frameworks	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 13	Cultural Competence and Ethics	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 14	Legal Aspects of Pharmacy Ethics	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams
Week # 15	Emerging Ethical Issues in Pharmacy	1.1.1, 1.1.2, 1.1.3, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5, 2.5.6, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.1.6, 4.1.7, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.3.1, 4.3.2, 4.3.3, 4.3.4.	Lectures and class activities	Written exams

**Name and Signature
Course Coordinator**

Associate Prof. Rofida Salem



**Name and Signature
Program Coordinator**

Prof. Abdelaziz Elsayed





Course Specification

(2025)

Basic information

Course Title (according to the bylaw)	Alternative medicinal therapy			
Course Code (according to the bylaw)	PG E8			
Department/s participating in delivery of the course	pharmacognosy			
Number of credit hours/points of the course (according to the bylaw)	Theoretical	Practical	Other (specify)	Total
	1	1		2
1. Course Type	Elective			
2. Prerequisite	Registration			
Academic level at which the course is taught	Level five, Semester (2)			
Academic Program	Bachelor in pharmacy (Pharm D)			
Faculty/Institute	Pharmacy			
University/Academy	Kafrelsheikh University			
Name of Course Coordinator	Assistant Prof. Mai H. Elnaggar			
Course Specification Approval Date	9/2025			
Course Specification Approval (Attach the decision/minutes of the department /committee/council)	Department council			

1. Course Overview (Brief summary of scientific content)

This course aims to introduce different alternative medicine systems around the world such as traditional Chinese medicine (TCM), Ayurveda and Graco-Arabic (Unani) medicine, also it will allow the students to learn how to evaluate different practices to treat different ailments in such systems using evidence-based approaches

2. Course Learning Outcomes CLOs

Matrix of course learning outcomes CLOs with program outcomes POs (NARS/ARS)

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
Domain 1 (FUNDAMENTAL KNOWLEDGE) 1-1- COMPETENCY		Integrate knowledge from basic and applied pharmaceutical and clinical sciences to standardize materials, formulate and manufacture products, and deliver population and patient-centered care.	
1.1.1	Demonstrate understanding of knowledge of pharmaceutical, biomedical, social, behavioral, administrative, and clinical sciences.	1.1.1	Describe the historical and cultural basis of TCM, Ayurveda, and Unani medicine.
		1.1.2	Compare alternative medicine concepts with biomedical and pharmaceutical sciences.
		1.1.3	Explain the role of complementary therapies in global health systems.
1.1.2	Utilize the proper pharmaceutical and medical terms, abbreviations and symbols in pharmacy practice.	1.1.4	Apply correct medical terminology when discussing traditional therapies.
		1.1.5	Interpret symbols and abbreviations used in traditional pharmacopeias.
		1.1.6	Employ internationally recognized terms when documenting alternative therapies.
1.1.3	Integrate knowledge from fundamental sciences to handle, identify, extract,	1.1.7	Identify natural sources and preparation methods in TCM, Ayurveda, and Unani medicine.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	design, prepare, analyze, and assure quality of synthetic/natural pharmaceutical materials/products.	1.1.8	Relate modern validation methods to quality control of traditional formulations.
		1.1.9	Discuss standardization challenges in herbal product manufacturing.
1.1.4	Articulate knowledge from fundamental sciences to explain drugs' actions and evaluate their appropriateness, effectiveness, and safety in individuals and populations.	1.1.10	Explain pharmacological actions of key traditional remedies.
		1.1.11	Critically appraise their effectiveness and safety using biomedical evidence.
		1.1.12	Relate mechanism-based explanations to traditional therapeutic concepts.
1.1.5	Retrieve information from fundamental sciences to solve therapeutic problems.	1.1.13	Use evidence-based references to evaluate traditional therapies for diseases.
		1.1.14	Develop solutions for case-based problems involving alternative medicine.
		1.1.15	Integrate biomedical and traditional data to optimize therapeutic choices.
1.1.6	Utilize scientific literature and collect and interpret information to enhance professional decisions.	1.1.16	Critically analyze published studies on alternative medicine.
		1.1.17	Apply systematic review approaches to assess safety and efficacy.
		1.1.18	Use databases to retrieve validated scientific data on traditional therapies.
DOMAIN 2: PROFESSIONAL AND ETHICAL PRACTICE 2-2- COMPETENCY		Work collaboratively as a member of an inter-professional health care team to improve the quality of life of individuals and communities and respect patients' rights.	
2.1.2	Adopt ethics of health care and pharmacy profession respecting patients' rights and valuing people diversity.	2.1.1	Respect patients' cultural preferences for traditional medicine.
		2.1.2	Identify ethical concerns in recommending unverified therapies.
		2.1.3	analyze case studies on socioeconomic barriers to integrative care.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
2.1.3	Recognize your own personal and professional limitations and accept the conditions of referral to or guidance from other members of the health care team.	2.1.4	Identify the scope and limits of alternative medicine in disease care.
		2.1.5	Justify referral to conventional medicine when needed.
		2.1.6	Communicate referral decisions professionally within the healthcare team.
2.2.4	Standardize pharmaceutical materials, formulate and manufacture pharmaceutical products, and participate in systems for dispensing, storage, and distribution of medicines.	2.2.1	Relate methods of herbal product standardization in TCM and Ayurveda.
		2.2.2	Compare WHO and modern pharmacopeial guidelines for quality control.
		2.2.3	Discuss practical challenges in regulating traditional formulations.
2.4.1	Actively share professional decisions and proper actions to save patient's life in emergency situations including poisoning with various xenobiotics and effectively work in forensic fields.	2.4.1	Recognize risks of poisoning from misused herbal remedies.
		2.4.2	Explain emergency management of toxicity due to traditional products.
		2.4.3	Outline referral steps for poisoning cases involving alternative medicine.
2.4.3	Take actions to solve any identified medicine-related and pharmaceutical care problems.	2.4.4	Identify herb-drug interactions common in complementary medicine.
		2.4.5	Provide strategies to minimize risks when combining therapies.
		2.4.6	Develop pharmaceutical care plans involving traditional medicine.
2.5.2	Retrieve, interpret, and critically evaluate evidence-based	2.5.1	Review evidence from clinical trials of alternative therapies.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	information needed in pharmacy profession .	2.5.2	Explain regulatory requirements for traditional medicine research.
		2.5.3	Assess the role of pharmacists in alternative medicine trials.
2.5.3	Contribute in planning and conducting research studies using appropriate methodologies.	2.5.4	Design simple research proposals on alternative therapies.
		2.5.5	Apply evidence-based tools to validate herbal remedies.
		2.5.6	Interpret statistical findings from complementary medicine studies.
Domain 3: Pharmaceutical Care 3-1 COMPETENCY		Apply the principles of body functions to participate in improving health care services using evidence-based data	
3.1.1	Apply the principles of body function and the basis of genomics in health and disease states to manage different diseases.	3.1.1	Relate holistic concepts in TCM and Ayurveda to body functions.
		3.1.2	Compare genomic/pharmacogenomic insights with traditional personalized medicine.
		3.1.3	Discuss links between mind–body practices and disease prevention.
3.1.4	Relate etiology, epidemiology, pathophysiology, laboratory diagnosis, and clinical features of infections/diseases and their pharmacotherapeutic approaches.	3.1.4	Compare disease etiology in traditional and biomedical models.
		3.1.5	Evaluate alternative therapy applications in specific conditions.
		3.1.6	Relate clinical features of diseases to traditional treatment plans.
	3-1- Competency	Provide counseling and education services to patients and communities about safe and rational use of medicines and medical devices.	
3.2.1	Integrate the pharmacological properties of drugs including mechanisms of action, therapeutic	3.2.1	Summarize pharmacological properties of alternative remedies.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	uses, dosage, contra-indications, adverse drug reactions and drug interactions.	3.2.2	Identify contraindications and adverse reactions of phytotherapy and aromatherapy.
		3.2.3	Explain herb-drug interactions relevant to pharmacy practice.
3.2.2	Apply the principles of clinical pharmacology and pharmacovigilance for the rational use of medicines and medical devices.	3.2.4	Assess the role of pharmacovigilance in herbal/natural product monitoring.
		3.2.5	Recommend safe and rational use of alternative therapies.
		3.2.6	Develop risk-benefit assessments for traditional medicines.
3.2.3	Provide evidence-based information about safe use of complementary medicine including phytotherapy, aromatherapy, and nutraceuticals.	3.2.7	Critically evaluate safety and efficacy evidence of phytotherapy, aromatherapy, and nutraceuticals.
		3.2.8	Educate patients and communities on rational use of complementary medicine.
		3.2.9	Summarize global guidelines for safe integration of traditional therapies.
3.2.5	Educate and counsel patients, other health care professionals, and communities about safe and proper use of medicines including OTC preparations and medical devices.	3.2.10	Provide patient counseling on the safe and rational use of phytotherapy, aromatherapy, and nutraceuticals.
		3.2.11	Guide healthcare professionals in identifying potential risks, benefits, and interactions of complementary medicine.
		3.2.12	Deliver community education campaigns on evidence-based alternative therapies and OTC herbal products.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
Domain 4: Personal Practice 4-1- Competency		Express leadership, time management, critical thinking, problem solving, independent and teamwork, creativity and entrepreneurial skills.	
4.1.1	Demonstrate responsibility for team performance and peer evaluation of other team members, and express time management skills.	4.1.1	Participate actively in group discussions on case studies.
		4.1.2	Manage collaborative assignments related to evidence-based validation.
		4.1.3	Apply time management skills in project-based tasks.
4.1.2	Retrieve and critically analyze information, identify and solve problems, and work autonomously and effectively in a team.	4.1.4	Independently research alternative medicine practices and present findings.
		4.1.5	Collaborate in problem-based learning scenarios involving traditional therapies.
		4.1.6	Evaluate and integrate information from multiple sources to form evidence-based conclusions
	4.2 Competency	Effectively communicate verbally, non-verbally and in writing with individuals and communities	
4.2.1	Demonstrate effective communication skills verbally, non-verbally, and in writing with professional health care teams, patients, and communities.	4.2.1	Develop the ability to counsel patients on safe and effective use of complementary medicine.
		4.2.2	Enhance personal communication skills through active participation in peer discussions and presentations.
		4.2.3	Enhance personal skills in adapting health education to diverse cultural contexts.
4.2.2	Use contemporary technologies and media to demonstrate effective presentation skills.	4.2.4	Develop digital presentations on TCM, Ayurveda, and Unani medicine.
		4.2.5	Utilize research databases for evidence-based reports.
		4.2.6	Apply modern tools (multimedia, infographics) for communication.
	4-3 Competency	Express self-awareness and be a life-long learner for continuous professional improvement.	
4.3.2		4.3.1	Develop self-directed tasks on global traditional medicine systems.

Program Outcomes (NARS/ARS) (according to the matrix in the program specs)		Course Learning Outcomes Upon completion of the course, the student will be able to:	
Code	Text	Code	Text
	Practice independent learning needed for continuous professional development.	4.3.2	Reflect on lifelong learning needs in pharmacy and complementary medicine.
		4.3.3	Create a personal development plan to keep updated in alternative medicine.

3. Teaching and Learning Methods

1. Lectures
2. Practical training / laboratory
3. Seminar / Workshop
4. E-learning
5. Class Activity
6. Discussion
7. Brain storming

Course Schedule

Number of the Week	Scientific content of the course (Course Topics)	Total Weekly Hours	Expected number of the Learning Hours			
			Theoretical teaching (lectures/discussion groups/.....)	Training (Practical /Clinical/.....)	Self-learning (Tasks/Assignments/Projects/...)	Other (to be determined)
1	Introduction to Alternative Medicinal Therapy-1	3	1	2		
2	Traditional Chinese medicine (TCM) part-1	3	1	2		
3	Traditional Chinese medicine (TCM) part-2	3	1	2		
4	Traditional Chinese medicine (TCM) part-3	3	1	2		
5	Ayurveda part-1	3	1	2		
6	Ayurveda part-2	3	1	2		
7	Graco-Arabic (Unani) medicine part-1	3	1	2		
8	Graco-Arabic (Unani) medicine part-2	3	1	2		
9	Body mind and manipulative technique-1	3	1	2		
10	Body mind and manipulative technique-2	3	1	2		
11	Evidence-based tools for validation of traditional medicine-1	3	1	2		
12	Evidence-based tools for validation of traditional medicine-2	3	1	2		
13	Evidence-based tools for validation of traditional medicine-3	3	1	2		
14	Evidence-based tools for validation of traditional medicine-4	1	1	Practical exam		
15	Revision.	1	1	Practical exam		

4. Methods of students' assessment

No.	Assessment Methods *	Assessment Timing (Week Number)	Marks/ Scores	Percentage of total course Marks
1	Midterm Exam	3,7,11	15	15%
2	Final Practical Exam	14,15	25	25%
3	Final Written Exam	16, 17	50	50%
4	Final Oral Exam	16, 17	10	10%

5. Learning Resources and Supportive Facilities *

Learning resources (books, scientific references, etc.) *	The main (essential) reference for the course (must be written in full according to the scientific documentation method)	Al-Worafi, Y. M. (2024). Handbook of Complementary, Alternative, and Integrative Medicine: Education, Practice, and Research Volume 3: Research Evidence Based Clinical Practice. CRC Press Rakel, D. P., & Minichiello, V. (Eds.). (2022). <i>Integrative medicine</i> (5th ed.). Elsevier. .□
	Other References	Micozzi, M. S. (2018). Fundamentals of Complementary, Alternative, and Integrative Medicine (6th ed.). Elsevier Health Sciences.
	Electronic Sources (Links must be added)	
	Learning Platforms (Links must be added)	
	Other (to be mentioned)	
Supportive facilities & equipment for teaching and learning *	Devices/Instruments	- Data show -Computers.
	Supplies	
	Electronic Programs	
	Skill Labs/ Simulators	
	Virtual Labs	
	Other (to be mentioned)	

**Name and Signature
Course Coordinator**



**Name and Signature
Program Coordinator**