

The University of Jordan Accreditation & Quality Assurance Center

Course Syllabus

1	Course title	Pharmaceutical Technology II			
2	Course number	1202333			
3	Credit hours (theoryy, practical)	2 (theory)			
3	Contact hours (theory, practical)	2 (theory)			
4	Prerequisites/corequisites	Prerequisite: Pharmaceutical Technology I (1212331)			
5	Program title	BSc in Pharmacy			
6	Program code				
7	Awarding institution	The University of Jordan			
8	Faculty	Pharmacy			
9	Department	Pharmaceutics and Pharmaceutical Technology			
10	Level of course	Undergraduate			
11	Year of study and semester (s)	Second semester of the 3rd year			
12	Final Qualification	BSc in Pharmacy			
13	Other department (s) involved in teaching the course	N/A			
14	Language of Instruction	English			
15	Teaching methodology	□Blended ⊠ Online			
16	Electronic platform(s)	⊠ Moodle ⊠ Microsoft Teams □ Skype □Zoom □Others			
17	Date of production/revision	26 February 2021			

16. Course Coordinator:

Office numbers, office hours, phone numbers, and email addresses should be listed.

Hatim S. AlKhatib, Office 221, Pharmacy Building

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Office hours:

17. Course instructors:

Office numbers, office hours, phone numbers, and email addresses should be listed.

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18. Course Description:

The course introduces students to the formulation and manufacturing aspects of coated solid dosage forms, capsules, disperse systems and parenteral products. It provides students with knowledge of materials, processing technologies and quality testing procedures and allows them to combine such knowledge into pharmaceutical products capable of satisfying therapeutic objectives.

19. Course aims and outcomes:

A- Aims:

- 1. Know the reasons behind developing pharmaceutical products as coated solid dosage forms, capsules, disperse systems or injectable dosage forms.
- 2. Understand the interplay of materials (excipients) properties, processing technology and conditions when attempting to develop dosage forms (coated solid dosage forms, capsules, disperse systems and

parenteral products)

- 3. Recognize critical quality attributes of coated solid dosage forms, capsules, disperse systems and parenteral products.
- 4. Recommend technical solutions to resolve manufacturing problems.
- 5. Design formulations, choose processing technologies and recognize quality testing procedures needed for the development of pharmaceutical products capable of satisfying therapeutic objectives.

B- Intended Learning Outcomes (ILOs):

Upon successful completion of this course students will be able to:

- Develop, integrate, and apply knowledge from the foundational sciences (learner)
 - 1. Know the types of coatings applied to solid dosage forms.
 - 2. Understand the processes of sugar, film and press coating and types and performance characteristics of equipment used in such processes.
 - 3. Know the classes and examples on each class of excipients used in sugar, film and press coating.
 - 4. Understand the contribution of different excipient classes in the manufacturing and performance of coated dosage forms.
 - 5. Categorize polymers according to their functionality in coated dosage forms and identify their structure function relationships.
 - 6. Recognize coating defects; understand their causes and potential consequences on dosage form performance and therapeutic activity.
 - 7. Propose technical solutions for coating defects.
 - 8. Know the types of gelatin capsules and their applications as dosage forms.
 - 9. Understand the process of capsule shell manufacturing.
 - 10. Know the classes and examples on each class of excipients used in capsule shell manufacturing.
 - 11. Know the different types of capsule fill material.
 - 12. Understand the different capsule filling techniques.
 - 13. Propose suitable filling mechanism for each type of capsule fills.
 - 14. Know the different types of disperse systems.
 - 15. Understand the interactions between dispersed phase and dispersion medium (wettability, aggregation, separation)
 - 16. Understand the electrical properties of interfaces.
 - 17. Understand the physical instability of disperse systems, how to evaluate the stability of disperse systems.
 - 18. Know the classes and examples on each class of excipients used in disperse systems.

- 19. Understand the contribution of excipients in stabilizing disperse systems.
- 20. Understand the processes of preparation of disperse systems and types and performance characteristics of equipment used in such processes.
- 21. Understand the special quality requirements for parenteral dosage forms.
- 22. Know the characteristics and functions of excipients used in preparing parenteral dosage forms.
- 23. Know the different types of excipients and packaging materials for parenteral products.
- 24. Understand the specific requirements of excipients for parenteral products.
- 25. Understand the process of freeze drying used in the preparation of parenteral products.
- 26. Provide patient and health care professionals education on the proper storage and usage requirements of coated solid dosage forms, capsules, disperse systems and parenteral products.
- Exhibit behaviors and values that are consistent with the trust given to the profession by patients, other healthcare providers, and society (*Professional*)
 - 27. Communicate effectively and respectfully with professors and classmates
 - 28. Show responsibility, accountability and commitment by complying with tutor's instructions and relevant university regulations
 - 29. Demonstrate integrity by not cheating and not committing plagiarism
- Dispense, compound, distribute, and manage so as to operate a successful pharmacy outlet/store; (*Pharmacy System Manager*).
 - 30. Develop and provide accurate and usable dosage forms information regarding dosing and use instructions.
 - 31. Utilize proper documentation in management.
- Carry out compounding procedures to produce an effective and safe medicine (*Compounder*), and implement quality control measures and tests (*Quality Manager*); Pharmaceutical Product Expert *Manufacturer*).
 - 32. Propose remedies for the problems encountered during the manufacturing of coated solid dosage forms, capsules, disperse systems or injectable dosage forms.
 - 33. Develop formulations and manufacturing procedure for coated solid dosage forms, capsules, disperse systems or injectable dosage forms.
- Identify problems; explore and prioritize potential strategies; and design, implement, and evaluate a viable solution; Problem Solving and critical thinking (*Problem Solver*).
 - 34. Identify key elements of problems and choose appropriate methods for their resolution in a systematic manner.
 - 35. Outline and solve the problems encountered during manufacturing processes of pharmaceutical

dosage forms in pharmaceutical firms.

• Demonstrate self-directed learning through ongoing reflection and analysis to identify areas and methods necessary to expand professional knowledge and competence in a changing practice environment; (Self-learner).

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- 36. Seek actively new knowledge related to coated solid dosage forms, capsules, disperse systems or injectable dosage forms, their composition, manufacturing, critical quality attributes, testing procedures, storage, dispensing and administration.
- Communicate effectively with patients, caregivers, pharmacy personnel, other health care professionals, community members, policy makers and administrators; (Communicator).
 - 37. Communicate effectively and respectfully with professors and classmates
 - 38. Show responsibility, accountability and commitment by complying with tutor's instructions and relevant university regulations
 - 39. Develop skills and confidence required for assertive, persuasive, and clear communications.
- Exhibit behaviors and values consistent with the trust given to the profession by patients, other healthcare providers, and society; (*Professional*).
 - 40. Demonstrate integrity by not cheating and not committing plagiarism.
 - 41. Demonstrate respect to professors and classmates by observing active listening inside the classroom

C. Program Competencies Achieved:

- **1.** *Learner*: Develop, integrate, and apply knowledge from the foundational sciences (Biomedical sciences, Pharmaceutical sciences, Clinical sciences, Social/behavioral/administrative).
- **2.** *Pharmacy System Manager*: Dispense, compound, distribute, and manage so as to operate a successful pharmacy outlet/store.
- **3.** <u>Pharmaceutical Product Expert (Manufacturer)</u>: Carry out compounding procedures to produce an effective and safe medicine (Compounder), and implement quality control measures and tests (Quality Manager).
- **4. Problem Solving and critical thinking (Problem Solver)**: Identify problems; explore and prioritize potential strategies; and design, implement, and evaluate a viable solution.
- **5. Self-learner**: Demonstrate self-directed learning through ongoing reflection and analysis to identify areas and methods necessary to expand professional knowledge and competence in a changing practice environment.
- **6.** *Communicator*: Communicate effectively with patients, caregivers, pharmacy personnel, other health care professionals, community members, policy makers and administrators.
- **7.** *Professional*: Exhibit behaviors and values that are consistent with the trust given to the profession by patients, other healthcare providers, and society.

20. Topic Outline and Schedule:

Topic	Week	Instructor	Teaching Methods/ platform	Achieved ILOs	Evaluation Methods	Reference
Introduction, Reasons for coating	1	Hatim AlKhatib	MS Teams, JU E learning, Synchronous.	1, 26, 27- 41	Exams	Aulton's Pharmaceutics
Sugar Coating: Definition and process. Stages of sugar coating	1	Same as above	Same as above	2,3,4, 27- 41	Exams	Same as above
Ideal characteristics of sugar- coated tablets, Sugar coating process, Coating pan designs (classic pans, side vented pans, baffles, atomization)	1	Same as above	Same as above	2,4, 27- 41	Exams	Same as above
Film Coating definition, film formation from solutions and dispersions (Tg and curing)	2	Same as above	Same as above	2, 3, 5, 27-41	Exams	Same as above
Film formers (cellulosics, vinyl, acrylic, silicone elastomer, natural polymers)	2	Same as above	Same as above	3, 4, 5, 27-41	Exams, Quiz	Same as above
Formulation Components: Excipients in film coating (Solvents, Plasticizers, Surfactants, Coloring agents, Pore formers, Antitack agents)	3	Same as above	Same as above	3,4, 27- 41	Exams	Same as above
Fluidized bed coaters: Top spray, Tangential spray, Bottom spray.	3	Same as above	Same as above	2, 4, 27- 41	Exams	Same as above
Coating Process Parameters: Product bed temperature, Spraying pressure, Pan rotation speed, Curing temperature.	4	Same as above	Same as above	2, 4, 27- 41		
Coating defects and solutions: Capping and Lamination, Sticking (twining) and Picking, Roughness / Orange-peel, Bridging and Filling, Cracking / Splitting, Cratering, Hazing, Color Variations	4	Same as above	Same as above	6, 7, 26, 27-41	Exams	Same as above
Press coating: Applications and process.	4	Same as above	Same as above	1, 2, 3, 27-41		
Capsules: Definition, Types, Composition of capsule shells: (Gelatin preparation and properties, and quality control), colorants and wetting agents.	5	Same as above	Same as above	8, 9, 10, 26, 27-41	Exams, Quiz	Same as above
Manufacturing of capsule shells, Capsule Sizes, Self- locking capsules	5	Same as above	Same as above	9, 10, 27- 41	Exams	Same as above
Hard Gelatin Capsule Filling: Types of fills, bench scale filling and industrial filling, Powder filling (dependent "Auger" and independent	6	Same as above	Same as above	11, 12, 13, 27-41	Exams	Same as above

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systems "dosators" and						
"tamping fingers"), pellet						
filling, tablet filling, semisolid						
and liquid filling.						
Softgels: Rationale for Using		Same as	Same as			
Softgels, composition of shells	6	above	above	8, 10, 26,	Exams	Same as above
(plasticizers). Manufacture of	U			27-41	Lains	Sallie as above
Softgels						
Softgels: Fill materials: types		Same as	Same as			
of vehicles, solutions,	7	above	above	11, 12,	Г	C 1
suspensions, self- emulsifying	7			13, 27-41	Exams	Same as above
systems				-,		
Suspensions: definition and		Same as	Same as	14, 26,		_
Classification	8	above	above	27-41	Exams	Same as above
Formulation of suspensions:		Same as	Same as			
Wetting and evaluation of	8	above	above	15, 16,	Exams	Same as above
11	O	above	above	17, 27-41	Lains	Sallie as above
wettability.		Same as	Camaga	+		
Formulation of suspensions:			Same as	15 16		
Electrokinetics, Electrical	9	above	above	15, 16,	Exams	Same as above
double layer, Effect of				17, 27-41		
electrolytes				1		
Formulation of suspensions:		Same as	Same as			
Particle Interactions and		above	above	15, 16,		
Behavior, DLVO theory, Steric	10			17, 27-41	Exams	Same as above
stabilization, States of				17,27-41		
aggregation						
Formulation of suspensions:	11	Same as	Same as	15, 16,	Г	C
Sedimentation	11	above	above	17, 27-41	Exams	Same as above
Formulation of suspensions:		Same as	Same as			
Solid Bridging and Related	11	above	above	15, 16,	Exams	Same as above
Phenomena, Ostwald ripening				17, 27-41		
Methods of suspension		Same as	Same as			
preparation: Precipitation	12	above	above	18, 19,	Exams	Same as above
methods and Dispersion.	12	above	above	27-41	Exams	Same as above
Evaluation of suspension		Same as	Same as			
stability: Rheologic,		above	above			
	12	above	above	16, 27-41	Exams	Same as above
Electrokinetic and Particle size						
analysis		0		11.06		
Emulsion: Definition and	13	Same as	Same as	14, 26,	Exams	Same as above
types.	_	above	above	27-41		
Formulation of emulsions:		Same as	Same as	15, 16,	_	
Phase Volume Ratio,	13	above	above	17, 27-41	Exams	Same as above
Emulsifying Agents						
Formulation of emulsions:	13	Same as	Same as	15, 16,	Exams	Same as above
Viscosity Imparting Agents	13	above	above	17, 27-41	Exaills	Same as above
Emulaification Tashniauss	12	Same as	Same as	15, 16,	Evens	Same as above
Emulsification Techniques	13	above	above	17	Exams	Same as above
Emulsions Instability, Stress		Same as	Same as		·	
testing: Thermal and	4.4	above	above	15, 16,	Б	C
Gravitational, Physical	14			17, 27-41	Exams	Same as above
Parameters of Stability						
Mechanical equipment for		Same as	Same as	1		
emulsification: Stirrers,		above	above	19, 20,		
homogenizers, ultrasonifiers	14	above	above	27-41	Exams	Same as above
and colloid mills.						
		Same as	Same as	+		
Liquid filling machines	14	above	above	20, 27-41	Exams	Same as above
Davantaval products: Davits	1 ୮			21 22	Evrence	Campagabarra
Parenteral products: Routes of	15	Same as	Same as	21, 22,	Exams	Same as above

administration, classifications, Characteristics of a parenteral dosage form		above	above	26, 27-41		
Formulation of parenterals: Vehicles: Water, water miscible vehicles and water immiscible vehicles.	15	Same as above	Same as above	23, 24, 27-41	Exams	Same as above
Formulation of parenterals: Solutes: Added substances, Antimicrobial agents, Buffers, Antioxidants, Tonicity agents, Cryoprotectants and lyoprotectants	16	Same as above	Same as above	23, 24, 25, 27-41	Exams	Same as above
Guidelines for developing formulations of injectable drugs: Route of administration, Pharmacokinetics of the drug, Solubility, Stability and compatibility	16	Same as above	Same as above	23, 26, 27-41	Exams	Same as above

21. Teaching Methods and Assignments:

Development of ILOs is promoted through the following teaching and learning methods:

- A. Teaching Methods:
- Lectures
- Self-Reading
- Multimedia demonstrations
- B. Learning Skills:
- Critical thinking
- Scientific reasoning
- Digital literacy
- Communication skills
- Problem-solving skills
- Self-directed learning

22. Evaluation Methods and Course Requirements:

Opportunities to demonstrate achievement of the ILOs are provided through the following <u>assessment methods and requirements</u>:

- Exams
- Ouizzes

23. Course Policies:

- A- Attendance policies:
 - As per the applicable university regulations
- B- Absences from exams and handing in assignments on time:
 - As per the applicable university regulations
- C- Health and safety procedures:
 - N/A
- D- Honesty policy regarding cheating, plagiarism, misbehavior:
 - As per the applicable university regulations
- E- Grading policy:
 - Assignment (10%)
 - Quizzes (35%) - Final Exam (50%)
- F- Available university services that support achievement in the course:

- University libraries
- Student computer labs
- University website (including E-Learning and faculty member websites)

24. Required equipment:

- Computer connected to the internet and data show projector
- Whiteboard and associated equipment

25. References:

- A- Required book (s), assigned reading and audio-visuals:
 - Aulton's Pharmaceutics: The Design and Manufacture of Medicines, by M.E. Aulton and K.M.G. Taylor. 4th Ed., 2013. Published by Churchill Livingstone.
- B- Recommended books, materials, and media:
 - Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, by L.V. Allen, N.G. Popovich and H.C. Ansel. 9th Ed., 2011. Published by Lippincott Williams & Wilkins.
 - Pharmaceutical dosage forms (Tablet V1, V2 and V3), by H.A. libberman and L. Lechman. 1990. Published by Marcel Dekker. Inc., N.Y., USA.
 - The theory and practice of Industrial Pharmacy, by L. Lechman, H.A. Libberman and J.L. Kanig. 3rd Ed., 1986. Published by Lea and Febiger, Philadelphia, USA.
 - Martin's Physical Pharmacy and Pharmaceutical Sciences. 6th Ed., 2011. Published by Lippincott Williams & Wilkins, USA.

26. Additional information:
Name of Course Coordinator: Hatim S. AlKhatib Signature:Date: February 26th, 2021
Head of curriculum committee/Department: Signature:
Head of Department: Signature:
Head of curriculum committee/Faculty: Signature:
Dean:

Copy to: Head of Department Assistant Dean for Quality Assurance Course File