

PHRD 40089, 61105, Pharmaceutics I

I. Contact information

Course Coordinator/ Instructor:

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II. Course description

Pharmaceutics I. 3 Credit hours. Fundamentals of physical pharmacy; Introduction to Liquid and Oral Dosage Forms

III. Course prerequisites/co-requisites

First year pharmacy standing and registration; or credit in PHRD 4020

IV. Course Objectives/Curricular Outcomes

- Understand the various types of pharmaceutical dosage forms
- Gain basic understanding of the USP/NF and regulations and concepts that govern compounding and manufacturing
- Demonstrate knowledge of buffer systems and buffer capacity and their applications in biological and pharmaceutical systems
- Understand basic theories on drug solubility and intermolecular forces that govern solute-solvent interactions and solvent classifications
- Discuss factors (temperature, salt, pH, cosolvency) that affect drug solubility in pharmaceutical solutions and in biological fluids
- Calculate concentrations in milliequivalents
- Understand the relationship between drug solubility and diffusion
- Gain an understanding of chemical kinetics and stability
- Comprehend the significance of interfacial phenomena
- Gain knowledge of compounding, composition, and stability of oral dosage forms, e.g. solutions, suspensions, emulsions
- Demonstrate an understanding of colligative properties of solutions and their application in determination of drug molecular weight
- Calculate osmotic pressure

Educational (based on CAPE outcomes)

Domain 1 – Foundational Knowledge

1.1. Learner (Learner) - Develop, integrate, and apply knowledge from the foundational sciences (i.e., *pharmaceutical, social/behavioral/administrative, and clinical sciences*) to evaluate the scientific literature, explain drug action, solve therapeutic problems, and advance population health and *patient-centered care*.

Domain 3 - Approach to Practice and Care

3.1. Problem Solving (Problem Solver) – Identify problems; explore and prioritize potential strategies; and design, implement, and evaluate a viable solution.

ACPE Appendix 1 (required elements)

Pharmaceutics/Biopharmaceutics

Physicochemical properties of drugs, excipients, and dosage forms important to the rational design and manufacture of sterile and non-sterile products. Application of physical chemistry and dosage form science to drug stability, delivery, release, disposition, pharmacokinetics, therapeutic effectiveness, and the development of quality standards for drug products.

Pharmacokinetics

Mathematical determination of the rate of drug movement from one therapeutic or physiologic compartment to another. Application of physicochemical and kinetic principles and parameters to therapeutically important issues, such as drug delivery, disposition, therapeutic effectiveness, and beneficial or adverse interactions in general and specific populations.

V. Course Topics

- States of matter
- Acid-base chemistry
- Equilibrium phenomena
- Chemical kinetics and stability
- Solubility
- Diffusion and dissolution
- Rheology
- Oral drug delivery: solutions, emulsions, suspensions

VI. Instructional methods and activities

A traditional lecture format will be used, and supplemented with in-class discussion.

VII. Evaluation and grade assignment

To assess student performance, three tests (each of approximately 50 minutes in duration) and a final examination will be administered. Each exam is "closed-book". No informational resources or personal electronics of any kind will be used during an examination, unless authorized by the course coordinator. Exams may be multiple-choice, fill-in-the-blank, short answer, essay, or any other format deemed necessary.

Unless otherwise specified, exams will be administered in electronic format using Examsoft. Each student will be required to arrive at each scheduled exam with a working computer onto which the exam has been downloaded. Scratch paper will be provided and must be returned prior to exiting the classroom following the exam.

- The exam will be made available for students to download prior to the scheduled test time. Students will not be given extra time for downloading.
- Students must upload the exam in a timely fashion. Failure to do so will result in a zero on that exam. Students who experience an issue uploading the exam should immediately contact test proctors, who will address the issue.
- Students will not be allowed to take their computer out of the classroom prior to exam uploading.

While each test will focus primarily on new material, questions may by necessity require mastery of comprehensive information.

The final may include new as well as comprehensive material.

Students who wish to review their exams with the course instructors must do so within a two week period after test scores are posted. In the event that a question is eliminated from an exam, the exam may be re-scored to reflect earned points out of total cumulative points derived from remaining questions.

Students wishing to challenge a test question must provide the course coordinator with a written statement (email or hard copy) that identifies the question or questions being challenged, and outlines why the student feels his or her answer(s) is/are correct. Discussion of a dispute will occur only after a written query is submitted. Challenges of test questions will only be considered within 1 week after posting of test scores. If there is a conflict between lecture notes versus textbook or other reference material, precedence will be given to the lecture notes.

Available Points per Exam and Total Course Points:

	<u>Points</u>
Exam 1	100
Exam 2	100
Exam 3	100
Final Exam	100
Total Points	400

Point Total for Final Course Grade:

	<u>Total Points Earned</u>
A	360 to 400
B	320 to 359
C	280 to 319
D	240 to 279
F	239 or less

Any student earning a non-passing grade of “D” or “F” on an exam will be required to participate in mandatory tutoring sessions offered by the course instructor(s) until such a time that they obtain a passing average in the course.

Undergraduate mid-term grades will be posted on-line for students to view via Banner. Mid-term grades indicate a student’s status at mid-semester only and do not indicate the final performance outcome of a student.

A. Early Intervention

Students who earn less than 70 points on any exam and have an overall exam average <70% will be required to submit, to the course coordinator, written, narrative responses to lecture objectives that will be provided within 24 hours after posting of the failing exam grade to Moodle. These objectives will represent unit- or lecture-level objectives to be tested upon in the next scheduled course exam. Written responses must be submitted no later than one calendar

week before the next scheduled exam. Responses must be written in complete sentences and may not be copied or pasted from any source, including class notes, treatment guidelines, textbooks, or any internet site. Submissions determined to contain responses that have not been written in a student's own words will be considered a failure to submit.

Students will also be required to review each failed exam's ExamSoft-generated missed item report with the course coordinator or instructor responsible for each section of material. The discussion should include the student's reasoning for the incorrect answer as well as the reason for the correct answer.

In addition to the above, students scoring <70% on any exam and having an overall exam average <70% (excludes quizzes, assignments, bonus, etc.) will meet with the Director of Progressions.

B. Remediation Policy

1. Rationale or background to policy:

- a. Remediation is a sequence of events beyond the standard course curriculum that are designed to bring underperforming students to a level of competency expected at the conclusion of a course. The process of remediation should provide opportunities for students to develop and demonstrate required knowledge, skills, and/or attitudes through self-directed learning and purposeful interactions with faculty. Students and faculty should both be active participants in the remediation process; however, remediation is a privilege that should be earned by the student through demonstrated attendance and active participation throughout the course.
- b. Within the School, the current progression standard states that students who do not earn a minimum grade of "C" in a professional pharmacy course are not permitted to progress to subsequent courses for which it is a prerequisite. In the event that a student fails to obtain a grade of "C" or better in a required professional pharmacy course, the student will either have to repeat the course or remediate.

2. Policy Statement:

- a. Remediation is a privilege that must be earned through demonstrated attendance and active participation throughout the semester that the non-progressing grade was earned.
- b. To be eligible for remediation, the student must have completed all assigned work in the course. If <7% of students enrolled in a class fail to achieve a passing grade of "C" in a required course, students must have fulfilled all the requirements of the Early Intervention program as outlined in the Student Success Policy to be eligible for remediation. Remediation will be offered to any student earning a course average of ≥65% regardless of the total number of students failing.
- c. If the student makes a grade of <70% on the targeted final, their original grade will take the place of the "I" grade. The student can then re-enroll in the course at the next offering if eligible based on school progression policies. If this is the student's second "F" grade in the curriculum, the student will be dismissed from the program.
- d. Students will be allowed to remediate with a targeted remediation exam no more than three (3) times total in their P1-P3 years. Students may not remediate a class more than once. There will be no make-up exams in the remediation.
- e. Students with a grade of "C" or better are not eligible to use remediation in an attempt to improve their grade in that course.
- f. Students receiving a non-progressing grade as a result of a disciplinary action are not eligible to remediate that course in that semester.

3. Procedures:

- a. Remediation will take place during Winter Break for the fall semester and during Maymester for the spring semester. A targeted final of a format to be determined by the course coordinator and instructors will be administered prior to the June "I" removal date for spring semester and prior to the February date for the fall semester.
- b. Required characteristics of the remediation process for all courses shall include the following:
 - i. Remediation will be targeted to cover the material tested on any exam where the student scored < 70%.
 - ii. Students will be instructed to view recorded lectures, which will be made available for each lecture as the semester progresses and archived for one year after the course is complete.
 - iii. Students will demonstrate achievement of all or specifically assigned lecture objectives by completing narrative responses in their own words.
 - iv. Copying and pasting from any source (including instructor-provided resources, such as slides) will forfeit a student's right to remediate.
 - v. These responses will be submitted at least three days before the targeted final exam.
 - vi. Students must schedule a time to contact the instructors with their questions or to seek feedback on their submission.
 - vii. Students will complete a targeted remediation exam that will cover material on exam(s) where student failed to show mastery of the exam material and scored < 70%.
- c. Course coordinators may make modifications to the process, after consultation with Associate Dean of Academic Affairs.
- d. Prior to offering remediation, the course coordinator must contact the Director of Professional Affairs with a list of names for potential remediation. The Director of Professional Affairs will inform the course coordinator of the student's eligibility for remediation.

C. Class policies and procedures

At a minimum, all policies stated in the current *ULM Student Policy Manual & Organizational Handbook* should be followed (see <http://www.ulm.edu/studentpolicy/>). Additional class policies include:

1. *Textbooks (Recommended):* Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 10e; available online:

LWWHealth Library

<http://pharmacy.lwwhealthlibrary.com/book.aspx?bookid=881>

2. *Attendance Policy:* Class attendance is regarded as an obligation and as a privilege, and students are expected to know attendance regulations and to attend regularly and punctually at classes in which they are enrolled. Students are required to be in class on time, according to the published class schedule. For a student entering the classroom after the scheduled starting time, the student will be considered as absentee.

The School of Pharmacy follows the University Attendance Policy:

<http://catalog.ulm.edu/content.php?catoid=23&navoid=2875&hl=attendance&returnto=search#Class Attendance Regulations Excused Absences>

3. *Make-up Policy:* Attendance at all tests is mandatory. If you must miss an examination, please call the Office of Student and Professional Affairs in advance. Consult instructions in COP Student Manual for instructions pertaining to missed examinations and their make-up. If an examination must be missed for valid and verifiable reasons or because of an emergency, a make-up examination will be administered at the convenience of the instructor. In each instance what constitutes “valid and verifiable reasons” or an emergency will be determined by the course coordinator. Exams will not be given early. Failure to attend a scheduled makeup exam will result in a zero (0) grade for that exam. The format of the make-up exam may be written or oral. In the event that the final exam is missed, for reasons stated below, a grade of “I” will be assigned and the student will follow the University policy for adjusting the “I” grade. In the case that an exam is missed, the student must follow and adhere to the time frame in the College of Pharmacy’s excused absence policy.

Acceptable excuses will include, but not be limited to:

1. Medical or dental care – validated by the attending physician or dentist. The student will present a statement from the attending health care provider indicating the date and time of treatment, the nature of the treatment and a statement that he/she was not able to take the examination at the appointed time.
 2. A death in the student’s immediate family.
 3. A family emergency
 4. An official university function. It is the student’s responsibility to have the faculty in charge of the function notify the course coordinator prior to the function.
4. *Course Evaluation Policy:* Students are expected to complete the online course evaluation.
 5. *Academic Integrity:* Faculty and students must observe the ULM published policy on Academic Dishonesty (see the ULM Student Policy Manual – <http://www.ulm.edu/studentpolicy/>). All professional students will adhere to the standards set forth in the College of Pharmacy’s Code of Conduct. <http://www.ulm.edu/pharmacy/documents/ospa/codeofconductv82011.pdf>
 6. *Student Services:* Information about ULM student services, such as Student Success Center (<http://www.ulm.edu/cass/>), Counseling Center (<http://www.ulm.edu/counselingcenter/>), Special Needs (<http://www.ulm.edu/counselingcenter/special.htm>), and Student Health Services, is available at the following Student Services web site <http://www.ulm.edu/studentaffairs/>.
 7. *Emergency Procedures:* Please review the emergency escape plan in the classrooms and hallways of the Bienville building. Move quickly and orderly to the appropriate stairwell and exit the building. The meeting place for this class will be the far end of the north parking lot between Bienville and Broadmoor Blvd. Under no circumstances is the elevator to be used for emergency evacuation. Any student needing assistance should notify the instructor immediately. For emergencies, to contact University Police, call 1-911 from landlines and 342-5350 from cell phones.
 8. *Discipline/Course Specific Policies:* Students are responsible for all course information on Moodle and/or instructor websites. They are expected to check these sources regularly to access class materials, required readings, assignments, and other information necessary to excel in this course. Lecture notes might be posted on Moodle. Posting time; however, is at the discretion of the course coordinator. Lecture notes are not intended to be the entire

content of the course. They do not take the place of class attendance, personal note-taking, and reading the assigned and/or required text. Course coordinator may revise the notes at any time during the course.

Student Services: The University of Louisiana at Monroe strives to serve students with special needs through compliance with Sections 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act. These laws mandate that postsecondary institutions provide equal access to programs and services for students with disabilities without creating changes to the essential elements of the curriculum. While students with special needs are expected to meet our institution's academic standards, they are given the opportunity to fulfill learner outcomes in alternative ways. Examples of accommodations may include, but are not limited to, testing accommodations (oral testing, extended time for exams), interpreters, relocation of inaccessible classrooms, permission to audiotape lectures, note-taking assistance, and course substitutions.

Information about ULM student services can be found via these links:

- Student Success Center: <http://www.ulm.edu/studentsuccess/>
- Counseling Center <http://www.ulm.edu/counselingcenter/>
- Special Needs at <http://www.ulm.edu/studentaffairs/>
- Library <http://www.ulm.edu/library/reference.html>
- Computing Center Help Desk <http://www.ulm.edu/computingcenter/helpdesk>

Current college's policies on serving students with disabilities can be obtained on the ULM website: <http://ulm.edu/counselingcenter/>

- If you need accommodation because of a known or suspected disability, you should contact the Director for Disabled Student Services at:
 - Voice phone: 318-342-5220
 - Fax: 318-342-5228
 - Walk-In: ULM Counseling Center, 1140 University Avenue (this building and room are handicapped accessible).
- Mental Wellness on the ULM Campus

If you are having any emotional, behavioral, or social problems and would like to talk with a caring, concerned professional, please call one of the following numbers:

- The ULM Counseling Center: 318-342-5220
- The Marriage and Family Therapy Clinic: 318- 342-9797
- The Community Counseling Center: 318-342-1263

Remember that all services are offered free to students, and all are strictly confidential.

If you have special needs that I need to be made aware of, you should contact me within the first two days of class.

Sexual Harassment or Gender-Based Discrimination

Title IX of the Education Amendments of 1972 prohibits sex discrimination against any participant in an educational program or activity that receives federal funds, including federal loans and grants. Furthermore, Title IX prohibits sex discrimination to include sexual misconduct, sexual violence, sexual harassment and retaliation. If you encounter sexual harassment or gender-based discrimination, please contact the Title IX Coordinator at 318-342-1004; you may also file a complaint online, 24 hours a day, at: www.ulm.edu/titleix.

Tentative Lecture Schedule

Course instructors reserve the right to change the following schedule

PHRD 4008, Pharmaceutics I Rooms 202; 10:00 am – 10:50 am; M-W-F				
#	Day	Date	Instructor	Topic
1	Monday	8/16/21	Dr. Matthaiolampakis	<i>Introduction to Pharmaceutics</i>
2	Wednesday	8/18/21	Dr. Matthaiolampakis	<i>Drug Standards</i>
3	Friday	8/20/21	Dr. Matthaiolampakis	<i>Drug Regulation</i>
4	Monday	8/23/21	Dr. Matthaiolampakis	<i>Drug Discovery</i>
5	Wednesday	8/25/21	Dr. Matthaiolampakis	<i>Toxicology</i>
6	Friday	8/27/21	Dr. Matthaiolampakis	<i>(Pre)-formulation Studies</i>
7	Monday	8/30/21	Dr. Matthaiolampakis	<i>New Drug Development</i>
8	Wednesday	9/1/21	Dr. Matthaiolampakis	<i>New Drug Development</i>
9	Friday	9/3/21	Dr. Matthaiolampakis	<i>States of Matter</i>
	Monday	9/6/21	<i>Labor Day</i>	
10	Wednesday	9/8/21	Dr. Matthaiolampakis	<i>Beyond-use Date</i>
11	Friday	9/10/21	Dr. Barabutis	<i>Acid-Base Chemistry</i>
	Monday	9/13/21	EXAM 1 (covering Lectures 1-10)	
12	Wednesday	9/15/21	Dr. Barabutis	<i>Buffer Solutions</i>
13	Friday	9/17/21	Dr. Barabutis	<i>Solubility</i>
14	Monday	9/20/21	Dr. Barabutis	<i>Protein Binding and Complexes</i>
15	Wednesday	9/22/21	Dr. Barabutis	<i>Factors affecting Solubility</i>
16	Friday	9/24/21	Dr. Barabutis	<i>Three Component Systems</i>
17	Monday	9/27/21	Dr. Barabutis	<i>Milli-equivalence</i>
18	Wednesday	9/29/21	Dr. Barabutis	<i>Milli-equivalence</i>
19	Friday	10/1/21	Dr. Matthaiolampakis	<i>Rheology</i>
20	Monday	10/4/21	Dr. Matthaiolampakis	<i>Rheology</i>
	Wednesday	10/6/21	EXAM 2 (covering Lectures 11-20)	
21	Friday	10/8/21	Dr. Hill	<i>Chemical Kinetics and Stability</i>
22	Monday	10/11/21	Dr. Hill	<i>Chemical Kinetics and Stability</i>
23	Wednesday	10/13/21	Dr. Hill	<i>Chemical Kinetics and stability</i>
24	Friday	10/15/21	Dr. Hill	<i>Chemical Kinetics and Stability</i>
25	Monday	10/18/21	Dr. Hill	<i>Chemical Kinetics and Stability</i>
26	Wednesday	10/20/21	Dr. El Sayed	<i>Antimicrobials Preservatives</i>
27	Friday	10/22/21	Dr. El Sayed	<i>Antioxidants</i>
28	Monday	10/25/21	Dr. El Sayed	<i>Water in Pharmaceut. Preparations</i>
29	Wednesday	10/27/21	Dr. Chamcheu	<i>Diffusion</i>
Fall Break: 10/29 – 11/01				
30	Wednesday	11/3/21	Dr. Chamcheu	<i>Diffusion</i>
31	Friday	11/5/21	Dr. Chamcheu	<i>Transport across Biological Barriers</i>
	Monday	11/8/21	EXAM 3 (covering Lectures 21-30)	

32	Wednesday	11/10/21	Dr. Chamcheu	<i>Transport across a Tissue</i>
33	Friday	11/12/21	Dr. Matthaiolampakis	<i>Oral Liquid Dosage Forms</i>
34	Monday	11/15/21	Dr. Matthaiolampakis	<i>Principles of Surface Phenomena</i>
35	Wednesday	11/17/21	Dr. Matthaiolampakis	<i>Solutions</i>
36	Friday	11/19/21	Dr. Matthaiolampakis	<i>Suspensions</i>
37	Monday	11/22/21	Dr. Matthaiolampakis	<i>Emulsions</i>
Thanksgiving Break: 11/24-11/26				
38	Monday	11/29/21	Dr. Matthaiolampakis	<i>Emulsions</i>