

Fall 2019

PHEN 603-101: Pharmaceutical Unit Operations - Processing of Liquid and Dispersed-Phase Systems

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Dr. P. M. Armenante
New Jersey Institute of Technology
September 2, 2019

Pharmaceutical Unit Operations: Processing of Liquid and Dispersed-Phase Systems – PhEn 603

Syllabus

Term: 2019 Fall Semester

NJIT Course Title: Pharmaceutical Unit Operations: Processing of Liquid and Dispersed-Phase Systems

NJIT Course Number: PhEn 603, Section 101

Course Day and Time: Monday, 6:00 – 8:50 p.m.

Classroom: Kupfrian Hall, Room 202

Course Instructor: Piero M. Armenante, Ph.D.
Distinguished Professor of Chemical Engineering
New Jersey Institute of Technology
Otto H. York Department of Chemical and Materials Engineering
Newark, NJ 07102

Office: YCEES Building - Room 120
Telephone: (973) 596-3548; **Mobile: (908) 347-8734 (preferred)**
Fax: (973) 596-8436
E-Mail Address: piero.armenante@njit.edu

Availability of Instructor and WebEx Sessions:

Students can contact the instructor for questions in different ways:

- In-person meetings: Typically, Thursday, 5:00-6:00 pm or by appointment (for students who can come to NJIT: meetings will likely take place in 150 Tiernan Hall – CBPE Departmental Office). Students are strongly encouraged to contact Prof. Armenante via e-mail to arrange for a meeting. *Please note that Prof. Armenante will **not** be available for consultation when he is on business travel.*
- Via telephone: students can contact the instructor at the mobile number above
- Through WebEx sessions: WebEx question/answer sessions will be also held as appropriate, as specified below. The exact time and day of these sessions will be decided after the last day to add a course, i.e., once the class roster is complete.

Computer Hardware and Software Requirements

In order to follow the course, students will require the following:

- Hardware
 - Computer with internet access (to retrieve course material, access WebEx, etc.)
 - Scanner or access to a scanner (to scan homework and then e-mail it as an attachment)
 - Speakers with a microphone (for WebEx access), typically built in already in most laptop computers, or headphones
 - Camera (optional; in case, only for WebEx use)

- Software and Access
 - NJIT e-mail account, including UCID and password, to access Moodle (<http://moodle.njit.edu/>)
 - Web browser (Firefox, Chrome, Safari, etc. - Internet Explorer is not recommended)
 - Adobe Acrobat and Adobe Flash installed and up-to-date (freeware)
 - Other software to complete assignments (e.g., Microsoft Word, Microsoft Excel, etc.)

Course Notes, Textbooks, and Other Reference Material:

- **Course Lectures:** Armenante, P. M., 2019, *PhEn 603-Pharmaceutical Unit Operations: Processing of Liquid and Dispersed-Phase Systems Course Lectures*. The *Lectures* are videos containing course lectures identical in content and length to the face-to-face PhEn 603 lectures routinely offered at NJIT. The *Lectures* are available through Moodle and can be accessed as described below
- **Course Notes:** Armenante, P. M., 2019, *PhEn 603-Pharmaceutical Unit Operations: Processing of Liquid and Dispersed-Phase Systems: Course Notes*. The *Notes* are exact duplicates of the overheads used in the lectures. The *Notes* are also available through Moodle and can be accessed as described below.
- **Textbooks:** The following books are suggested but **not** required as textbooks:
 - McCabe, W. L., Smith, J. C. and Harriott, P., 2005, *Unit Operations of Chemical Engineering*, 7th Edition, McGraw-Hill, New York.
 - am Ende, M. T. and am Ende, D. J. (Eds.), 2019, *Chemical Engineering in the Pharmaceutical Industry, Drug Product Design, Development, and Modeling*, 2nd Edition, Hoboken, NJ, Wiley.
 - am Ende, D. J. and am Ende, M. T. (Eds.), 2019, *Chemical Engineering in the Pharmaceutical Industry, Active Pharmaceutical Ingredients*, 2nd Edition, Hoboken, NJ, Wiley.
- A list of additional reference books (not required) is attached.

Availability of Course Notes, Homework Assignments, Textbook, and References:

- Links to the *Course Lectures* are available to the students through Moodle. Students can access Moodle directly by going to <http://moodle.njit.edu/> and following the instructions there. Once the appropriate course is selected, students will be able to watch streaming videos of the *Lectures* for that class period by clicking on the appropriate links
- The *Course Notes* can be downloaded from the NJIT website using Moodle, as described above. The *Course Notes* will be posted on the internet as PDF files
- The homework, homework solutions, and projects will be posted through Moodle as appropriate, depending on the material covered in that week (typically but not always on a weekly basis)
- Additional material (e.g., videos, reading material, etc.) will be posted through Moodle as appropriate
- If students experience problems and they are unable to log in or access the course material, they should contact the NJIT Helpdesk at 973-596-2900
- The textbook is available in the NJIT bookstore (973-596-3200; <http://www.bkstr.com/njitstore/home>) or from the publishers
- Most additional references (not required as textbooks) as well as the textbooks are available in most university libraries and have been being placed on reserve at the NJIT library.

WebEx Sessions:

- WebEx sessions are long distance conference calls, conducted via computer, that will enable students to meet (i.e., talk, show material, etc.) with the course instructor and the other students in the class
- WebEx sessions will be held periodically, typically once a week or as needed, as a forum to discuss topics covered in class, address questions, review selected homework, clarify examples, etc. In other words, WebEx sessions will replace office hours for long-distance students
- In order to use WebEx students should first visit <http://webex.njit.edu>, click on the "Participating in a WebEx Session" link, retrieve the PDF file with detailed instructions, and read it
- The date and time of a WebEx session will be announced via e-mail or through Moodle, and invitations to join a WebEx meeting will be sent to students, together with the appropriate web link, as needed

- At the time of the meeting, students should go to <http://njit.webex.com> (notice the similarity but also the difference between this link and the previous one)
- If a WebEx meeting number is needed, it will be made available by the instructor to the students prior to the meeting and will be specified in the e-mail invitation for that meeting
- Remark: students do not need to open a WebEx account to attend a WebEx session

Course Prerequisites:

- **PhEn and ChE Students:** Currently, students are admitted to the PhEn program if they have baccalaureate degree in chemical engineering or equivalent with a minimum GPA of 3.0. This is a satisfactory prerequisite for this course. Students with undergraduate degrees in biology, chemistry, physics, and equivalent who are admitted to the PhEn program on condition that they additionally take undergraduate courses, specified at the time of admission, must have taken and successfully completed those courses. Students enrolled in the old PhEn program should have completed the bridge program (PhEn 500, PhEn 501 and PhEn 502) if required in the student's admission conditions, as well as any other undergraduate-level courses, if any. *PhEn students who do not have these prerequisites will have to drop the course.* Additionally, PhEn 601 is recommended but not required as a prerequisite.
- **Non-PhEn and non-ChE Students:** Students with appropriate engineering backgrounds (e.g., BME, ME) can also take this course. Students with non-engineering background should have the **appropriate background** in math (up to differential equations), mass and energy balances, fluid flow, heat transfer, and mass transfer in order to be able to follow the course. Therefore, they should talk to Prof. Armenante to make sure that they are adequately prepared for this course before taking it. Additionally, PhEn 601 is recommended but not required as a prerequisite.

Course Objective: This course is one of the common core courses for the Pharmaceutical Engineering MS Degree Programs. The main objective of the course is to examine methodologies, both applied and fundamental, to analyze and scale up pharmaceutical manufacturing processes involving liquid and dispersed-phase systems, such as liquid and multiphase mixing, sterilization and sanitation, filtration, centrifugation and others. The emphasis is primarily on the engineering aspects of the pharmaceutical processes examined in the course.

Course Description: This course covers state-of-the-art pharmaceutical processing involving primarily liquid and dispersed-phase systems, identifying underlying chemical process engineering principles and providing quantitative approaches to drug product manufacturing process design and optimization.

Course Outline by Topic Areas: Chemical/pharmaceutical development activities; sterilization and sanitation processes, aseptic manufacturing; sedimentation; centrifugation; filtration; processing of liquid systems and dispersed-phase systems; liquid mixing and dispersion fundamentals; liquid mixing calculations; solid-liquid suspensions; equipment selection and scale-up for homogeneous and dispersed-phase systems.

Course Learning Outcomes: Upon successful completion of this course, students will be able to:

- Identify, categorize, and describe the most relevant industrial operations and equipment encountered in the pharmaceutical industry to process liquids and dispersed phase systems
- Construct and assemble mathematical models (typically based on mass, energy and momentum balances) best suited to analyze the performance of each process and equipment components
- Identify critical parameters for the operation of the process and its equipment, device experiments to extract them from lab/pilot scale equipment, and analyze the results to quantify them
- Select, preliminarily design, size, and scale-up equipment needed to achieve the desired process objectives
- Examine, assess, and compare different equipment and process alternatives to achieve optimal desired process objectives.

Course Requirements:

- Examinations: Two exams, i.e., a midterm exam and a final exam
- Homework: Assigned by the instructor at the end of each classes
- Quizzes: Possibly, several very short quizzes on homework just completed
- Projects: One, or possibly two, short projects will be assigned after the midterm exam (see below for details)

Grading Policy*:

- Midterm exam*38%
- Final exam*38%
- Homework.....12%
- Projects12%
- Total100%

(*) Students performing very poorly on the exams will **fail** the course irrespective of their performance in the homework and projects, as specified below.

Course Final Grade: a tentative guideline for the assignment of final grades is the following:

<u>Cumulative Points</u>	<u>Overall Grade</u>
85-90 to 100%	A
70-75 to 85-90%	B/B+
60 to 70-75%	C/C+
50 to 60%	"D"
0 to 50%	F

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

Please remember that this is only a guideline designed to help the students understand how they are performing in the course. Dr. Armenante will feel free to change the grading scale (both ways) when assigning the final grades.

Important Remark: Each exam (midterm and final) will be graded on a point scale from 0 to 100 (100 points in an exam=38% of the final grade; see above). However, **failing to achieve a combined average of at least 55/100 in the two exams** will imply **failing the course (F grade) irrespective of the points obtained through the homework and the projects.** In other words, students who perform extremely poorly in the exams will not be able to use the homework and the projects to pass the course. If this minimum requirement is satisfied, the final grade will be assigned based on the grading policy outlined above.

Exams:

- A calendar of exams is included in the Course Outline given below
- All exams are typically 3 hours long unless otherwise stated
- All exams are typically open-book and open-note. However, changes could be made and will be announced by the instructor prior to the exams
- No computers, telephones, i-Pads, etc. will be allowed during the exams
- Possible additional exam policy changes will be announced by the instructor prior to the exams
- The final exam will be on all material covered throughout the course (although the main emphasis of the exam will be on the material covered after the midterm exam);
- Make-up exams will only be given to students who cannot attend the regular exam 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. *If a student will simply not come to an exam, the exam grade will automatically be zero.*

- Because of confidentiality issues, the Office of the **Dean of Students** now handles all issues related to **medical conditions** (including justification for postponing exams)
- Exams will be administered either at NJIT or at testing centers, as described below:
 - According to NJIT policy, all students taking e-learning classes but **living within 50 miles of NJIT must** take the required exams at NJIT's main campus in Newark, NJ. The exact time and the room where the exam will take place will be specified by the instructor prior to the exam;
 - Students living outside this 50-mile zone can only take the exams at predefined testing locations. The National College Testing Association (NCTA) lists the participating institutions nationwide (<http://www.ncta-testing.org/cctc/find.php>) where students can take proctored tests according to the rules set up by the course instructor. Students should visit this website, identify the testing location where they plan to take the exams, and inform the course instructor within two weeks from the beginning of classes of which testing location they have selected. **Students should be aware that they will be required to pay a fee to the chosen testing center for each exam that they take there.** Such a fee is typically on the order of \$25-\$50 per exam, depending on the testing center. Prior to each exam, students should make arrangements with the selected testing center to ensure that they can take the exam at the predefined location at a given day and time.

Homework:

- The homework will be posted on Moodle
- It will be assigned as appropriate (typically on a weekly basis), depending on the material covered in that week
- Students should turn in the homework by scanning it and attach it as a PDF file to an e-mail message addressed to the TA for the course
- The homework will not be returned to the students unless practical to do so
- No late homework will be accepted unless a valid reason is provided in advance (e.g., an upcoming business trip)
- Homework solutions will be posted on Moodle after the homework has been collected.

Important Remark: *Previous experience has clearly shown that those students who do not work on the assigned problems (or at least seriously try to solve them) typically perform very poorly on the exams.*

Homework Grading: The homework will be graded by the TA on the basis of the effort that the student puts into using solving it using a simplified grading scale, i.e., 0 (no or minimal effort); 5 (intermediate effort); 10 (significant effort). Any questions regarding homework grades should be discussed with the instructor.

Projects: Every student will complete one, or possibly two, small projects, which will be assigned after the midterm exam and collected on the day of the final exam. The first project will consist of critically reviewing (critiquing) 2 papers published in scientific journals (as if the papers had been submitted for publication to the student). The papers will have to be related to each other and to be within the scope of the course. The students will be asked to write a short review of the papers. The student will have to justify whatever conclusions he/she may reach. The second project (if assigned) will consist of a small design problem for a case study assigned by the instructor. The problem will be open-ended to allow each student to come up with his/her own original design.

Class Attendance: As with all graduate courses at NJIT, attendance is not mandatory, but strongly recommended. Experience shows that students who do not regularly attend class typically perform poorly in the course. In addition, examples are worked out during the lectures. These examples are not in the *Course Notes*. Students are responsible for all material covered in class.

Time Commitment: Students are expected to allocate some three to six hours per week to study and work on the assignments for this course.

Code of Conduct and Academic Integrity: The NJIT University Code on Academic Integrity, found at <http://www.njit.edu/doss/code-student-conduct-article-11-university-policy-academic-integrity/>, will be followed. The Code is being upheld on all issues related to the course. Students are expected to be familiar with the code and conduct themselves accordingly. Academic integrity is fundamental to the activities and principles of a university. All members of the academic community must be confident that each person's work has been responsibly and honorably acquired, developed, and presented. Any effort to gain an advantage not given to all students is dishonest whether or not the effort is successful. The academic community regards breaches of the academic integrity rules as extremely serious matters. Sanctions for such a violation may include academic sanctions from the instructor, including failing the course for any violation, to disciplinary sanctions ranging from probation to expulsion. When in doubt about plagiarism, paraphrasing, quoting, collaboration, or any other form of cheating, consult the course instructor.

Plagiarism and Academic Integrity: The approved "University Code of Academic Integrity" is currently in effect for all courses. Should a student fail a course due to a violation of academic integrity, they will be assigned the grade of "XF" rather than the "F," and this designation will remain permanently on their transcript. All students are encouraged to look at the University Code of Academic Integrity and understand this document. Students are expected to uphold the integrity of this institution by reporting any violation of academic integrity to the Office of the Dean of Students. The identity of the student filing the report will be kept anonymous. NJIT will continue to educate top tier students that are academically sound and are self-disciplined to uphold expected standards of professional integrity. ***Academic dishonesty will not be tolerated.***

Students with Disabilities: NJIT adheres to Section 504 of the Rehabilitation Act (ADA) of 1990. Appropriate accommodations are provided at no cost to the student. Additional questions should be directed to the NJIT Office of Accessibility Resources and Services. For further information, students should visit <https://www.njit.edu/studentssuccess/accessibility/>.

Important Dates According to NJIT Calendar (Fall 2019):

September	2	Monday	Labor Day
September	3	Tuesday	First Day of Classes
September	7	Saturday	Saturday Classes Begin
September	9	Monday	Monday Classes Meet
September	13	Friday	Last Day to Add/Drop a Class
September	13	Friday	Last Day for 100% Refund, Full or Partial Withdrawal
September	14	Saturday	W Grades Posted for Course Withdrawals
September	16	Monday	Last Day for 90% Refund, Full or Partial Withdrawal - No Refund for Partial Withdrawal after this date
September	30	Monday	Last Day for 50% Refund, Full Withdrawal
October	21	Monday	Last Day for 25% Refund, Full Withdrawal
November	11	Monday	Last Day to Withdraw
November	26	Tuesday	Thursday Classes Meet
November	27	Wednesday	Friday Classes Meet
November	28	Thursday	Thanksgiving Recess Begins
December	1	Sunday	Thanksgiving Recess Ends
December	12	Thursday	Last Day of Classes. Saturday Classes Meet
December	13	Friday	Reading Day
December	14	Saturday	Final Exams Begin
December	20	Friday	Final Exams End
December	22	Sunday	Final Grades Due

Additional important dates are available at: <http://www.njit.edu/registrar/calendars/>.

Course Outline (Fall 2019)

<u>Week</u>	<u>Date</u>	<u>Topic</u>
1	September 9	Introduction Chemical/Pharmaceutical Development Activities Sterilization and sanitation processes
2	September 16	Sterilization and sanitation processes
3	September 23	Mathematical modeling of sterilization processes
4	September 30	Mathematical modeling of sterilization processes
5	October 7	Review of flow in confined systems
6	October 14	Filtration
7	October 21	Mathematical modeling of filtration processes
8	October 28	<u>Midterm Exam</u>
9	November 4	Mathematical modeling of filtration processes
10	November 11	Sedimentation
11	November 18	Sedimentation Centrifugation
12	November 25	Processing of liquid systems and dispersed-phase systems
13	December 2	Liquid mixing and dispersion fundamentals Liquid mixing calculations
14	December 9	Equipment selection and scale-up of equipment for dispersed-phase systems
15	December 16	<u>Final Exam</u>

Important: It is conceivable that some changes in the above outline will take place, depending on the overall performance of the class and the time actually required to cover the most important subjects of the course.

Additional References

- *The United States Pharmacopoeia & The National Formulary. The Official Compendia of Standards, USP 42–NF 37*, Pharmacopeial Convention Inc., 2019.
- *ISPE Baseline Pharmaceutical Engineering Guides* (the following volumes are available from ISPE; www.ispe.org):
 - Water and Steam Systems
 - Commissioning and Qualification
 - Packaging and Warehousing
 - Bulk Pharmaceutical Chemicals
 - Oral Solid Dosage Forms
 - Sterile Manufacturing Facilities
 - Biotechnology
 - R&D Facilities
 - Oral Liquids and Aerosols
- am Ende, M. T. and am Ende, D. J. (Eds.), 2019, *Chemical Engineering in the Pharmaceutical Industry, Drug Product Design, Development, and Modeling*, 2nd Edition, Hoboken, NJ, Wiley.
- am Ende, D. J. and am Ende, M. T. (Eds.), 2019, *Chemical Engineering in the Pharmaceutical Industry, Active Pharmaceutical Ingredients*, 2nd Edition, Hoboken, NJ, Wiley.
- Michael Levin (ed.), *Pharmaceutical Process Scale-Up*, 3rd Ed., Informa Health Care, New York, 2011.
- Allen, L. V., Popovich, N. G., and Ansel, H. C., *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*, 9th Edition, Lippincott Williams & Wilkins Publishers, 2010. [Remark: this is the textbook used in PhEn 601].
- Hickey, A. J. and Ganderton, D., *Pharmaceutical Process Engineering*, Marcel Dekker, New York, 2001.
- Banker, G. S. and Rhodes, C. T., *Modern Pharmaceutics*, 3rd Edition, Marcel Dekker, New York, 1995.
- Lieberman, H. A., Rieger, M. M., and Banker, G. S. (eds.), *Pharmaceutical Dosage Forms: Dispersed Systems*, Vol. 1 (1996); Vol. 2 (1996), Vol. 3, (1998), Marcel Dekker, New York.
- Lieberman, H. A., Lachman, L. and Schwartz, J. B. (eds.), *Pharmaceutical Dosage Forms: Tablets*, Vol. 1 (1989); Vol. 2 (1990), Vol. 3 (1990), Marcel Dekker, New York.
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- Gennaro, A. R. (editor), *Remington: The Science and Practice of Pharmacy*, 20th Edition, Philadelphia College of Pharmacy and Science, 2000.
- Geankoplis, C. J., *Transport Processes and Unit Operations*, 4th Edition, 2003, Prentice Hall.
- McCabe, W. L., Smith, J. C. and Harriott, P., *Unit Operations of Chemical Engineering*, 7th Edition, 2005, McGraw-Hill.