The University of Jordan

Accreditation & Quality Assurance Center

Course Syllabus

1	Course title	Pharmaceutical Technology I
2	Course number	1212331
3	**Credit hours (theory, practical)**	2 (theory)
	Contact hours (theory, practical)	2 (theory)
4	Prerequisites/corequisites	Prerequisite: 1202230 (Pharmaceutical Calculations and Compounding of Dosage Forms)
5	Program title	BSc in Pharmacy and PharmD
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)	First semester of the 3rd year
12	Final Qualification	BSc in Pharmacy or PharmD
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	8 October 2020

18. Course Coordinator:

Office numbers, office hours, phone numbers, and email addresses should be listed.
Dr. Lorina Bisharat
Office 110
E-mail: l.bisharat@ju.edu.jo

19. Course instructors:

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

Dr. Lorina Bisharat
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20. Course Description:

The course explains the process of a product development in the pharmaceutical industry and the organizational structure of a pharmaceutical manufacturer. In addition, the course provides students with an understanding of the unit processes used in pharmaceutical manufacturing including: milling, granulation, drying, mixing and tableting in terms of rationalization for processing, equipment used and characterization of the product.

21. Course aims and outcomes:

A- Aims:

- To recognize the responsibilities and duties of the departments of a pharmaceutical firm.
- To be able to conduct preformulation studies.
- To recognize various processes and equipment used in the unit operation: particle size analysis, size reduction, mixing and drying.
- To understand the consolidation process of solid dosage forms, and the operation of tablet presses.

- To recognize various manufacturing methods for solid dosage forms.
- To recognize the ingredients used in the formulation of solid dosage forms.
- To recognize the problems encountered during the manufacturing of solid dosage forms.

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 duties of the department of a pharmaceutical firm: Research and development department, quality control department, quality assurance department and quality control department.
2. Know preformulation programs in terms of types of studies and data collected.
3. Describe the commonly used equipment used in the operation unit: particle size analysis, size reduction, mixing and drying.
4. Understand the consolidation process of powders and the operation of equipment used for solid powder consolidation.
5. Recognize various manufacturing process for solid dosage forms with their advantages, utility, and limitations: wet granulation, dry granulation and direct compression.
6. Know the categories of inactive ingredient used in the manufacturing of solid dosage forms, the function of each category and examples of each category.
7. Know various problems encountered during the manufacturing of solid dosage forms, such as capping, weight variation, and sticking, and the possible remedies for each problem.
8. Understand quality control tests for the intermediate and final solid dosage forms.
9. Be able to suggest formulations and manufacturing procedure for solid dosage forms.
10. Be able to suggest remedies for the problems encountered during the manufacturing of solid dosage forms.

- **Dispense, compound, distribute, and manage so as to operate a successful pharmacy outlet/store; (*Pharmacy System Manager*).**

11. Understand specific storage requirements of different types of tablets and solid dosage forms and instruction for use.

- **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*).**

12. Propose remedies for the problems encountered during the manufacturing of pharmaceutical powders and tablets.
13. Develop formulations and manufacturing procedure for pharmaceutical powders and tablets.

- **Identify problems; explore and prioritize potential strategies; and design, implement, and evaluate a viable solution; Problem Solving and critical thinking (*Problem Solver*).**

14. Identify key elements of problems and choose appropriate methods for their resolution in a systematic manner.
15. 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)*.**

16. Seek actively new knowledge related to pharmaceutical powders and tablets, 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)*.**

17. Communicate effectively and respectfully with professors and classmates
18. Show responsibility, accountability and commitment by complying with tutor's instructions and relevant university regulations
19. 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)*.**

20. Communicate effectively and respectfully with professors and classmates
21. Show responsibility, accountability and commitment by complying with tutor's instructions and relevant university regulations
22. Demonstrate integrity by not cheating and not committing plagiarism.

22. Topic Outline and Schedule:

Week	Lecture	Topic	Teaching Method (platform)	Evaluation Methods	References
1	1.1	Topic 1 Introduction: Extemporaneous dispensing vs. Mass Production, Elements of the manufacturing process, Challenges of mass production.	Synchronous (MS Teams)	Exam	Textbook, handouts
	1.2	Product development, Departments of a pharmaceutical firm.	Synchronous (MS Teams)	Exam	Textbook, handouts
2	2.1	Topic 2 Preformulation: Definition, Scope: Organoleptic properties, Solubility.	Synchronous (MS Teams)	Exam	Textbook, handouts
	2.2	Dissolution, Partitioning, Bulk properties (density, flow, particle size, hygroscopicity, compactability).	Synchronous (MS Teams)	Exam	Textbook, handouts
3	3.1	Solid state properties, Stability & compatibility studies.	Synchronous (MS Teams)	Exam	Textbook, handouts
	3.2	Topic 3 Particle size analysis: Significance of particles sizing, Diameter and equivalent diameter, Methods of Particle Size Measurement (Sieve analysis, microscopy).	Synchronous (MS Teams)	Exam/ assignment	Textbook, handouts
4	4.1	Methods of Particle Size Measurement (sedimentation methods), Statistical analysis and graphical presentation: Particle Size and Size Distribution, Evaluation of particle sizing data: Normal Distribution.	Synchronous (MS Teams)	Exam/ assignment	Textbook, handouts
	4.2	Statistical analysis and graphical presentation: Evaluation of particle sizing data: Skewed Distribution.	Synchronous (MS Teams)	Exam/ assignment	Textbook, handouts
5	5.1	Topic 4 Particle Size Reduction: Objectives and applications, Disadvantages, Material properties affecting size reduction, Mechanisms of size reduction.	Synchronous (MS Teams)	Exam	Textbook, handouts
	5.2	Size reduction equipment: cutter mill, hammer mill, ball mill	Synchronous (MS Teams)	Exam	Textbook, handouts
6	6.1	Size reduction equipment: Fluid energy mill, Oscillating granulator.	Synchronous (MS Teams)	Exam	Textbook, handouts
	6.2	Topic 5 Mixing: Definition, Ideal mix vs Random mix, Factors affect mixing process (unit dose size, particle size and distribution, particle shape, mixing time).	Synchronous (MS Teams)	Exam/Quiz	Textbook, handouts
7	7.1	Mechanism of mixing (Diffusion, convection, shear), Segregation (types), Types of mixers	Synchronous (MS Teams)	Exam/Quiz	Textbook, handouts
	7.2	Types of mixers, Testing for blend homogeneity.	Synchronous (MS Teams)	Exam/Quiz	Textbook, handouts
8	8.1	Topic 6 Granulation: Definitions, Reasons for Granulation, Methods of Granulation (Wet and Dry).	Synchronous (MS Teams)	Exam/Quiz	Textbook, handouts
	8.2	Particle Bonding Mechanisms (Adhesion and cohesion forces in immobile liquid films, Interfacial forces in mobile liquid films, Solid bridges).	Synchronous (MS Teams)	Exam/Quiz	Textbook, handouts
9	9.1	Mechanism of granule growth, Pharmaceutical Granulation Equipment (Shear granulators, High speed mixer granulators).	Synchronous (MS Teams)	Exam/Quiz	Textbook, handouts
	9.2	Pharmaceutical Granulation Equipment (Spheronizers / pellitizers). Dry Granulation: sluggers, roller compacters.	Synchronous (MS Teams)	Exam/Quiz	Textbook, handouts
10	10.1	Topic 7 Drying: Definition, Relative humidity (RH) of air, Equilibrium moisture content, Static Bed Dryers, Intergranular migration of solutes during drying.	Synchronous (MS Teams)	Exam	Textbook, handouts
	10.2	Fluidized bed dryers, Intragranular migration of solutes during drying, Spray drying and freeze drying.	Synchronous (MS Teams)	Exam	Textbook, handouts
11	11.1	Topic 8 Tableting: Definition, Advantages of tablets, Qualities of a well prepared tablet, Methods of tablet preparation.	Synchronous (MS Teams)	Exam	Textbook, handouts
	11.2	Comparison between granulation and direct compression: cost (equipment and excipient), dose of the API.	Synchronous (MS Teams)	Exam	Textbook, handouts
12	12.1	Comparison between granulation and direct compression: risk of segregation, moisture sensitive API, incompatibility, colorant addition.	Synchronous (MS Teams)	Exam	Textbook, handouts
	12.2	Tableting machines (single punch, rotary).	Synchronous (MS Teams)	Exam	Textbook, handouts
13	13.1	Mechanism of powder compaction.	Synchronous (MS Teams)	Exam	Textbook, handouts
	13.2	Tablet components and excipients.	Synchronous (MS Teams)	Exam	Textbook, handouts
14	14.1	Tablet components and excipients./ Tableting problems and their remedies, Quality of tablets	Synchronous (MS Teams)	Exam	Textbook, handouts
	14.2	Tableting problems and their remedies, Quality of tablets.	Synchronous (MS Teams)	Exam	Textbook, handouts

23. Course Requirements:

Students should have:
- Computer
- Internet connection
- Webcam
- Active university account on Moodle (e-learning) website
- Active university account on Microsoft Teams

24. Evaluation Methods and Course Requirements:

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

Evaluation Activity	Mark	Topic(s)	Period (Week)	Platform
Assignment	5	• Particle size analysis	4th week	Moodle (e-learning)
Midterm Exam	30	• Introduction, • Preformulation • Particle size analysis • and Particle size reduction	To be determined (≈7th week)	On campus
Quiz	15	• Mixing • Granulation	10th week	Moodle (e-learning)
Final Exam	50	All Topics	To be determined (≈15th week)	On campus

25. 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:
- **Midterm exam (30%)**
- **Course work (20%)**
- **Final exam (50%)**

F- Available university services that support achievement in the course:
- Moodle (e-learning) website
- Microsoft Teams institutional subscription

26. 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.

27. Additional information:

Name of Course Coordinator: **Lorina Bisharat** Signature: ---------- Date: 8/10/2020

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

Head of Department: ---------- Signature: ----------

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

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

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