

Spring 2024

PHEN 605-852: Pharmaceutical Packaging Technology

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Orosz, Stephen, "PHEN 605-852: Pharmaceutical Packaging Technology" (2024). *Chemical and Materials Engineering Syllabi*. 268.

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PhEn605:852

Pharmaceutical Packaging Technology

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COURSE OVERVIEW

This is a core course within the Pharmaceutical Engineering M.S. Degree Program. The main objectives of this course are for students to develop a working knowledge of:

- 1) The various components and associated materials of construction utilized in the packaging of pharmaceuticals;
- 2) The individual unit operations and integrated equipment trains required to assemble pharmaceutical packages; and
- 3) The Regulatory, quality, and testing aspects associated with pharmaceutical packaging.

Prerequisites

- PhEn601: Principles of Pharmaceutical Engineering
- PhEn603: Pharmaceutical Unit Operations
- Completion of the Bridge Program (for those students required to take it)

For additional information on the Masters of Science Degree Program in Pharmaceutical Engineering, please refer to the program website at:

<http://chemicaleng.njit.edu/academics/graduate/masters/pharm.php>

Course Dates

The Spring 2024 semester runs from January 16th through May 9th, 2024. Please refer to the Spring 2024 Academic Calendar for all official dates at the Registrar's website:

<https://www.njit.edu/registrar/calendars>

This course is being administered in the “online” delivery mode. Please review the important information about the university's modes of instructional delivery at:

<https://www5.njit.edu/registrar/instructionaldelivery/>

COURSE ADMINISTRATION (Canvas: PHEN 605582)

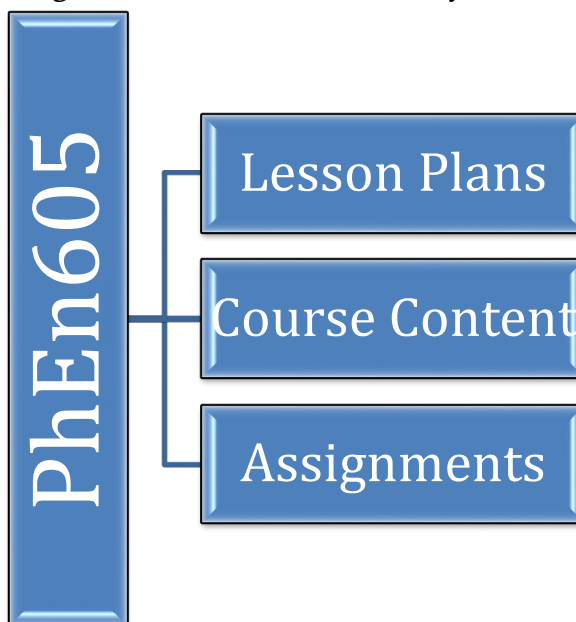
This course is being administered through Canvas, a learning content management system (LCMS), which you should become comfortable utilizing. A number of training videos and PDF handouts have been created to assist you with using Canvas. Please access Canvas and the tutorials here:

<https://canvas.njit.edu>
<https://canvas.njit.edu/getting-started-canvas-students>

Structure within Canvas

This course is broken into meaningful lessons or learning **modules**, each represented as a “Week.” Weeks start on a Monday (except for Week 1) and end on a Sunday. For example, Week #2 is from January 22nd (Monday) to January 28th (Sunday). Within Canvas you should become familiar with Resources (delivery of course content) and Assignments. Each Module (week), the following will be made available to you (it is highly recommended that you follow this order of content):

- 1) **Lesson Plan:** Instructions on how to successfully complete the learning module.
 - a. A brief orienting statement relating the topic(s) of the week to the course objectives
 - b. Observable learning objectives (3-5)
 - c. Suggested readings, links, and other supportive class materials
 - d. Overview of weekly assignments
- 2) **Course Content:** Lectures, slides, text, videos and other media will be posted.
 - a. Lectures will be made available each week from Monday through the following Sunday, containing the lecture content. Please note that lectures with instructor audio may only be available for the current week.
 - b. All content other than audio lectures will be provided in PDF format and remain available throughout the semester. This includes lecture slides.
- 3) **Assignments:** Graded work (homework, quizzes, etc.) is assigned almost weekly.
 - a. Assessments are closely aligned with the learning objectives
 - b. Due dates and student deliverables/expectations are clearly defined
 - c. Instructor feedback and grades are returned in a timely manner (within 1 week)



REFERENCE MATERIALS AND RELATED-INFORMATION

Lesson Plans, Lecture Materials and Required Activities

Each week, no later than Monday, course content will be posted to Canvas under PHEN 605852—PHARMACEUTIAL PACKAGING TECH. Although audio lectures may only be available for the current week, all other materials (including lecture slides) will remain posted throughout the semester.

Textbook and Other Reference Books

The following textbook is suggested, but not required:

- Lockhart, H. and Paine, F.A., *Packaging of Pharmaceuticals and Healthcare Products*, Springer, US, 2012.

Additional reference books, also not required:

- Dean, D.A., Evans, E.R., and Hall, I.H. (Eds), *Pharmaceutical Packaging Technology*, Taylor and Francis, London, 2000.
- Brody, A.L. and Marsh, K.S. (Eds), *The Wiley Encyclopedia of Packaging Technology*, 3rd Edition, Wiley-Interscience, New York, 2009.
- Soroka, W., *Fundamentals of Packaging Technology*, 4th Edition, Institute of Packaging Professionals (IoPP), Virginia, 2009.

Additional Reference Materials

Other materials may be provided throughout the semester and will always be referenced in Lesson Plans as associated with specific topics. Students are expected to take lecture notes and review any referenced or linked content, as these materials are considered part of the course and may appear on examinations or other assessments (homework assignments, quizzes, discussion forums, etc.).

Instructor's Office Hours

As an adjunct faculty member, Dr. Orosz does not maintain an office on campus. Students may contact him, preferably through e-mail, to schedule a meeting. Meetings may occur off-campus at a location convenient to both the student and the instructor. Specific questions and/or clarifications related to the course should be handled through the News Forum within Canvas. In this way all students can benefit from the information exchanged. General news and class announcements will also be communicated through this channel. Any issue of a personal nature or that a student is not comfortable discussing on the Forum should be addressed through e-mail. Please reserve the use of phone contact for emergency situations.

Guest Speakers

Guest speakers/lecturers may be utilized for certain topics throughout the course. Guest speakers will be announced in advance. Students are expected to take notes during these lectures, as the information presented will be included on exams. The availability of handouts is questionable, as certain information may be considered proprietary. However, the information presented will be reviewed prior to the exams.

BASIS FOR STUDENT GRADING

Grading Policy

A *tentative* guideline for the assignment of final grades is as follows:

CUMULATIVE POINTS	OVERALL GRADE
90 – 100	A
80 – 89	B
70 – 79	C
60 – 69	D
< 59	F

Cumulative points required for plus grades (i.e., B+) will be determined based on the overall performance of the class.

The grade of “D” is not assigned to students taking graduate courses. Students averaging a cumulative point total corresponding to a “D” in the above table could either receive a C or an F, depending on their overall individual performance.

Grade Composition

The following represents the course requirements and respective weighting:

COURSE REQUIREMENT	WEIGHT
Weekly Assessments	25%
Midterm Exam	25%
Project	25%
Final Exam	25%
Total =	100%

Course Requirements

Weekly Assessments will take the form of homework, quizzes, short answers/essays or other small assignments. All assessments will be closely aligned to the learning objectives and responses to open-ended activities will be defined each week in the Lesson Plan. Due dates for these activities will be clearly defined on the assignments, but will be no sooner than the end of the current week (Sunday). All graded work will be returned to the student in a timely manner with instructor feedback, as necessary. All assignments, student work product, instructor feedback and grades will be communicated through Canvas. Grades for each weekly assessment will be points earned out of a possible ten (10) points (i.e., 8/10). The cumulative points earned divided by the total possible points will be used to calculate 25% of the overall course score. Late assignments are not accepted and will receive 0 points, unless prior arrangements have been made with the instructor.

Examinations—There are two (2) formal examinations during this course, a midterm during Week #7 and a final during Week #16. Exams are closed-book and closed-note. The final exam will be cumulative, in that you are expected to understand the course content covered prior to the midterm, although the main emphasis will be on material covered after the midterm exam. Each exam will be worth 100 total points, comprised of twenty-five (25) multiple choice questions (2 points each) and 5-10 short answer/essay/diagram/matching-type questions (5 or 10 points each). Each exam will account for 25% of the overall course score. Make-up exams will only be given to students who cannot complete the exam during the regularly scheduled time, and only under *documented and extraordinary circumstances*. In any case, no student will be allowed to take a make-up exam unless he/she has the prior consent of the instructor. The following are examples of typical exam questions:

Multiple Choice (2 points)

In the manufacture of pharmaceutical quality glass containers, which of the following statements are TRUE?

- I. The primary raw materials are silicon oxide (silica sand), sodium carbonate (soda ash) and calcium carbonate (limestone).
 - II. An annealing lehr is utilized to gradually cool recently formed glass containers, thereby reducing internal stresses.
 - III. A batch manufacturing process is commonly utilized (rather than a continuous manufacturing process).
- A. I Only
 - B. I & II
 - C. II & III
 - D. I & III
 - E. I, II & III

Short Answer/Essay (10 points)

Your company currently markets Product X (150 mg, oval tablets) only in HUD (Hospital Unit Dose) blisters. Marketing has convinced senior management that a plastic bottle presentation containing thirty (30) tablets would increase sales tremendously. As the Package Development Manager, you must design a packaging line to support this initiative. Upon reviewing the development report, you determine that Product X is sensitive to moisture (chemical degradation) and that the tablets exhibit high friability (dusts, chips and breaks).

Diagram your proposed packaging line, indicating the sequence of unit operations, packaging components utilized at each station, and any in-process testing requirements.

1. **Project**—Each student will be responsible for completing one (1) individual project related to pharmaceutical packaging technology. Students will have a choice regarding the format of the project deliverable. Suggested topics include advances in packaging materials or modes of testing (high barrier films, packaging integrity testing through trace gas detection), packaging equipment/technology innovations (advances in form/fill/seal technology, bar-code systems), Regulatory changes (child-resistant/senior friendly testing protocols) or other specialized packaging applications (needle-free injection devices). All project topics must be pre-approved by the end of the third week of class (**04 February 2024**).

Term Paper Option

Students will prepare and submit a typewritten term paper. Term papers should be limited to 10-15 pages in length. Students may use any format, font and style they wish, providing that the requirements of acceptable English grammar and technical writing are satisfied (this includes the proper use of references and/or footnotes). Grades are based on the following criteria: Content; Development; Organization; Style and Format; and Grammar, Punctuation and Spelling. Term papers must be submitted no later than the end of the last week of class, prior to the final exam **(28 April 2024)**.

Short-Presentation Option

Students will present their project to the class and provide a summary handout. Presentations should be limited to approximately 15-20 minutes. Presenters should be prepared to answer any follow-up questions or clarifications that fellow students or I may have posted on the Forum within Canvas. Grades are based on the following criteria: Identification of Key Points; Discussion of Key Issues; Presentation Effectiveness; Communication Effectiveness; and Use of Presentation Aids. Those choosing this option will be required to utilize CaptureSpace (formerly Camtasia Relay, formerly TechSmith Relay) to capture screen movement and audio for their PowerPoint presentation. This software is user-friendly and available from NJIT for free below:

<https://mediaspace.njit.edu>

Presentations will be due to the instructor by **21 April 2024** and posted to Canvas for Week 15 viewing by the fellow students.

Previous Student's Project Topics

- *Rapid Prototyping for Injection Molding*
- *Reducing Medication Errors through Advances in Barcoding*
- *RFID Technology and Applications*
- *INTERPHEX / Seminar Option*
- *Advances in Package Integrity Testing*
- *Outsourcing Packaging Operations*
- *Smart Labeling in Pharmaceutical Packaging*
- *In-Line Inspection of Sterile Vials*

ACADEMIC INTEGRITY

Academic Integrity is the cornerstone of higher education and is central to the ideals of this course and the university. Cheating is strictly prohibited and devalues the degree that you are working on. As a member of the NJIT community, it is your responsibility to protect your educational investment by knowing and following the academic code of integrity policy that is found at:

<http://www5.njit.edu/policies/sites/policies/files/academic-integrity-code.pdf>

Please note that it is my professional obligation and responsibility to report any academic misconduct to the Dean of Students Office. Any student found in violation of the code by cheating, plagiarizing or using any online software inappropriately will result in disciplinary action. This may include a failing grade of F, and/or suspension or dismissal from the university. If you have any questions about the code of Academic Integrity, please contact the Dean of Students Office at dos@njit.edu

IMPORTANT DATES

Week 1	16 January 2024	Spring semester begins
Week 3	04 February 2024	Project format and topic are due
Week 7	26 February – 03 March 2024	MIDTERM EXAM
Week 9	11 – 17 March 2024	Spring Recess
Week 14	21 April 2024	Project deliverable (Presentation option) due
Week 15	28 April 2024	Project deliverable (Term paper option) due
Week 16	03 – 09 May 2024	FINAL EXAM

PhEn605:852—Tentative Course Schedule

WEEK	DATES	TOPIC(S)
1	16 January – 21 January	Course Introduction
2	22 January – 28 January	Perspectives on Packaging Functions of a Package
3	29 January – 04 February	Function of the Packaging Department Regulatory CMC Documentation
4	05 February – 11 February	Specifications & Quality Introduction to Attribute Sampling and AQLs
5	12 February – 18 February	Polymer Chemistry—An Introduction Extractables and Leachables (E&L)
6	19 February – 25 February	Shaping Plastics Plastic Applications
7	26 February – 03 March	<i>MIDTERM EXAM</i>
8	04 March – 10 March	Flexible Packaging Laminates Adhesives
9	11 March – 17 March	<i>SPRING RECESS – No Classes Scheduled</i>
10	18 March – March 24	Glass Containers Glass Bottle Manufacturing
11	25 March – 31 March	Metal: Cans, Containers and Tubes
12	01 April – 07 April	Closures and Closures Systems The Poison Prevention Act
13	08 April – 14 April	The Packaging Line Miscellaneous Components
14	15 April – 21 April	Graphic Design Package Printing and Decorating
15	22 April – 28 April	Student Presentations & Course Review
16	03 May – 09 May	<i>FINAL EXAM</i>