I. Contact Information

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II. Course Prerequisites/Corequisites

Prerequisite(s): Principles of Drug Action I (PHRD4002), Pharmaceutics I (PHRD4008).

III. Course Description

BIOPHARMACEUTICS AND PHARMACOKINETICS. 3 cr. The study of the interrelationships between formulation and physiological factors and pharmacokinetic aspects of drug absorption, distribution, metabolism, and excretion.
IV. Curricular Objectives and Outcomes

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.

   1.1.1. Develop and demonstrate depth and breadth of knowledge in pharmaceutical [...] sciences.
   1.1.4. Apply knowledge in foundational sciences to solve therapeutic problems and advance patient-centered care.
   1.1.5. Critically analyze scientific literature related to drugs and disease to enhance clinical decision making.

2.1. Patient-centered care (Caregiver) - Provide patient-centered care as the medication expert (collect and interpret evidence, prioritize, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities).

   2.1.2. Interpret evidence and patient data.
   2.1.4. Formulate evidence based care plans, assessments, and recommendations.
   2.1.5. Implement patient care plans.
   2.1.6. Monitor the patient and adjust care plan as needed.

V. Course-Specific Objectives and Outcomes

The major objective of the course is to provide the student with fundamental foundational understandings of the principles of biopharmaceutics and pharmacokinetics that can be applied to drug therapy and dispensing. Biopharmaceutics is the science that examines the interrelationships between physicochemical properties of a drug, the dosage form, specific formulation, and route by which it is administered on the one hand, and the rate and extent of drug absorption into the systemic circulation and distribution to the tissues where it produces its actions (desired and undesired) on the other hand. Consideration of the physiology of drug absorption, distribution, metabolism, and excretion is integral to the subject. Pharmacokinetics is the science of the kinetics (rates) of drug absorption, distribution and elimination in an in-vivo system.

A student finishing this course should attain an understanding and appreciation of:

1. The general terms and definitions associated with biopharmaceutics and pharmacokinetics;
2. The philosophies behind the development of pharmacokinetic models;
3. Various mathematical approaches and models that are applied to the analysis of pharmacokinetic data;
4. The meaning of various pharmacokinetic parameters (some examples: \( \text{AUC}, k_e, \text{Cl}, V_d \)), including (a) definitions, (b) the typical ways estimates for the value of a parameter are obtained, (c) the biological significance of the parameter, and (d) the effects and significance of variations in a given parameter, in terms of comparisons between individual patients, patient populations, dosage forms, and different drugs;
5. Basic statistical approaches used for the analysis of biopharmaceutical and pharmacokinetic data, including regression/curve-fitting and parameter estimation;
6. The ways that physicochemical and molecular characteristics of a drug interrelate with physiological factors (such as serum protein binding, and GI tract, hepatic, and renal function), and the resulting effects on bioavailability at the systemic and tissue levels, and on pharmacokinetics;
7. The ways in which drug and formulation properties, route of administration, and physiological processes affect drug bioavailability (rate and extent of uptake);
8. The ways in which pharmaceutical products are tested to ensure proper biopharmaceutical characteristics;
9. Exceptional characteristics among various drugs or drug classes that demand particular routes of administration, pharmacokinetic monitoring, or other special considerations (e.g., aminoglycoside antibiotics);
10. The nature of drug-drug or drug-dietary interactions having biopharmaceutical or pharmacokinetic origin;
11. The difference between linear and nonlinear pharmacokinetics, and significances thereof;
12. The mathematic principles and concepts relevant to multiple-dose regimens, and considerations in the design of patient-individualized dosage regimens;
13. Basic ways in which pharmacodynamics and pharmacokinetics may be linked (i.e., PK-PD models), and various clinical implications thereof.

Upon finishing this course, the student will be able to:

1. Identify biopharmaceutically and pharmacokinetically pertinent information from various sources, including package inserts (official FDA labels), prescriber-level information provided in other secondary drug information resources (including the Physician’s Desk Reference (PDR)), and current biopharmaceutics and clinical pharmacokinetics literature; read this information with a foundational application-level understanding; and critically assess its meaning and value to ongoing or proposed pharmacotherapy regimens.
2. Construct simple linear or semilogarithmic graphs of biopharmaceutical or pharmacokinetic data, and use such plots for basic parameter estimation;
3. Carry out basic manipulations of various pharmacokinetic equations, and accurately carry through calculations using these equations;
4. Propose an appropriate route or routes of administration for a drug, given some basic biopharmaceutical or pharmacokinetic information;
5. Predict the effects of changes in route-of-administration, dose, and administration rate on plasma concentration vs. time profiles;
6. Apply knowledge of biopharmaceutics and pharmacokinetics in conjunction with pertinent information about a patient (see next objective) to design an appropriate dosing regimen (single- or multiple-dose) for individualized drug therapy, based on information from single-dose studies or from literature.
7. Predict or recognize alterations in a drug’s pharmacokinetics arising from drug-drug or drug-dietary interactions, current health status (including functional status of key organs such as liver and kidney, and body fat presence and distribution) and changes thereof, or genetic variations as manifested phenotypically.

This course is also intended to provide necessary background so that more-advanced objectives can be developed in a subsequent course or courses, including the following:

1. The student will appreciate the clinical pharmacokinetic significance of individual patient and population variations, including the implications of “pharmacogenomics” and considerations of disease states that affect absorption or elimination rates;
2. The student will be able to propose appropriate changes in route-of-administration or dosage regimen according to individual patient considerations;
3. The student will be able to decide whether or not clinical pharmacokinetic monitoring is likely to be needed with a particular drug or patient, and if so, propose an appropriate method of doing so.
4. The student will be able to apply their knowledge of dosage form strategies for modifying a drug release profile so as to control uptake rates (e.g., controlled, sustained, or delayed release), in conjunction with their overall knowledge of biopharmaceutics and pharmacokinetics, in order to propose therapeutically sound dosage form changes.
5. The student will know and able to apply basic experimental design considerations for pharmacokinetic and bioavailability studies in order to critically analyze their validity and limits-of-interpretation, and to participate in the design of such studies;
6. The student will apply their knowledge of procedures for setting confidence limits, testing statistical validity, and establishing statistical significance, in order to draw conclusions from intra- and inter-study comparisons;
7. The student will be able to critically evaluate the results of a biopharmaceutics or pharmacokinetics study presented in the literature, in a talk, in product information, on the internet, or by other means; to assess the conclusions drawn by the authors or presenters; and reach some reasonable independent conclusions concerning the meaning, significance, and validity of reported study results, so as to determine the overall clinical significance of the study.

Additional detailed information concerning study and learning objectives, beyond what is given here, will be provided as we go through the course, with further clarifications provided either in class (typically, within the context of grappling with particular types of content), or on the Moodle site, aiming to address questions such as…

- How should I study?
- On what aspects should I particularly focus?
- What will be expected of me on the quizzes and exams?

Question and Answer (Q&A) sessions will be offered at specially scheduled times (not during regular class time) a day or two prior to the exams, and possibly on other selected occasions during the semester. These may also prove useful in guiding your study strategies and emphases.

VI. Course Topics

See Section X below.

VII. Instructional Methods and Activities

Instructional methods will include: traditional and technology-based content presentations, generally aiming to be highly interactive in nature, and various formative exercises designed to invoke active learning, including outside homework/study assignments that in most cases will not be collected for a grade.
VIII. Evaluation and Grade Assignment

- Three Exams 66% (22% each exam), and final exam 34% (comprehensive)
- Additional items may or may not contribute to the grade this semester, to a maximal amount of 10%, which would reduce the weight of the exams accordingly.

According to university guidelines (as given in The University of Louisiana at Monroe 2017-2018 Graduate Catalog, wherein the Pharm.D. program is currently listed as a professional degree program), grades should reflect the following:

A - EXCELLENT    B - AVERAGE    C - BELOW AVERAGE
D – POOR          F - FAIL

Grading will be straight-scale: An overall class grade of ≥ 70% is required to pass the course. Fractional grades will be rounded up – a score of 69.50000000% will be awarded a “C” grade.

Students scoring ≥ 90% will receive an “A” grade, those scoring ≥ 80% but < 90% will receive a “B” grade, and those scoring ≥ 70% but < 80% will receive a “C” grade.

Mid-term grades will be posted online for students to view via Banner, per the established deadline. 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 will be followed (see http://www.ulm.edu/studentpolicy/). Additional class policies include:

**Preparation for class.** For each class period, you will typically be held responsible for varying degrees of prior preparation, involving: (1) viewing any e-presentations as may be assigned in advance; (2) completing one or more advance readings if assigned as preparation for a particular class; (3) answering or attempting to answer any assigned pre-class study questions. Pre-class and post-class study assignments will be constrained to a modest length, and will serve to illustrate and elaborate key concepts, emphasizing application, in accord with content objectives provided. You should plan for a minimum of 5-6 hours per week of outside study time in support of your learning in this class; some students may find that they need more time than this in some topic areas, depending in part on strength of pertinent prior academic preparation. Any advance assignments and any materials needed to complete it (notes, handouts, study questions) will typically be posted on Moodle at least several days in advance. For other advance information, you should habitually check the Moodle page the evening before class.
IX Class Policies and Procedures, contd.

Portable Computers and Clickers. Exercises conducted on portable computers ("laptops" or equivalent) or with clickers may occur on any given day to generate grades for certain activities (such as a quiz). Therefore, please bring your computer and your clicker to every class period: if you do not have it, you may not be afforded an alternative means to provide responses (i.e., you may earn a ‘0’ on the graded activity), depending on the nature of the activity and the circumstances. Also, please note that allowing someone else to use your clicker to register responses for you, or to generate in-class responses for you by any other means, or to help enable a student who is not physically present in the classroom to complete an in-class assignment, constitutes Academic Misconduct, and any instances of such use will be prosecuted accordingly.

Exams. Four examinations will be administered during the course. The three hourly exams (Tests 1, 2, & 3) will emphasize topics as mentioned in the class schedule, but beginning with Test 2, will have some degree of comprehensive coverage, the nature of which will be communicated to you soon enough for any needed review. Almost every topic in this course builds on previously covered topics, and the entirety of this course is foundational for major portions of your future education and training. The final exam will be comprehensive to a considerable extent.

Dropped Test Questions. When, due to faculty concerns regarding a question appearing on an administered examination, or as the result of a student-generated appeal that is judged to be valid and of merit by course faculty, the question will generally be omitted from the grade calculation for all students—the total points for the course will be reduced, without altering the percentages required to earn a particular course grade given above in section VIII. Course faculty reserve the right to deviate from this general guideline, however, according to their professional judgement as pertains to the specifics of the issue with the question deemed to be flawed.

Exams will almost certainly be conducted using ExamSoft/SofTest on your portable computer. All students will be required to download the exams prior to the time of the scheduled exam. In the event that a student cannot take an exam that has already been downloaded on the scheduled date and at the scheduled time, the student must reverse-download the exam, without having opened it, at earliest pragmatically possible opportunity (i.e., at the first occasion when an internet connection becomes available to you). Seating charts will be used for examinations, and screen privacy covers must be used during exams and during any other activity during which computers are used as part of a grade-generating activity. For examinations and some quizzes, official scratch paper will be issued, and all students will be required to print and sign their name on the scratch paper and return it to the proctor, even if otherwise unused, prior to leaving the room. For exams and some quizzes, when turning in this sheet, students will also be required to show a proctor that the exam/quiz has been irreversibly closed, and also uploaded, before leaving the room; in the event of a power outage or loss of Wi-Fi connection, students are required to upload the exam/quiz at the earliest possible reconnection time.

During exams as well as during some grade-generating activities, the use of programmable calculators and electronic devices capable of storing, receiving or transmitting data are prohibited unless expressly authorized by the course instructor. Such devices must be turned off and placed in a location that is not readily accessible to you during the exam or activity.
IX Class Policies and Procedures, contd.

**Early Intervention and Remediation Policies.** The School of Pharmacy *Early Intervention and Remediation Policies, as revised August 2016, will be followed.* In addition, any student earning a non-passing grade of “D” or “F” on an exam, and whose average (exams only, beginning after Test 2) is below 70.00%, will be required to meet with the course coordinator, at earliest mutually possible opportunity, but at latest within one week of when test scores are posted, to (1) review the test, if not already done as part of a group debriefing session (documented attendance); and (2) establish a mandatory academic performance improvement plan that will be undertaken by the student prior to the subsequent exam, which will include adherence to the Early Intervention Policy, but which may also include tutoring sessions offered by course faculty and/or other documented assistance (such as student tutoring and mentoring—Rho Chi tutoring, e.g.) in content areas identified as weaknesses as per a student’s exam performance(s), and continuing until such a time as the student secures a solid passing average in the course.

*The opportunity for remediation is a privilege that, should a student need and wish to avail themselves of it, must be earned.* To be eligible for remediation, the student must have demonstrated regular attendance, completed all assigned work in the course, including assignments arising from the Early Intervention Policy, and taken full advantage of other academic assistance, as outlined in the paragraph above. As one further reminder concerning the School of Pharmacy Remediation Policy, students receiving a non-progressing grade as a result of a disciplinary action are not eligible for remediation.

A. **Textbook(s) and Materials:**
   - Lecture slides (provided online)
   - Microsoft Office Excel software
   - Small ruler and scientific calculator or laptop (In class)
   - Rectilinear and semi logarithmic graph papers (printable forms provided on Moodle)

*The following textbook is required:*


*This textbook is available online via library/accesspharmacy website:*


B. **Attendance Policy:**
   The School of Pharmacy attendance policy, which is in accord with the ULM Attendance Policy, will be followed.
IX Class Policies and Procedures, contd.

C. Make-up Policy:

*Exams, Graded In-class Exercises, and Assignment Deadlines:* The university requires that you are given a fair opportunity to complete missed grade opportunities when circumstances warrant. For examinations (and in most other instances) such circumstances must be compelling, including: (1) you are sick enough to require medical attention and be confined to bed; (2) there is a death in the immediate family (see ULM policy definition); (3) there is a personal or family emergency. In most instances, physical proof will be needed or you will not be provided the opportunity to make up the grade. If the absence is predictable (e.g., a scheduled surgery), a prior approval must be obtained from Dr. Hill (as the Instructor-of-Record). **If you miss an examination or assignment deadline, and intend to request a makeup under the above policy, the coordinator (Dr. Hill) MUST be informed BY PHONE, by E-mail*, OR IN-PERSON no later than the day following the missed event, unless circumstances are clearly prohibitive. Excuses will be validated. If a makeup is allowed under these guidelines, it will be arranged on an individual basis. *If you choose E-mail, please assure that Dr. Hill acknowledges receipt within 24 hours, else send again.

D. Academic Integrity:

Faculty and students must observe the ULM published policy on Academic Dishonesty (see the *ULM Graduate Catalog, ULM Student Policy Manual* [http://www.ulm.edu/studentpolicy/]). All professional students will adhere to the standards set forth in the ULM College of Pharmacy’s Code of Conduct ([http://www.ulm.edu/pharmacy/documents/ospa/codeofconduct.pdf](http://www.ulm.edu/pharmacy/documents/ospa/codeofconduct.pdf)). These policies will be strictly enforced—notably, CHEATING WILL NOT BE TOLERATED, AS ANY ACADEMIC ADVANCEMENT THEREBY GAINED IS CONSIDERED A POTENTIAL THREAT TO THE PUBLIC. Any instances of academic dishonesty will be dealt with vigorously and doggedly, and to the fullest extent possible.

E. Course Evaluation Policy:

At a minimum, students are expected to complete the on-line course evaluation.
IX Class Policies and Procedures, contd.

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 College’s technical standards and policies concerning students with special needs (http://www.ulm.edu/pharmacy/documents/ospa/specialneeds.pdf). ULM student services, such as the Student Success Center (http://www.ulm.edu/studentsuccess/), Counseling Center (http://ulm.edu/counselingcenter/), and Student Health Services, is available at the following Student Services web site: http://ulm.edu/studentaffairs/.

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, re-location 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. In the event we must evacuate the building, move quickly and in an orderly fashion 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 professor immediately. For emergencies, to contact University Police, call 1-911 from landlines and 342-5350 from cell phones.
X. Course Schedule *(Note: Although somewhat unlikely, the faculty reserves the right to adjust the schedule if needed.)*

Bienville Bldg., Room 202; **M&W 11:00-11:50 a.m**

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<th>Lecturer</th>
<th>Date</th>
<th>Other Info</th>
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<td>1. Introduction to Biopharmaceutics and Pharmacokinetics.</td>
<td>R. Hill</td>
<td>8/21, 8/23, 8/25</td>
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<td>2. Rates and rates constants</td>
<td>R. Hill</td>
<td>8/28</td>
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<td>3. Half-life, bioavailability, bioequivalence and volume of distribution</td>
<td>R. Hill</td>
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<td><strong>Labor day holiday</strong></td>
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<td>4. One-Compartment Open Model: Intravenous Bolus Administration</td>
<td>R. Hill</td>
<td>9/6, 9/8, 9/11, 9/13</td>
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<tr>
<td><strong>EXAM 1</strong></td>
<td>R. Hill</td>
<td>9/25</td>
<td>Includes topics 1, 2, 3 and 4</td>
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<td>6. Intravenous Infusion</td>
<td>R. Hill</td>
<td>9/22, 9/27, 9/29</td>
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<td>7. Drug Elimination and Clearance.</td>
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<td>R. Hill</td>
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<td>8. Pharmacokinetics of Oral Absorption and Physiologic Factors Related to Drug Absorption</td>
<td>R. Hill</td>
<td>10/11, 10/13, 10/16</td>
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<td><strong>Fall holiday</strong></td>
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<td>10/19 to 10/22</td>
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<td>9. Hepatic Elimination of Drugs</td>
<td>R. Hill</td>
<td>10/23, 10/25, 10/30</td>
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<td>10. Nonlinear Pharmacokinetics</td>
<td>R. Parish</td>
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<td>11. Multiple-Dosage Regimens</td>
<td>R. Hill</td>
<td>11/6, 11/8, 11/10, 11/13</td>
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<td>EXAM 3</td>
<td>R. Hill</td>
<td>11/20</td>
<td>Includes topics 8-11</td>
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<td>12. Clearance-half-life relationship</td>
<td>R. Hill</td>
<td>11/15</td>
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<td>Thanksgiving Holiday</td>
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<td>11/23 (after 12 pm)-25</td>
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<td>TBA/Review Day</td>
<td>R. Hill</td>
<td>12/01</td>
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<td>R. Hill, R. Parish</td>
<td>F 12/8</td>
<td>Comprehensive</td>
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