Faculty: Pharmacy	
Department: Pharmaceutics and Pharmaceutical Technology	**Program: Pharmacy**
Academic year: 2024/2025	**Semester: First**

Course Plan

First: Course Information

Course Title:	***Pharmaceutical Product Development and Manufacturing (1)***			***Course No. 1102701***	
Credit Hours:	***3***	***Theoretical:***	***3***	***Practical:***	***0***
Prerequisite:		***Section No.: 1***		***Lecture Time: Sat. 9:00 – 12:00***	
Level in JNQF	***9***		***Virtual hours in the JNQF***	***120 hrs***	
Type Of Course:	☐ ***Obligatory University Requirement*** ☐ ***Elective University Requirement*** ☐ ***Obligatory Faculty Requirement*** ☐***Elective Faculty Requirement*** ■ ***Obligatory Specialization Requirement*** ☐ ***Elective Specialization requirement*** ☐***Ancillary course***				
Type of Learning:	■ ***Face-to-Face Learning*** ☐ ***Blended Learning (2 Face-to-Face + 1 Asynchronous)*** ☐ ***Online Learning (2 Synchronous + 1 Asynchronous)***				

Second: Instructor's Information

Course Coordinator:		
Name: Prof Bashar Altaani	***Academic Rank: Professor***	
Office Number: 214	***Ext. Number:***	***E-mail: baltaani@zu.edu.jo***
Course Instructor:		
Name: Prof Bashar Altaani	***Academic Rank: Professor***	
Office Number: 214	***Ext. Number:***	***E-mail: baltaani@zu.edu.jo***

Office Hours:	***To be announced***

Third: Course Description

Pharmaceutical development courses series is designed to enable the students to develop quality pharmaceutical dosage forms that meet international and regulators requirements. This course is divided into two parts. In the first part, the students will be introduced pre-formulation studies of drug candidate for development. In this part, the students will be able to conduct solid state characterization of drug substance, evaluate drug micromeritics characteristics, evaluate the solubility and dissolution properties of the drug, select the suitable form (salt, crystal form, prodrug, etc.) of the drug, evaluate drug stability characteristics and select the suitable additives for its formulation. The ultimate purpose of this part is to provide rational drug design into a pharmaceutical product in the future. In the second part, the students will study how to develop a solid dosage form for a drug. In this part, the students will know the ideal properties of solid dosage form, select the most appropriate additives for the drug, select the suitable methods to prepare the formulation and the final products and evaluation of the prepared pharmaceutical product.

Fourth: Course objectives

The objectives for this course are:

1) Conduct preformulation studies for a drug entity
2) Identify potential barrier for drug entity development
3) Solve the problems that may face drug development
4) Conduct drug development of drug entity
5) Manufacturing of the drug entity

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 50% **
Knowledge	**K1**	**Identify** the different physicochemical properties that may affect the development of a drug.	**P.K1: knowledge**	Midterm exam Final exam Assignments	20	70% (14)
	K2	**Recognize** the main stages of the drug development process.	**P. K1: knowledge**	Midterm exam Final exam Assignments	15	70% (10.5)
Skills	**S1**	**Solve** problems related to the design of various relevant pharmaceutical dosage forms	**P. S1: Skills**	Midterm exam Final exam	25	70% (21)
	S2	**Distinguish** the ingredients and techniques needed in designing a quality pharmaceutical solid dosage form for a drug entity	**P. S2: skills**	Final Assignments	10	70% (7)
Competencies	**C1**	**Conduct** pre-formulation studies for a new drug entity	**P.C1 competencies**	Midterm exam Final Assignments	15	70% (10.5)
Competencies	**C2**	**Solve** processing issues during manufacturing of the developed pharmaceutical product	**P. C1: competencies**	Final Assignments	15	70% (7)

*For each CILO, the PILO could be the same or different.

Sixth: Learning Source

Main Reference:	Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice		
Editor: Yihong Qiu et al	***Issue No.:***	***Print:1st***	***Publication Year: 2009***
Additional Sources &Websites:	- **The Theory and Practice of Industrial Pharmacy, Lachman/Lieberman** - **Assigned literature** - **ICH guidelines** - **FDA website: www.fda.gov**		
Teaching Type:	■ ***Classroom*** ☐ ***Laboratory*** ☐ ***Workshop*** ☐ ***MS Teams*** ☐ ***Moodle***		

Seventh: Course Structure

Lecture Date	Intended Teaching Outcomes (CILOs)	Topics	Teaching Procedures*	Teaching Methods**	References***
Sat 19/10/2024	K2	- Course outline - Introduction to Drug Discovery and Development Processes	Face to Face	• Direct teaching • Teaching through discussion • Problem solving based teaching	- Course outline - FDA website - Reference 1: Chapter 36 (845-860)
Sat 26/10/2024	K1, S1, C1	- Introduction to pre-formulation studies - Pre-formulation: Solubility and dissolution of Pharmaceuticals	Face to Face		Reference 1: Chapter 1 (3-24) Chapter 13 (309-318) Chapter 14 (319-340) Reference 2: Chapter 8 (171-196) Assignment
Sat 2/11/2024	K1, S1, C1	- Pre-formulation: Solid state of pharmaceutical substances	Face to Face		Reference 1: Chapter 2 (25-60) Chapter 3 (61-74) Chapter 8 (163-186) Reference 2: Chapter 8 (171-196) Assignment
Sat 9/11/2024	K1, S1, C1	- Pre-formulation: Drug Stability and Degradation Studies	Face to Face		Reference 1: Chapter 5 (87-124) Chapter 6 (125-145)

					Reference 2: Chapter 8 (171-196) Assignment
Sat 16/11/2024	K1, S1, C1	Pre-formulation: Salt Screening and Selection of pharmaceutical substances	Face to Face		Reference 1: Chapter 4 (75-86) Assignment
Sat 23/11/2024	K2, S1, S2	Integration of Physical, Chemical, Mechanical, and Biopharmaceutical Properties in Solid Dosage Form Development	Face to Face		Reference 1: Chapter 18 (409-441) Assignment
Sat 30/11/2024	K2, S1, S2	Specification Setting and Manufacturing Process Control for Solid Oral Drug Products	Face to Face		Reference 1: Chapter 26 (599-614) Reference 2: Chapter Assignment
Sat 7/12/2024	K2, S1, S2	Specification Setting and Manufacturing Process Control for Solid Oral Drug Products	Face to Face		Reference 1: Chapter 26 (599-614) Reference 2: Chapter Assignment
Sat 14/12/2024	K2, S1, S2	Packaging Selection for Solid Oral Dosage Forms	Face to Face		Reference 1: Chapter 24 (563-576) Assignment
Sat 21/12/2024	K2, S1, S2	Stability Studies for Drug Products	Face to Face		Reference 1: Chapter 23 (539-561) Assignment
Sat 4/1/2025	C2	Manufacturing processes	Face to Face	• Direct teaching • Teaching through discussion • Problem solving based teaching	Reference 1: Chapter 29 Chapter 30 Assignment
Sat 11/1/2025	C2	Manufacturing processes	Face to Face		Reference 1: Chapter 31 Chapter 32 Assignment
Sat 18/1/2025	C2	Manufacturing processes	Face to Face		Reference 1: Chapter 33 Chapter 34 Assignment

Teaching procedures: (Face-to-face, synchronous, asynchronous). * * Teaching methods: Lecture, video…..). *** Reference: Pages of the book, recorded lecture, video….)

Eighth: Assessment methods

Methods	Online Learning	Blended Learning	Face-To-Face Learning	Specific Course Output to be Assessed *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	S5	C1	C2	C3	C4	C5
Mid-term Exam			30	**14**	**9**	**7**									
Final Exam			40	**4**	**4**	**12**	**5**				**8**	**7**			
Assignment 1			4	**2**	**2**										
Assignment 2			6			**6**									
Assignment 3			5				**5**								
Assignment 4			15								**7**	**8**			
Total out of 100			100	**20**	**15**	**25**	**10**				**15**	**15**			

***Refer to document (CC-2023-03)**

Ninth: Course Policies

- All course policies are applied on all teaching patterns (online, blended, and face-to-face Learning) as follows:
  a. Punctuality.
  b. Participation and interaction.
  c. Attendance and exams.
- Academic integrity: (cheating and plagiarism are prohibited).
- Meeting the deadline for the lecture.
- Commitment to interaction and participation.
- University regulations for attendance and absence from lectures and examinations are in force.
- Academic Integrity: According to university regulations and instructions, fraud or moral impersonation is unacceptable and punishable.

Approval	Name	Date	Signature
Head of Department	Dr. Randa	6/10/2024	
Faculty Dean	Dr. Ahlam	6/10/2024	