



<b>Faculty: Pharmacy</b>	
<b>Department: Pharmaceutical Sciences</b>	<b>Program: MSc.</b>
<b>Semester: 1<sup>st</sup></b>	<b>Academic year: 2023-2024</b>

## Course Plan

### First: Course Information

<b>Course Name:</b>	<b>Drug Analysis and Charactrization</b>	<b>Course No. 1101701</b>		
<b>Credit Hours:</b>	<i>Theoretical</i>	<b>3</b>	<i>Practical</i>	<b>NA</b>
<b>Prerequisite:</b> <b>Instrumental Analysis</b> <b>1101313</b>	<b>Class Number: Section 1</b>		<b>Lecture Time:</b> <b>Saturday</b> <b>(12:00-15:00)</b>	
<b>Level in JNQF</b>	<b>9</b>	<i>Virtual hours in the JNQF</i>	120h	
<b>Course Nature:</b>	<input checked="" type="checkbox"/> <b>Mandatory Faculty Requirement</b> <input type="checkbox"/> <b>Optional University Requirement</b> <input type="checkbox"/> <b>Mandatory University Requirement</b> <input type="checkbox"/> <b>Faculty Requirement</b> <input type="checkbox"/> <b>Ancillary Course</b> <input type="checkbox"/> <b>Optional Specialty Requirement</b> <input type="checkbox"/> <b>Mandatory Specialization requirement</b>			
<b>Type of Education:</b>	<input checked="" type="checkbox"/> <b>Fully Face-to-Face Education</b> <input type="checkbox"/> <b>Blended Education (3 Face-to-Face + 1 Asynchronous)</b> <input type="checkbox"/> <b>Electronic Education Fully (1 Asynchronous + 2 Synchronous)</b>			

### Second: Instructor's Information

<b>Course coordinator:</b>		
<b>Name: Dr. Anas Alshishani</b>	<b>Office Number: PRC</b>	<b>Email: aalshishani@zu.edu.jo</b>
<b>Instructor:</b>		
<b>Name: Dr. Anas Alshishani</b>	<b>Office Number: PRC</b>	<b>Email: aalshishani@zu.edu.jo</b>
<b>Office Hours: 8 hours</b>	<b>Sunday and Wednesday (10:00 – 12:00)</b>	

### 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

<i>Level descriptor according to (JNQF)</i>	<i>CILOs Code</i>	<i>CILOs</i> If any CLO will not be assessed in the course, mark NA.	<i>Associated PILOs Code</i> Choose one PILO for each CILO*	<i>Assessment method</i> Choose at least two methods	<i>Scores out of 100</i> State the total score identified for each CILO**	<i>Minimum acceptable Score/percentage (%)</i> <i>The percentage should not be less than 70% ***</i>
<b>Knowledge</b>	<b>K1</b>	Recognize assays and method validation in advanced pharmaceutical analysis.	<b>P. K1</b>	Midterm and final Exam & Quizzes	10	7 (70%)
	<b>K2</b>	Describe recent trends, innovative strategies, and research in pharmaceutical analysis.	<b>P. K1</b>	Midterm Exam Final Exam & Quizzes	10	7 (70%)
<b>Skills</b>	<b>S1</b>	Solve problems and challenges frequently encountered in drug analysis through optimization of analytical methods, impurities determination, and troubleshooting of instrumentation.	<b>P. S1</b>	Midterm Exam Final Exam & Quizzes	20	14 (70%)
	<b>S2</b>	Conduct precise measurements and interpretation of complex data pertinent to quality and purity of pharmaceutical formulations.	<b>P. S1</b>	Midterm Exam Final Exam & Quizzes	15	10.5 (70%)
	<b>S3</b>	Examine creative approaches in pharmaceutical analysis.	<b>P. S2</b>	Case studies	5	3.5 (70%)
	<b>S4</b>	Design analytical methods that are robust and reliable.	<b>P. S2</b>	Assignments	10	7 (70%)

Competencies	C1	Conclude innovative solutions for problems in analytical methods	P. C1	Assignment, Quizzes and Final Exam	10	7 (70%)
	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	15	10.5 (70%)
	C3	Execute independently pharmaceutical analysis projects, ensuring accountability and efficiency in their work.	P.C3	Assignments	5	3.5 (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

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

## Seventh: Course Structure

Lecture Date	Topics	Teaching Procedures*	Teaching Methods**	Covered CILOs	References*** Principles of Instrumental Analysis, Seventh Edition – By Skoog
October 21, 2023	Course Outlines and Preview about the course content	Face to Face Teaching	Lecture	-----	-----
October 28, 2023	Assay	Face to Face Teaching	Lecture	K1, K2	USP
November 4, 2023	Assay	Face to Face Teaching	Lecture	K1, K2, S1	USP
November 11, 2023	Content Uniformity	Face to Face Teaching	Lecture	K1, K2, S1,S2	USP
November 18, 2023	Content Uniformity/Dissolution	Asynchronous	Lecture	K1, K2, S1, S2	USP
November 25, 2023	Dissolution	Face to Face Teaching	Lecture	K1, K2, S1, S2	USP
December 2, 2023	Dissolution	Face to Face Teaching	Lecture	K1, K2, S1	USP
December 9, 2023	Impurities	Face to Face Teaching	Lecture	K1, K2, S1	USP
December 16, 2023	Impurities	Asynchronous	Lecture	K1, K2, S1	USP
December 23, 2023	Impurities	Face to Face Teaching	Lecture	K1, K2, S1	USP
December 30, 2023	Validation	Face to Face Teaching	Slides/Lecture	K2, S4, C1, C2, C3	ICH
January 6, 2024	Validation	Face to Face Teaching	Slides/Lecture	K2, S4, C1, C2, C3	ICH

January 13, 2024	Validation	Asynchronous	Slides/Lecture	K2, S4, C1, C2, C3	<b>ICH</b>
January 20, 2024	Validation	Face to Face Teaching	Slides/Lecture	K2, S4, C1, C2, C3	<b>ICH</b>

\*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	S3	S4	C1	C2	C3
*Mid-term Exam			30	5	5	5	5			5		
*Final Exam			40	4	4	13	8			4	5	
*Quizzes			10	1	1	2	2			1		
*Assignment			10					5	10			5
* presentation			10								10	
<b>Total out of 100</b>		100		10	10	20	15	5	10	10	15	5

\* 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			
Faculty Dean			