

Dr. P. M. Armenante  
New Jersey Institute of Technology  
September 2, 2009

## **Pharmaceutical Unit Operations: Processing of Liquid and Dispersed-Phase Systems**

### **PhEn 603**

### **Syllabus**

**Term:** 2009 Fall Semester

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

**NJIT Course Number:** PhEn 603, Section 101

**Course Instructor:** Piero M. Armenante, Ph.D.  
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**Instructor's Office Hours:**

- Tuesday, 5:00-6:00 pm
- Wednesday, 5:00-6:00 pm

However, 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.*

**Grader:** Kwang Seok Kim, Chemical Engineering Ph.D. Candidate

**Course Day and Time:** Wednesday, 6:00 - 9:05 p.m.

**Classroom:** NJIT, Cullimore Hall, Room 110

### Course Notes, Textbooks, and Other Reference Material:

- **Notes:** Armenante, P. M., 2009, *Pharmaceutical Unit Operations: Processing of Liquid and Dispersed-Phase Systems: Course Notes*. The Notes are duplications of the overheads used in class. The Notes are available on the internet and can be accessed using the procedure described below.
- **Textbook:** The following textbook is suggested but **not** required:
  - Lieberman, H. A., Rieger, M. M., and Banker, G. S. (eds.), *Pharmaceutical Dosage Forms: Dispersed Systems*, Vol. 3, Marcel Dekker, New York, 1998.Additional reference books (also not required) are:
  - Allen, L. V., Popovich, N. G., and Ansel, H. C., *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*, 8<sup>th</sup> Edition, Lippincott Williams & Wilkins Publishers, 2005. [Remark: this is the textbook used in PhEn601].
  - Michel Levin (ed.), *Pharmaceutical Process Scale-Up*, Marcel Dekker, New York, 2001.
- A list of additional reference books is attached.

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

- “*Pharmaceutical Unit Operations: Processing of Liquid and Dispersed-Phase Systems: Course Notes*” will be posted on the internet as PDF files (i.e., you will need Adobe Acrobat to read and print them). The *Course Notes* can be downloaded from the NJIT website using Moodle. Students can **either** access Moodle directly (<http://moodle.njit.edu/>) and follow the instructions there, **or** go through Highlander Pipeline as follows:
  1. Go to <http://my.njit.edu> and login using your UCID
  2. Click on the “My Courses” tab
  3. Click on the link towards the bottom of the screen for “NJIT Moodle Rooms: Click here to access your course in Moodle”
  4. You will automatically be logged into NJIT's new Moodle server
  5. Locate your course and click on the link with the course title
  6. If at any time you are experiencing problems and are unable to log in please let the helpdesk know at 973-596-2900.
- The homework is also posted weekly through Moodle
- The Lieberman et al. book and Ansel et al. book are available from the NJIT bookstore (973/596-3200; [njit@bkstr.com](mailto:njit@bkstr.com)) or from the publishers
- Additional material (reading material, etc.) will be distributed in class. For additional information, please contact Prof. Armenante
- Most additional references (not required as textbooks) as well as the textbooks are available in most university libraries, including the NJIT library.

**Course Prerequisites:** PhEn 601 (this requirement can be waived – please discuss this with Prof. Armenante); **and** successful completion of the bridge program (PhEn 500, PhEn 501 and PhEn 502), **as well as** any other undergraduate-level courses specified in the student's admission conditions, if any. PhEn students who do not have these prerequisites will have to **drop** the course. Students enrolled in other degree programs should talk to the instructor to make sure that they have the appropriate prerequisites.

**Course Objective:** The course is one of the common core courses for the Pharmaceutical Engineering M.S. Degree Program. 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, lyophilization, 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; lyophilization; processing of liquid and dispersed-phase systems; liquid mixing and dispersion fundamentals; liquid mixing dispersion calculations; solid-liquid suspensions; liquid-liquid dispersions; equipment selection and scale-up for homogeneous and dispersed-phase systems.

**Course Requirements:**

- Examinations: Two exams, i.e., a midterm exam and a final exam
- Homework: Assigned by the instructor at the end of some classes
- 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 ..... 9%
- Projects ..... 15%
- Total ..... 100%

(\*) 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>
85-100%	A
70-85%	B/B+
60-70%	C/C+
50-60%	“D”
0-50%	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;
- 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.*

**Homework:** it will be assigned at the end of selected class periods, collected the following week at the beginning of the class period, and returned the week after that. No late homework will be accepted. The homework problems will be posted on the internet and can be retrieved by the students as described previously for the *Class Notes*. If appropriate (typically for quantitative problems) homework solutions will be posted on the internet (as described for the *Class Notes*) after the homework has been collected.

**Important:** 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 using a simplified grading scale, i.e., 0 (no or minimal effort); 5 (intermediate effort); 10 (significant effort). Any questions regarding the homework grade 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 for 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 *Class Notes*. Students are responsible for all material covered in class.

**NJIT Honor Code:** The NJIT honor code is being upheld on all issues related to the course. Students are expected to be familiar with the code and conduct themselves accordingly.

**Important Dates According to NJIT Calendar (Fall 2009):**

August 31	Semester begins
September 8	Last day to add a course
September 14	Last day for a refund based on a partial withdrawal
<b>October 15</b>	Deadline to apply for <b>January graduation</b>
October 19	Last day for a refund based on a complete withdrawal
<b>November 2</b>	<b><i>Last day to withdraw from course(s)</i></b>
November 10	Spring registration begins
<b>November 15</b>	Deadline for applying for <b>May graduation and commencement</b>
November 25 (Wednesday)	Classes follow a Friday schedule – <b>No Wednesday classes</b>
November 26-29	Thanksgiving recess — No classes
December 10	Reading day
December 11-17	Final exam period

Additional important dates are available on the web (<http://www.njit.edu/registrar/calendars/index.php>)

## Course Outline

<u>Week</u>	<u>Date</u>	<u>Topic</u>
1	September 2	Introduction Chemical/Pharmaceutical Development Activities Sterilization and sanitation processes
2	September 9	Sterilization and sanitation processes
3	September 16	Mathematical modeling of sterilization processes
4	September 23	Principles of aseptic manufacturing
5	September 30	Filtration
6	October 7	Math of Filtration
7	October 14	Sedimentation and centrifugation
8	October 21	Sedimentation and centrifugation Lyophilization
<b>9</b>	<b>October 28</b>	<b>Midterm exam</b>
10	November 4	Exam review Processing of liquid systems
11	November 11	Liquid mixing and dispersion
12	November 18	Liquid mixing and dispersion
13	December 2	Solid-liquid suspensions
14	December 9	Scale-up of equipment for dispersed-phase systems
15	December 16	<b>Final exam</b>

**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 30–NF 25*, Pharmacopeial Convention Inc. November 2008 (official as of January 1, 2009 until December 31, 2009).
- *ISPE Baseline Pharmaceutical Engineering Guides* (the following volumes are available from ISPE; [www.ispe.org](http://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
- Michel Levin (ed.), *Pharmaceutical Process Scale-Up*, Marcel Dekker, New York, 2001.
- Allen, L. V., Popovich, N. G., and Ansel, H. C., *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*, 8<sup>th</sup> Edition, Lippincott Williams & Wilkins Publishers, 2005. [Remark: this is the textbook used in PhEn601].
- Hickey, A. J. and Ganderton, D., *Pharmaceutical Process Engineering*, Marcel Dekker, New York, 2001.
- Banker, G. S. and Rhodes, C. T., *Modern Pharmaceutics*, 3<sup>rd</sup> 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.
- Avis, K. E. Lieberman, Lieberman, H. A., and Lachman, L. (eds.), *Pharmaceutical Dosage Forms: Parenteral Medications*, Vol. 1 (1991); Vol. 2 (1992), Vol. 3 (1993), Marcel Dekker, New York.
- Cole, G., *Pharmaceutical Production Facilities: Design and Applications*, 2<sup>nd</sup> Edition, Taylor & Francis, 1998.
- Avis, K. E. and Wu, V. L. (eds.), *Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation* (Vol. 2), Interpharm Press, 1996.
- Armenante, P. M. and A. Kirpekar, "Chapter 11: Sterilization in the Pharmaceutical and Biotechnology Industry," in *Handbook of Downstream Processing*, by E. Goldberg (editor), pp. 261-308, Chapman & Hall, New York, NY, 1997.
- Gennaro, A. R. (editor), *Remington: The Science and Practice of Pharmacy*, 20<sup>th</sup> Edition, Philadelphia College of Pharmacy and Science, 2000.
- Geankoplis, C. J., *Transport Processes and Unit Operations*, 4<sup>th</sup> Edition, 2003, Prentice Hall.
- McCabe, W. L., Smith, J. C. and Harriott, P., *Unit Operations of Chemical Engineering*, 7<sup>th</sup> Edition, 2005, McGraw-Hill.