

COURSE TITLE: PHRD 408, Pharmaceutics I**I. Contact Information**

Course Coordinator: Michael D. DeGennaro, Ph.D.
Associate Professor of Pharmaceutics
Assistant Department Head
Department of Basic Pharmaceutical Sciences
Office: Bienville Room 360
Hours: Monday – Thursday: 2:00 PM – 4:00 PM
Friday: by appointment
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Course Instructors: Amal Kaddhoumi, Ph.D.
Sami Nazzal, Ph.D.

II. Course Prerequisites/Corequisites

First year pharmacy standing and registration or credit in PHRD 420

III. Course Description

Pharmaceutics I. 3 Cr. Fundamentals of physical pharmacy and an introduction to liquid oral dosage forms.

IV. Curricular Objectives and Outcomes**1. Provide Comprehensive Patient Specific Pharmaceutical Care.**

- A) Evaluate the appropriateness of a given prescription or medication order based on patient and disease-specific factors.
Analyze the prescription regarding the dose and delivery form
Determine availability and appropriateness of medications and dosage form.
- B) Compound and/or dispense the most optimal formulation for drug delivery consistent with the patient needs and in harmony with the law.
1. Identify pertinent patient and drug specific biopharmaceutic issues and select the most appropriate dosage form, route, method of administration, and formulation. Identify chemical stability and incompatibility issues
 2. Appropriately package of the medication
 3. Discuss sterility issues
 4. Apply good compounding practices
 5. Utilize appropriate weights, measures, and calculations

2. Communicate Effectively

Demonstrate fluency in medical terminology.

Demonstrate appropriate written, verbal and non-verbal communication skills.

Communicate in a professional manner.

Read, write, speak, listen, and use data, media, and computers to send and respond effectively to communications for varied audiences and purposes.

Construct appropriate and professional presentations to support communication.

Demonstrate appropriate written, verbal, and non-verbal skills.

Present and defend ideas in a logical and effective order.
Demonstrate ethical use in the procurement, derivation, use, and reporting of data.

3. Appropriately Manage and Use Resources of the Health Care System.

Apply patient and population specific data, quality assurance strategies, and research processes to assure that medication use systems minimize drug misadventures and optimize patient outcomes.

4. Identify, Interpret, and Evaluate Literature Needed for the Provision of Drug Information and Pharmaceutical Care.

Distinguish among lay, professional, and scientific literature.
Assess the potential impact and implication of published information on current practices.

5. Promote Health Improvement and Self-Care.

Identify health and disease prevention services needed.
Identify available health care resources (e.g., personal, education, equipment) necessary to provide services.
Identify a mechanism to promote the availability and benefits of service (e.g., marketing).
Evaluate the effectiveness of health improvement and disease prevention services.

6. Think Critically.

A. Identify, retrieve, understand, analyze, synthesize, and evaluate information needed to make informed and rational decisions.

i. Systematically gather, organize, and extract relevant information using a variety of methods and research tools.

ii. Analyze information within appropriate scientific, social, and clinical contexts.

a. Identify principles of organization and the logic of arguments.

b. Identify and test assumptions, biases, and prejudices implicit in arguments.

c. Employ appropriate mathematical and statistical tools and electronic technology to analyze information.

d. Assess accuracy, soundness, fairness, significance, relevance, completeness, and persuasiveness of information, arguments, and sources.

iii. Synthesize information in order to draw conclusions, hypothesize, conjecture alternatives, or plan a course of action.

iv. Evaluate conclusions and solutions according to appropriate criteria, and revise as necessary.

B. Solve complex problems

i. Interpret problems within appropriate contexts.

ii. Prioritize problems based on identifiable criteria and standards.

iii. Apply systematic problem-solving strategies.

C. Display habits, attitudes, and values associated with mature critical thinking.

i. Evaluate personal assumptions, biases, prejudices, and opinions.

ii. Display an openness to new ideas and a tolerance for ambiguity.

7. Demonstrate Appropriate Interpersonal, Professional, and Ethical Behaviors.

A. Maintain professional competence.

i. Continually strive to maintain knowledge and maintain professional competence.

ii. Continually assess his or her learning needs and develop the ability to respond appropriately.

B. Accept the responsibilities embodied in the principles of pharmaceutical care.

C. Demonstrate appropriate interpersonal, intergroup, and cross-cultural behaviors that promote respect and trust from peers, patients, and community members.

V. Course Specific Objectives and Outcomes

Upon completion of this course the student will be able to:

Discuss the need for dosage forms.

Make a distinction between different types of stability.

Relate to basic biopharmaceutical concepts.

Calculate stability parameters.

Discuss the significance of intermolecular forces and dosage forms.

Expound upon ionic equilibrium and pH.

Discuss the significance of the colligative properties.

Discuss factors affecting drug solubility.

Expound upon the relationship between drug solubility and dosage forms.

Relate to interfacial phenomena and its' significance to dosage forms.

Discus oral liquid dosage forms.

VI. Course Topics

Chemical Kinetics and Stability

Kinetic Phenomena

Solubility

Equilibrium Phenomena

Routes of Drug Administration

Oral Drug Delivery

A) Solutions

B) Emulsions

C) Suspensions

VII. Instructional Methods and Activities

Lectures accentuated with visual presentation

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. Each test will be comprehensive. Information acquired from previous courses in the pharmaceuticals sequence and from other courses in the professional pharmacy curriculum may be needed in preparing for these examinations.

Students wishing to review their exams with the course coordinator or instructor must do so within 2 weeks of when the test scores are posted. In the event that a question is eliminated from an exam after it has been printed, 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; why the student feels his or her answer(s) is/are correct and recent references from the literature to support the claim. 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.

Making the Grade

Description	Points	Percent of Final Grade
First Exam	100	25
Second Exam	100	25
Third Exam	100	25
Final Exam	100	25
Total	400	

Grades will be assigned according to the following scale:

Grade	Percentage (%)
A	90-100
B	80-89.9
C	70-79.9
D	60-69.9
F	Less than 60

There will be no curve or exception to the grading scale. This ensures that everyone has an equal opportunity to earn a desired grade.

NOTE: scores will NOT be rounded. Therefore, scores of 0.5 and greater will NOT be rounded upwards.

According to university guidelines (as given in *The University of Louisiana-Monroe 2005 – 2006 Graduate Catalog*), grades should reflect the following assessment:

- A – Excellent – Performance approaches complete mastery of course requirements.
- B – Good – Performance is above the level expected from most students, but does not approach complete mastery of course requirements.
- C – Average – Performance is about the level expected from most students.
- D – Below Average – Performance is at or above the minimum level to pass the course, but may not allow for progression in some programs.

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

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. Textbook(s) and Materials:

Required Textbooks

Applied Physical Pharmacy. Mansoor M. Amiji and Beverly J. Sandman. McGraw-Hill (ISBN 0-07-135076-4)

Recommended Textbooks

Pharmaceutical Calculations. 13th ed. Howard Ansel. Lippincott Williams and Wilkins (ISBN 978-1-5825-5837-0)

Pharmaceutical Dosage Forms and Drug Delivery. Ram Mahato. CRC Press (ISBN 0-8493-9285-3)

Martin's Physical Pharmacy and Pharmaceutical Sciences. 5th Ed. Patrick Sinko. Lippincott Williams and Wilkins (ISBN 0-7817-5027-X)

Other required items

TI-36X Calculator by Texas Instruments.

Note: This is the only calculator that will be allowed for use on examinations. This instrument has been approved by the Basic Pharmaceutical Sciences faculty for use in Pharmaceutical Calculations, Pharmaceutics I and II, and Pharmacokinetics and Biopharmaceutics courses to perform basic logarithmic and statistical tests as well as simple linear regression. Borrowing a calculator from someone else or using someone else's calculator during an examination will not be permitted.

B. Attendance Policy: Class attendance is mandatory and will be checked according to university regulations.

C. Make-up Policy:

Attendance as all tests is mandatory. If you must miss an examination, please call the Office of Student and Professional Affairs in advance. 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 and/or course instructors. Exams will not be given early. Failure to attend a scheduled make-up 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 above, a grade of "I" will be assigned and the student will follow the University policy for moving 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 instructor prior to the function.

D. Academic Integrity: Faculty and students must observe the ULM published policy on Academic Dishonesty (see Page 4 in ULM *Student Policy Manual* - <http://www.ulm.edu/studentpolicy/>).

E. Course Evaluation Policy: Students are expected to complete the on-line course evaluation.

F. Student Services: Information concerning student services in the College of Pharmacy can be found in the College of Pharmacy Student Handbook. In particular, students should pay special attention to the Colleges technical standards and policies concerning students with special needs (<http://www.ulm.edu/studentpolicy/studentpolicy.pdf>, pages 21-22). ULM student services, such as 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/>

G. 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.

H. 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.

X. Tentative Course Schedule

A. Contact Information:

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Sami Nazzal, Ph.D.

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

Introduction

- Drugs vs dosage forms
- Pharmaceutics as a Discipline
- Rationale for Dosage Forms
- Official Compendia

Chemical Kinetics and Stability

- Rates and Order of Reaction
- Zero-Order
- First-Order
- Factors Affecting Reaction Kinetics
- Accelerated Testing

Kinetic Phenomena

- Diffusion
- Biopharmaceutical and Physiological Considerations for Drug Delivery
 - Definitions
 - Drug Transport across Biological Membranes
 - Factors Affecting Absorption

Solubility

- Definitions
- Expressions of and calculations
- Factors affecting solubility and dissolution
 - Co-solvents
 - pH and pKa
 - Partition coefficient
 - Temperature
 - Particle Size
 - Polymorphism and Hydration

Equilibrium Phenomena

- Nonelectrolytes
- Solutions of Electrolytes
- Colligative properties

Osmols and Milliosmols
Ionic Equilibria
Buffer and buffer capacity

Routes of Drug Administration

Oral Drug Delivery

Oral Route and the Gastrointestinal Tracts
Physiologic Factors Affecting Oral Bioavailability

Solutions, Suspensions, and Emulsions

A) Solutions

Vehicles
Rheology

B) Emulsions

Types of emulsions
Interfacial phenomena
 Surface Active Agents
 Surface and Interfacial Tensions
 HLB

C) Suspensions

Formulation of Syuspension
Flocculation and Deflocculation
Suspension stability

Please note that the information in this syllabus is subject to change.