



The University of Jordan

Accreditation & Quality Assurance Center

COURSE Syllabus

1	Course title	Pharmaceutical Technology (2)
2	Course number	1202333
3	Credit hours (theory, practical)	2 (theory)
	Contact hours (theory, practical)	2 (theory)
4	Prerequisites/corequisites	Prerequisite: 1202231 (Pharmaceutical technology 1)
5	Program title	B.Sc. Program in Pharmacy
6	Program code	
7	Awarding institution	The University of Jordan
8	Faculty	Pharmacy
9	Department	Pharmaceutics & Pharmaceutical Technology
10	Level of course	Undergraduate
11	Year of study and semester (s)	Second semester of the 3rd year
12	Final Qualification	B.Sc. degree in Pharmacy
13	Other department (s) involved in teaching the course	None
14	Language of Instruction	English
15	Date of production/revision	15 Feb. 2016

16. Course Coordinator:

Dr. Ahmad Bani-Jaber, PhD.
<http://eacademic.ju.edu.jo/abjaber/default.aspx>
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 Phone 5 355 000, Ext. 23332.
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17. Other instructors:

Dr. Dina El-Sabawi, PhD.
<http://eacademic.ju.edu.jo/d.sabawi/default.aspx>
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 Phone 5 355 000, Ext. 23360.
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18. Course Description:

The course provides an overview of solid dosage forms (coated tablets, hard gelatin capsules and soft-gels), in addition to liquid and semisolid dosage forms. It covers dosage form design, rational uses, formulation, production, performance and stability evaluation of these dosage forms.

19. Course aims and outcomes:**A- Aims:**

1. To recognize the manufacturing process and formulation of coatings for solid dosage forms
2. To recognize the applications, formulation and manufacture of hard and soft gelatin capsules.
3. To recognize the applications, manufacturing process and formulation of suspensions and emulsions.
4. To recognize the preformulation and formulation of small volume parenterals.

B- Course Intended Learning Outcomes (ILOs):

Successful completion of the course should lead to the following outcomes:

A. Knowledge and Understanding: Student is expected to

A1) Acquire the knowledge of the physicochemical properties of polymers used in coating and have the ability to select polymers for certain coating purposes, such as enteric coating and sustained release coating. Have the ability to deal with coating equipment, such as pan coater and fluid bed drier. Have the ability to select ingredients for coating formulation. Have the ability to recognize coating problems.

A2) Know the material a hard gelatin capsule is made from. Knowing the manufacturing process of hard gelatin capsule shell. Recognize the capsule sizes. Recognize the filling process of hard gelatin capsule using bench scale equipment and industrial scale equipment. Be able to select inactive ingredients for the formulation of hard gelatin capsule fills.

A3) Be able to describe a soft gelatin capsule and how it differs from hard gelatin capsule. Recognize the properties of softgels. Know the rationale for the selection of softgels as a dosage form. Recognize the manufacturing process of softgels. Recognize the formulation of softgel fill materials.

A4) Be able to recognize the reasons why some drugs are formulated as suspensions. Be able to describe the destabilization mechanisms of suspensions. Differentiate between flocculated and deflocculated suspensions in terms of electrical properties of solid-liquid interfaces. Be able to compare between flocculated and deflocculated suspensions in terms of the physical behavior of the suspended particles. Know various approaches to stabilize suspensions. Be able to select ingredients for suspensions formulation. Recognize the process including equipment for the manufacturing of emulsions. Able to evaluate suspensions stability via various accelerated stability tests.

A5) Be able to recognize the reasons why some drugs are formulated as emulsions. Be able to differentiate between emulsion types. Be able to describe the destabilization mechanisms of emulsions. Know various approaches to stabilize emulsions. Be able to select ingredients for emulsion formulation. Recognize the process and equipment for the manufacture of emulsions. Be able to evaluate emulsion stability via various accelerated stability tests.

A6) Be able to describe the physico-chemical principles of drugs to be formulated as parenteral solution, among which is to be able to determine the drug solubility in various media for the purpose of formulation as parenteral solution and to correlate the solubility with the drug chemical structure. Know the ingredients used in parenteral product formulation. Know various packaging materials used for parenteral product. To recognize the problems encountered during the formulation of parenteral products. Have the ability to conduct accelerated stability studies for the evaluation of parenteral products.

B. Intellectual Analytical and Cognitive Skills: Student is expected to

B1) Be able to suggest coating formulations with the necessary calculations.

B2) Be able to suggest remedies for coating problems.

B3) Be able to suggest formulations for capsule filling, and to solve problems encountered during their manufacturing.

B4) Be able to suggest formulations for pharmaceutical suspensions and to solve problems encountered during their manufacturing and during their shelf-life.

B5) Be able to suggest formulations for pharmaceutical emulsions and to solve problems encountered during their manufacturing and during their shelf-life.

B6) Be able to suggest formulations for small volume parenterals and to solve problems encountered during their manufacture and during their shelf-life.

C. Transferable Key Skills: Students is expected to

C1) Gain knowledge and analytical skills to work with people in pharmaceutical firms.

C2) Have the ability for easy training in pharmaceutical firms

C3) have the ability to deal with and suggest solutions to the problems encountered during the manufacturing process of pharmaceutical dosage forms in pharmaceutical firms.

D1. Competencies

D1. Recognize the role of pharmaceutical excipients and their uses in drug formulations

D2. Characterize various pharmaceutical dosage forms

D3. Identify formulation principles and product development stages

D4. Recognize various pharmaceutical manufacturing processes

D5. Demonstrate the ability to perform pharmaceutical calculations

20. Topic Outline and Schedule:

Topic	Week	Instructor	Achieved ILOs	Evaluation Methods	Reference
1. Aqueous Polymeric coating of Pharmaceutical dosage forms Introduction, polymers used in coating (properties and chemistry), equipment used in coating (Pan coaters and Fluid-Bed drier), sequence of a coating process, process and polymer parameters that affect the coating process (Glass transition temperature, viscosity, pan velocity and air temperature), formulation of coating solutions and dispersions, coating problems and their remedies.	1-3	Dr. Dina or Dr. Ahmad	A1 B1-B2 C1-C3 D1-D5	Exams, Quizes	1. Specified in each lecture. General references provided below
2. Hard gelatin Capsules Introduction, raw materials (Gelatin, colorants, and process aids), manufacture (capsule filling, capsule filling machines), Filling of powder formulations (Bench scale filling and Industrial scale filling).	4-5	Dr. Dina or Dr. Ahmad	A2 B3 C1-C3 D1-D5	Exams, Quizes	Specified in each lecture. General references provided below
3. Soft Gelatin Capsules Introduction, description of soft gelatin capsule as a dosage form, manufacture of soft gels, formulation of soft gels, product quality considerations (in-process testing and finished product testing)	6	Dr. Dina or Dr. Ahmad	A3 B3 C1-C3 D1-D5	Exams, Quizes	Specified in each lecture. General references provided below
Midterm Exam	7				
4. Pharmaceutical suspensions (6 lectures) Definition, types of suspensions, pharmaceutical applications, Stability: Thermodynamic stability and physical stability (Sedimentation, polymorphic transformation and crystal growth). Stabilization: prevention of sedimentation, prevention of aggregation and caking. Electrical properties of solid interfaces (attractive and repulsive forces, zeta potential and Nernst potential). Flocculated and deflocculated suspensions Ingredients used in pharmaceutical suspension formulation. Incompatibility in suspensions. Production of	8-9	Dr. Dina or Dr. Ahmad	A4 B4 C1-C3 D1-D5	Exams, Quizes	Specified in each lecture. General references provided below

suspensions. Evaluation and testing of suspensions. Reconstituable suspensions.					
5. Pharmaceutical emulsions Definition, types of suspensions, pharmaceutical applications. Destabilization mechanism (thermodynamic stability: Stokes law and physical stability: creaming, coalescence and phase separation). Stabilization mechanisms. Ingredients used in emulsion. Typical formulations for topical, oral and intravenous emulsions. Equipment used for production of pharmaceutical emulsions.	10-12	Dr. Dina or Dr. Ahmad	A5 B5 C1-C3 D1-D5	Exams, Quizes	Specified in each lecture. General references provided below
6. Formulation of parenterals Definition and categories. Solubility and solubilization: effect of chemical structure, dielectric constant, effect of pH, salt formation, cosolvent approach. Formulation and ingredients. Stability: Oxidation, change in pH, precipitation, chemical degradation. Packaging materials: glass types and closures.	13-14	Dr. Dina or Dr. Ahmad	A6 B6 C1-C3 D1-D5	Exams, Quizes	Specified in each lecture. General references provided below
Final Exam	15				

21. Teaching Methods and Assignments:

Development of ILOs is promoted through the following <u>teaching and learning methods</u> :		
ILO/s	Learning Methods	Evaluation Methods
All	Lectures	Exams, Quizzes

22. Evaluation Methods and Course Requirements:

<p>Opportunities to demonstrate achievement of the ILOs are provided through the following <u>assessment methods and requirements</u>:</p> <ol style="list-style-type: none"> Exams Quizzes <p>Learning skills:</p> <ol style="list-style-type: none"> Critical thinking Digital literacy Problem-solving skills Self-directed learning
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23. Course Policies:

A- Attendance policies:

Attendance: Mandatory.

First warning – with 4 absences

Last warning – with 5 absences

Failing in the subject – with 6 absences

B- Absences from exams and handing in assignments on time:

Will result in zero achievement unless health report or other significant excuse is documented.

C- Health and safety procedures:

NA

D- Honesty policy regarding cheating, plagiarism, misbehavior:

The participation, the commitment of cheating will lead to applying all following penalties together

- 1) Failing the subject he/she cheated at
- 2) Failing the other subjects taken in the same course
- 3) Not allowed to register for the next semester. The summer semester is not considered as a semester

E- Grading policy:

Exams and Quizzes.

Mid Exam:	40 points
Quizz:	10 points
Final Exam:	50 points
Total	100 points

F- Available university services that support achievement in the course:

Classrooms, internet classes

24. Required equipment:

Datashow and internet connection

25. References:

1. The theory and practice of Industrial by Lechman and Libberman, 4th Ed.
2. Pharmaceutical Dosage Forms: Tablets by Lechman and Libberman, Vol. 1-3, 2nd Ed.
3. Pharmaceutical Dosage Forms: Disperse Systems ((Lechman and Libberman), Vol. 1-3, 2nd Ed.
4. Pharmaceutics: The Science of Dosage Form Design, by Michael E. Aulton, 2nd Ed.

26. Additional information:

Name of Course Coordinator: Nailya Bulatova -Signature: ----- Date: Jan, 31, 2016

Head of curriculum committee/Department: ----- Signature: -----

Head of Department: Nailya Bulatova Signature: -----

Head of curriculum committee/Faculty: ----- Signature: -----

Dean: ----- -Signature: -----

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