Faculty: Pharmacy	
Department: Pharmaceutics and pharmaceutical technology	**Program: MSc.**
Semester: 1st	**Academic year: 2024-2025**

Course Plan

First: Course Information

Course Name	**Quality Control**			*Course No.* **1102706**	
Credit Hours		*Theoretical*	*3*	*Practical*	*NA*
Prerequisite	*Class Number:* **Section 1**			*Lecture Time Satudrday (15:00-18:00)*	
Level in JNQF	**9**	*Virtual hours in the JNQF*		**120 h**	
Course Nature	■ *Mandatory Faculty Requirement* ☐ *Optional University Requirement* ☐ *Mandatory University Requirement* ☐ *Faculty Requirement* ☐ *Ancillary Course* ☐ *Optional Specialty Requirement* ☐ *Mandatory Specialization requirement*				
Type of Education	■ **Fully Face-to-Face Education** ☐ **Blended Education (3 Face-to-Face + 1 Asynchronous)** ☐ **Electronic Education Fully (1 Asynchronous + 2 Synchronous)**				

Second: Instructor's Information

Course coordinator		
Name: Dr. Anas Alshishani	*Office Number:* **PRC**	*Email:* **aalshishani@zu.edu.jo**
Instructor		
Name: Dr. Anas Alshishani	*Office Number:* **PRC**	*Email:* **aalshishani@zu.edu.jo**
Office Hours: **8 hours**	**Saturday (09:00 – 15:00)**	

Third: Short Description of the Course

Explore the depths of drug analysis and characterization in this advanced Pharmaceutical Sciences course. Gain proficiency in critical pharmaceutical tests, including Assay, Content Uniformity, Dissolution, and Impurities tests. Learn the essential concept of analytical method validation, allowing you to develop and validate methods with precision and reliability.

Evaluate pharmaceutical product quality, potency, and uniformity while adhering to industry standards and regulations. Hone your data interpretation skills to make informed decisions in drug development and quality control.

Embrace ethical conduct and Good Laboratory Practices (GLP) to ensure data integrity, patient safety, and regulatory compliance. Cultivate problem-solving abilities to tackle real-world challenges in drug analysis.

By course completion, you'll excel in communication, both written and oral, and stay current with evolving regulatory standards. You'll be equipped to contribute to the pharmaceutical industry, ensuring the highest standards of quality, safety, and efficacy through advanced analysis and characterization techniques.

Fourth: Course objectives

This course aims to :

- Equip students with a comprehensive understanding of advanced topics in pharmaceutical analysis.
- Enable students to proficiently conduct pharmaceutical tests such as Assay, Content Uniformity, Dissolution, and Impurities tests with precision and adherence to regulatory standards.
- Impart the crucial concept of analytical method validation for developing and verifying methods to achieve accurate and reproducible results.
- Teach students to evaluate the quality, potency, and uniformity of pharmaceutical formulations.
- Develop students' skills in data interpretation and application of Good Laboratory Practices.
- Ensure students stay up-to-date with regulatory guidelines.
- Cultivate problem-solving skills to tackle complex challenges in drug analysis.
- Promote professional communication of findings, both written and oral.
- Emphasize ethical conduct in pharmaceutical analysis, ensuring data integrity and patient safety.
- Prepare students to contribute effectively to the pharmaceutical industry's mission to ensure the quality, safety, and efficacy of drug products.

Fifth: Learning Outcomes

Level descriptor according to (JNQF)	*CILOs Code*	*CILOs* If any CLO will not be assessed in the course, mark NA.	*Associated PILOs Code* *Choose one PILO for each CILO**	*Assessment method* *Choose at least two methods*	*Scores out of 100* State the total score identified for each CILO**	*Minimum acceptable Score/percentage (%)* *The percentage should not be less than 70% ****
Knowledge	**K1**	Recognize assays and method validation in advanced pharmaceutical analysis.	**P. K2**	Midterm and final Exam & Quizzes	10	7 (70%)
	K2	Describe recent trends, innovative strategies, and research in pharmaceutical analysis.	**P. K2**	Midterm Exam Final Exam& Quizzes	10	7 (70%)
Skills	**S1**	Solve problems and challenges frequently encountered in drug analysis through optimization of analytical methods, impurities determination, and troubleshooting of instrumentation.	**P. S2**	Midterm Exam Final Exam& Quizzes	20	14 (70%)
	S2	Conduct precise measurements and interpretation of complex data pertinent to quality and purity of pharmaceutical formulations.	**P. S2**	Midterm Exam Final Exam& Quizzes	20	14 (70%)
	S3	Design analytical methods that are robust and reliable.	**P. S2**	Assignments	10	7 (70%)
Competencies	**C1**	Conclude innovative solutions for problems in analytical methods	**P. C2**	Assignment, Quizzes and	10	7 (70%)

				Final Exam		
	C2	Assess regulatory requirements, ensuring compliance in pharmaceutical analysis and contributing to the regulatory affairs aspects of drug development.	**P. C2**	Presentations and Final exam	20	14 (70%)

*Refer to document (CC-2023-02) and page 2 in document (CC-2023-01)
** Refer to document (CC-2023-05)
***80% of the students** must achieve the minimal acceptable percentage or higher for each CILO

Sixth: Learning Source

Designated Book1:	United State Pharmacopeia and ICH Guidelines	
Author: USP and ICH	***Print:*** 2023 version	***Year:2024***
Designated Book 2:	Pharmaceutical Analysis – A Text Book for Pharmacy Students and Pharmaceutical Chemists	
Author: David G. Watson	***Print:*** Harcourt Publisher; 4th Edition	***Year:2005***
Additional Sources: Website:	https://instrumentationtools.com/top-1000-analytical-instrumentation-questions-answers/	
Teaching Type:	***Classroom*** ***Laboratory*** ***Workshop*** **MS Teams** **Moodle**	

Seventh: Course Structure

Lecture Date	Topics	Teaching Procedures*	Teaching Methods**	Covered CILOs	References*** Principles of Instrumental Analysis, Seventh Edition – By Skoog
19/10/2024	Course Outlines and Preview about the course content	Face to Face Teaching	Lecture	----------	----------
26/10/2024	Assay	Face to Face Teaching	Lecture	K1, K2	**USP**
02/11/2024	Assay	Face to Face Teaching	Lecture	K1, K2, S1	**USP**
09/11/2024	Content Uniformity	Face to Face Teaching	Lecture	K1, K2, S1,S2	**USP**
16/11/2024	Content Uniformity/Dissolution	Asynchronous	Lecture	K1, K2, S1, S2	**USP**
23/11/2024	Dissolution	Face to Face Teaching	Lecture	K1, K2, S1, S2	**USP**
30/11/2024	Dissolution	Face to Face Teaching	Lecture	K1, K2, S1	**USP**
07/12/2024	Impurities	Face to Face Teaching	Lecture	K1, K2, S1	**USP**
14/12/2024	Impurities	Asynchronous	Lecture	K1, K2, S1	**USP**
21/12/2024	Impurities	Face to Face Teaching	Lecture	K1, K2, S1	**USP**
28/12/2025	Validation	Face to Face	Slides/Lecture	K2, S4, C1, C2,	**ICH**

		Teaching		C3	
04/01/2025	Validation	Face to Face Teaching	Slides/Lecture	K2, S4, C1, C2, C3	**ICH**
11/01/2025	Validation	Asynchronous	Slides/Lecture	K2, S4, C1, C2, C3	**ICH**
18/01/2025	Validation	Face to Face Teaching	Slides/Lecture	K2, S4, C1, C2, C3	**ICH**

*Education procedures: (Face to Face, synchronous, asynchronous)
** Refer to document (CC-2023-04)
***Reference: Pages of the book, number of the chapter, recorded lecture, video….)

Eighth: Assessment methods

Methods	Fully Electronic Education	Blended Teaching	Direct Teaching	Specific Course Output to be measured *State the score identified for each CILO for each method of assessment out of 100 **If any CILO will not be assessed in the course, mark NA.								
				K1	K2	S1	S2		S4	C1	C2	C3
*Mid-term Exam			30	8	7	7	8					
*Final Exam			40			10	10			10	10	
*Quizzes			10	2	3	3	2			1		
*Assignment			10						10			
* presentation			10								10	
Total out of 100		100		10	10	20	20		10	10	20	

* Refer to document (CC-2023-03)

Ninth: Course Polices

- Meeting the deadline for the lecture.
- Commitment to interaction and participation.
- Interactive lectures will be given through a platform (MS Teams).
- Duties and tests will be given through a platform (Moodle).
- Commitment to the right appearance in front of the camera with the proper background.
- University regulations for attendance and absence from lectures and examinations are in force.
- Academic Integrity: Fraud or moral impersonation are unacceptable and are punishable according to university regulations and instructions.

Approval	Name	Date	Signature
Head of Department	Dr. Randa Mansour	2024/10/07	
Faculty Dean	Dr. Ahlam Alkilani	2024/10/07