ULM College of Pharmacy

Pharmaceutics II
PHRD 4029
CRN# 61105

I. Contact Information

Course Coordinators:
Georgios Matthaiolampakis Ph.D.
Associate Professor of Pharmaceutics
Office: Bienville 380
Phone: 318-342-7930
Email: matthaiolampakis@ulm.edu (preferred method of contact)
*Office Hours: M-T 1-4 pm

Course Instructors:
Jessica Brady, Pharm.D., BCPS
Clinical Professor of Pharmacy Practice
Office: Bienville office 115
Phone: 342-1697
Email: Brady@ulm.edu (preferred method of contact)
*Office hours: M-Th 1:00-4:00 pm

Dr. Karen Briski, Ph.D.
Professor of Pharmacology and Neuroanatomy
Office: Bienville 356
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Email: briski@ulm.edu (preferred method of contact)
*Office hours: M-F 1-3 pm

II. Course Pre-requisites/Co-requisites
PHRD 4008 Pharmaceutics I

III. Course Description
Fundamentals and description of drug delivery systems and delivery routes. 3 Cr.

IV. Curricular Objectives and 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
Pharmaceutical Sciences
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.

V. Course Specific Objectives and Outcomes

At the conclusion of this course, students should be able to:

VI. Course Topics
   1) Oral drug delivery
      A. Powders
      B. Tablets
      C. Capsules
   2) Topical drug delivery systems and their formulation
   3) Transdermal drug delivery systems and their formulation
   4) Otic drug delivery
   5) Ocular drug delivery
   6) Nasal drug delivery
   7) Pulmonary drug delivery
   8) Rectal, vaginal, and urethral delivery
   9) Novel drug delivery carriers

Course objectives
- Understand the various types of pharmaceutical dosage forms
- Understand the utilization of excipients, their importance and their function
- Understand and perform HLB calculations
- Understand viscosity and the utilization of viscosity modifiers
- Be aware of the quality control experimentals and understand the different dissolution systems and their proper utilization
- Gain basic understanding of the USP/NF and regulations and concepts that govern compounding and manufacturing
- Recognize the importance of different routes of administration and first pass metabolism
- Gain knowledge of compounding, composition, and stability of oral dosage forms
- Demonstrate an understanding of compounding practices for various routes of administration
- Calculate surfactant mixtures for the development of stable emulsions
- Understand bases used in transdermal drug delivery systems
- Understand differences between nasal and pulmonary delivery and the systems utilized for each.
- Understand methodologies utilized for the development of modified/extended drug delivery systems

VII. Instructional Methods and Activities

Traditional lecture format. Instructional methods may include technology-driven lectures with in-class discussion, quizzes and exams.

VIII. Evaluation and Grade Assignment

In order to assess each student’s performance three tests, of approximately 50 minutes in duration, and a final examination will be given. Each exam is “closed-book”. No informational resources or personal electronics of any kind are to 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 by use of examsoft, each student will be required to present to the exam with a working computer on 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 in a time such that students will be able to download the exam prior to the test time. Students will not be given extra time to take the exam to allow for the downloading of the test document.
- Students must upload the exam in a timely fashion. Failure to do so will result in a zero on that exam. In the event of an internet issue, students who have an issue uploading the exam will contact the course coordinators immediately and it will be addressed at the discretion of the coordinators.
- Students will not be allowed to leave the classroom with their computer prior to the end of the examination period.

Each test throughout the semester will be primarily new material between exams. Due to the nature of the course, comprehensive questions may be included (ex. Materials in tablets can be used in capsules, thus the student must possess such comprehensive knowledge, even though the topics are separated by an exam). Information acquired from previous courses in the pharmaceutics sequence and from other courses in the professional pharmacy curriculum may be needed in preparing for these examinations.

The final may include new material as well as comprehensive material.

Students wishing to review their exams with the course instructors must do so within 2 weeks of when test scores are posted. In the event that a question is eliminated from an exam, the exam may be graded based on the remaining number of questions and adjusted to represent correct number of points.

Students wishing to challenge a question on the test must provide the course coordinator with a written statement (email or hard copy) that identifies which question or questions are being challenged; and 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 of when test scores are posted. If there is a conflict between the lecture notes and the textbook or any other reference material, precedence will be given to the lecture notes.

Grading will take place according to the following:

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<thead>
<tr>
<th>Points</th>
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<tbody>
<tr>
<td>First Exam</td>
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<tr>
<td>Second Exam</td>
<td>100</td>
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<tr>
<td>Third Exam</td>
<td>100</td>
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<td><strong>Total</strong></td>
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<thead>
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<tr>
<td>A</td>
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<td>B</td>
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<tr>
<td>C</td>
<td>280 to &lt;320</td>
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<tr>
<td>D</td>
<td>240 to &lt;280</td>
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<tr>
<td>F</td>
<td>Less than 240</td>
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**NOTE:** At the discretion of the course coordinator, bonus points may or may not be given to any of the above listed categories.

Two home assignments will provide the opportunity for students to be rewarded with 10 bonus points/assignment to the final sum of points, as determined by the course coordinator. The topic, the announcement and the deadline
submission will take place during the semester by the course coordinator/instructors. The assignments are not mandatory, and they will add to the total point count towards the maximum of 400.

Each question in each exam will have equal contribution to the calculation of the final grade, disregarding the question's format or level of difficulty.

During exams, the faculty supervising the exam will provide students with scratch paper for the students to take notes and make all necessary calculations. The scratch paper must remain blank up to the moment the student begins her/his exam (password entry).

Cellphone use during exam is not permitted, unless the student requests permission from the supervising faculty.

Students should arrive to class before the scheduled exam starting time, while having already downloaded the exam, maintaining reasonable gap while sitting from other students, using a screen protection to limit the viewing angle of their screen and not carrying with them any unauthorized documents or personal items unnecessary for their activities. If a student does not maintain the proper distance from other students or does not have a screen protector, the student must move to the back of the class, and the supervising faculty maintains the right to ask the student to move to a better position.

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.

NOTE: Scores are NOT rounded. Therefore, scores of 0.5 and greater will not be rounded up.

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. Objectives should be submitted to the IOR and respective instructors via email.

For further information, please visit the link below (Students need to be advised that if a conflict between syllabus statements and college defined policies exists, College defined policies supersede instructions included in the syllabus):


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 of students 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.
   c. If < 7% of students enrolled in a class fail to achieve a passing grade of “C” in a required course, students earning a course average of > 65% must have fulfilled all the requirements of the Early Intervention program as outlined the Student Success Policy to be eligible for remediation.
   d. If ≥7% of the enrolled students fail to earn a grade of “C” or better in a required course, then remediation will be allowed for any student earning a final non-progressing grade of “D” or “F” for the course.
   e. Those who choose remediation will be given an incomplete (“I”) until the time that remediation is finished.
   f. Students choosing remediation must make a score of ≥70% on the targeted remediation exam to pass and receive a final grade of “C” in the course. No grade higher than a “C” can be made in the course with remediation.
   g. 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.
   h. 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.
   i. Students with a grade of “C” or better are not eligible to use remediation in an attempt to improve their grade in that course.
   j. 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 occur during a period immediately following the final grade reporting deadline for fall or spring semesters. A targeted exam of a format to be determined by the course coordinator and other course faculty contributors will be administered within 5 weeks of the date for reporting of final grades.
   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.

For more information, please visit the following link (Students need to be advised that if a conflict between syllabus statements and college defined policies exists, College defined policies supersede instructions included in the syllabus):


IX. 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:

a. Textbooks (recommended):
   1. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 12e

b. Attendance Policy: Class attendance is regarded as an obligation as well as a privilege, and students are expected to know attendance regulations and to attend regularly and punctually at classes in which they are enrolled. Failure to do so may: (1) prevent access to the classroom during regularly scheduled times; (2) jeopardize a student's scholastic standing; and (3) lead to suspension from the School or University. Students must submit excuses for class absences to course coordinators within three class days after returning to classes.

   Professors shall accept an official University excuse. With the following exceptions, professors are to determine whether absences are excused or unexcused: 1) Absences arising from authorized trips away from the University or from special duties at the University shall be excused. 2) Absences arising from a student's confinement in a hospital or other in-patient facility or doctor's excused absences shall be excused. Students are responsible for verifying providing documentation to the faculty, which will be verified. 3) Absences arising from a death in the immediate family shall be excused. The immediate family is defined as spouse, child, step-child, mother, father, sister, brother, grandmother, grandfather, step-mother, step-father, step-brother, step-sister, aunt, uncle, mother-in-law or father-in-law.

c. Make-up Policy: Each student is expected to attend each exam at the date and time specified. If a student cannot attend an exam due to valid University excuse, he/she must speak directly with the course coordinator, as soon as possible. The course coordinator must be notified prior to an examination if a student misses an exam. The ULM SOP Excused Absence Policy must be followed. Please refer to the official document for details. In case of emergency, the course coordinator must be notified within 48 hours of the emergency. Failure to do so will result in a zero (0) grade for that exam. Make-up exams will be prepared at the same or higher level than the original exam. The format of the make-up exam may be written or oral. Failure to attend a scheduled make-up exam will result in a zero (0) grade for that exam. Students missing an exam due to a University approved excuse will take the make-up exam during the week of finals, or as determined by the course coordinator.


d. Academic Integrity: Faculty and students must observe the ULM published policy on Academic Dishonesty (see Page 4 of the ULM Student Policy Manual - http://www.ulm.edu/studentpolicy/). All professional students will adhere to the standards set forth in the School of Pharmacy's Code of Conduct (http://www.ulm.edu/pharmacy/documents/ospa/codeofconductv82011.pdf).
Censures (Penalties)
Academic dishonesty will result in a referral to the Committee on Ethical and Professional Standards with a recommendation for a grade of “F” for the course and expulsion from the School of Pharmacy. Academic dishonesty includes, but is not limited to, the use of information taken from others’ work or ideas, the provision of help to others on non-collaborative evaluations (tests, quizzes, etc.), collaboration on take home exams, or the use of unapproved information or electronic devices to assist in obtaining an answer to the question.

e. **Course Evaluation Policy:** At a minimum, students are expected to complete the online course evaluation.

f. **Student Services:** Information concerning student services in the School of Pharmacy can be found in the School of Pharmacy Student Handbook. In particular, students should pay special attention to the University’s technical standards and policies concerning students with special needs (http://www.ulm.edu/studentpolicy/studentpolicy.pdf). ULM student services, such as the Student Success Center (http://ulm.edu/cass/), Counseling Center (http://ulm.edu/counselingcenter/), and Student Health Services, is available at the following Student Services web site http://ulm.edu/studentaffairs/. Students with special needs requiring accommodations MUST follow the process described at http://rxwebulm.edu/pharmacy/student/specialneeds.pdf.

Mental Wellness on the ULM Campus
If you are having problems with emotional, social, and/or behavioral issues please call any of the mental health clinics on the ULM campus to make an appointment. All services are free to ULM students, staff, and faculty, and are strictly confidential.

- COP Office of Student and Professional Affairs: 342-3800
- ULM Counseling Center: 342-5220
- Marriage and Family Therapy Clinic: 342-5678
- Community Counseling Center: 342-1263
- ULM HELPS (Helping Educators and Learners Prevent Suicide) Project Office: 342-1335

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.

*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 unlawful sexual harassment or gender-based discrimination, please contact Student Services at 318-342-5230 or to file a complaint, visit www.ulm.edu/titleix.*

g. **Emergency Procedures:** Please review the emergency escape plan in the classrooms and hallways of the Bienville building. Move quickly and in an orderly manner 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 the Bienville building and Broadmoor Blvd. Under no circumstances is the elevator to be used for emergency evacuation. Any student needing assistance should notify the professor immediately. For emergencies, to contact University Police, call 1-911 from landlines and 342-
5350 from cell phones. The course coordinators reserve the right to adjust the syllabus or schedule, in accordance with University and School policies and procedures.

h. Federal Regulations require determination and verification of every students’ physical location while enrolled in classes (where they are physically located while taking classes), regardless of the delivery method (on campus, online). At the beginning of every semester and whenever physical location changes, students must update or verify their current location through banner https://ssb-prod.ec.ulm.edu/PROD/bwgkogad.P_SelectAtypUpdate. Students should do this by the end of the first week of classes.

i. This course may be/is a major requirement for the professional degree in Pharmacy. Completion of degree requirements leads to eligibility for professional licensure and/or certification in Louisiana upon graduation. Federal Regulations require universities to provide information to students about the alignment between Louisiana’s requirements and those of other states. ULM has created a web page with discipline-specific information containing hyperlinks to Licensure Boards in the United States https://www.ulm.edu/professional-licensure-disclosures/index.html. Program Directors and/or faculty will discuss this information with you during advising or other program meetings but is also available to answer questions and address any concerns you might have. It is also important to note that licensure or certification requirements are subject to change. Although ULM Program Directors annually review and update licensure information for every state, the faculty recommends that before enrolling in a program and throughout enrollment, students communicate with the applicable state board to confirm understanding and whether upon completion of ULM’s program, they will meet requirements.

X.

A. Schedule: The instructor reserves the right to adjust the schedule as needed.

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<tr>
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<th>Date</th>
<th>Instructor</th>
<th>Topic</th>
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<tbody>
<tr>
<td>1</td>
<td>Wednesday</td>
<td>17-Jan</td>
<td>Dr. Briski</td>
<td>Powders</td>
</tr>
<tr>
<td>2</td>
<td>Friday</td>
<td>19-Jan</td>
<td>Dr. Briski</td>
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<tr>
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<td>Dr. Matthaiolampakis</td>
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<td>9-Feb</td>
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<td>TEST (covering lectures 1 – 9)</td>
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<td></td>
<td>Monday</td>
<td>12-Feb</td>
<td></td>
<td>Mardi Gras</td>
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<td><strong>TEST (covering lectures 10 – 17)</strong></td>
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<td>18</td>
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<td>6-Mar</td>
<td>Dr. Matthaiolampakis</td>
<td>Topical and Transdermal Drug delivery</td>
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<td>19</td>
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<td>8-Apr</td>
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<td>Suppositories</td>
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**Final exam: May 5th**