

PHR 914: Basic Principles of Pharmaceutical Science I
Introduction to Pharmaceutical Dosage Forms
(aka Drug Design)

Fall 2007, MW 3-4:15 p.m. NURS 201

1. Course Description and Objective

This course deals with the science of delivery of drugs to the body and the dosage forms that enable the drug delivery. Material to be covered will include selected properties of drug substances that have an impact on the delivery of drugs to the human body, the dosage forms available for drug administration, and the therapeutic effect with respect to physical and chemical properties of drug in the solution. This material will provide the knowledge base upon which the pharmacist will depend to make rational decisions about drug product therapy for patients as well as to appropriately counsel patients. The objective of this course consists of (1) to understand the relationship between dosage forms and drug delivery and the physicochemical properties and structures of drug molecules; (2) to comprehend the underlying principles of drug development and be able to apply them to engage in critical thinking of drug stability, formulation and delivery; (3) to identify the relevant information from literature regarding a drug or drug product in order to solve specific questions; and (4) to build up the knowledge in drug development and delivery and develop problem-solving skills.

2. Faculty

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3. Teaching Assistants

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4. Course Secretary

Linda Sager

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5. Prerequisite

You are required to have a good understanding of organic chemistry, and to be competent in applying algebra and calculus to solve questions. It is expected that everyone in PY1 should be able to meet the prerequisite.

6. Textbooks and Supplies

Useful but not required:

- *Remington's Pharmaceutical Sciences*, 21st edition, Mack Publishing Co., Easton, PA (2005). This text is required for your CAPP sequence of classes.
- *Pharmaceutical Dosage Forms and Drug Delivery Systems*, 7th Ed., Ansel, Allen and Popovich, editors, Lippincott, Williams and Wilkins, Publishers (1999).

Required calculator: Must be able to perform linear regression analysis

You are required to use your Blackboard (<http://www.uky.edu/Blackboard/>) account for accessing information of this course. You may download class handouts, take quizzes, and upload your term papers.

7. Grading

7.1. Examinations

There are 3 scheduled examinations and one final examination. The following table contains the point value of each examination:

	POINTS	COVERAGE	DATE
Exam 1	100	<ul style="list-style-type: none">• Introduction to Pharmacokinetics (50%)• Overview of Dosage Forms (50%)	09/15
Exam 2	100	<ul style="list-style-type: none">• Fundamental Concepts of Drugs in Solution	10/15
Exam 3	100	<ul style="list-style-type: none">• Chemical Stability	11/09
Final Exam	150	<ul style="list-style-type: none">• Comprehensive (40%)• Formulation Design (60%)	12/13

In some instances, more than one professor will be providing material for an examination. The point value for such material on the examination will be split according to the contents of lectures by each professor.

7.2. Term Project (100 Points)

You need to form a team with a fellow student to work together throughout the whole semester carrying out a continuous project. Each team (you and your partner) needs to

turn in **four** reports for evaluation. You will be assigned a top-selling drug, and will conduct literature search to address specific questions raised by the lecturers during the class. Each report needs to be written in a professional, concise and clear manner stating the facts and arguments by you and your teammate. All references including online information need to be properly indicated and cited. It is expected that, by carrying out the project, both you and your teammate will gain substantial product-specific insights as to how the dosage form design is linked to the biopharmaceutical performance and physicochemical properties of the drug molecule. The evaluation of each report will be based on, but not limited to, the following:

- The information found is complete, and relevant to the class materials
- The discussion of current formulation and possible improvement is scientifically sound
- The report is presented in a clear and well-organized manner

The project consists of several stages as the following:

COVERAGE		Point	DUE
Report #1	Introduction to Pharmacokinetics, and Overview of Dosage Forms: <ul style="list-style-type: none"> ▪ To identify the commercial dosage forms of the drug and discuss their influence on the pharmacokinetic profile of the drug ▪ To describe the basic chemical and physical properties of the molecule based on its chemical structure 	25	09/20
Report #2	Fundamental Solution Concepts: <ul style="list-style-type: none"> ▪ To discuss the solution properties of the drug and the relationships between those properties, such as solubility and gastrointestinal stability, and dosage forms and their performance 	25	10/18
Report #3	Chemical Stability: <ul style="list-style-type: none"> ▪ To identify potential chemical degradation mechanisms based on molecular structure of the drug ▪ To explain how the chemical reactivity may be affected by solution properties ▪ To discuss how the chemical stability may affect the dosage form design and the pharmacokinetic profile of the drug 	25	11/14
Report #4	Formulation Design: <ul style="list-style-type: none"> ▪ To discuss formulation design with regard to solubility, pharmacokinetics and physical stability 	25	12/13

	<ul style="list-style-type: none"> ▪ To explain excipients and their roles ▪ To design a new formulation that may offer improved qualities 		
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7.3. Homework Assignments (80 Points)

	POINTS	COVERAGE	DATE
Homework #1	20	Drugs in Solution (Dr. Bummer)	10/03
Homework #2	20	Chemical Stability (Dr. Anderson)	10/24
Homework #3	20	Chemical Stability (Dr. Anderson)	11/07
Homework #4	20	Pharmaceutical Solids (Dr. Li)	11/28

7.4. Final Grade

Final grade in the course will be calculated on the number of points earned in lecture examinations, term project, quizzes and homework assignments. Grades will be awarded on the following scale:

Total Points	Exams	Term Project	Quiz	Homework	
630	450	100	0	80	
% Total Points	90% and above	80 to 89%	70 to 79%	60 to 69%	below 60%
Final Grade	A	B	C	D	F

8. Course Rules and Regulations

General policies on exam and quiz guidelines, HG 611, teacher/course evaluations, personal appearance standards, class attendance, cell phone and ipod use in class, class cancellations in severe weather, class and exam schedule changes, honor code and senate procedures related to academic dishonesty will be followed as listed in the 07-08 Student handbook. This material is also listed on web at: <http://www.mc.uky.edu/pharmacy/current/pharmd/files/handbook.pdf>. In addition, for this class, PHR914, the following should be added:

- 8.1. Professional behavior is expected at all times. Professionalism is defined as treating the instructors, teaching assistants, and your fellow students in a respectful and courteous manner; completing small group activities accurately and efficiently; and leaving the classroom or work area in a clean and orderly manner.

As part of treating others with respect, students and faculty alike are required to place cell telephones and pager devices in the non-audio mode so that students and faculty will not be disturbed during class. In no case will a student or faculty member speak on a cell telephone while in the classroom.

- 8.2. Cheating and Plagiarism: Except in those instances where students are explicitly instructed to submit work done as a group, students are expected to work and submit materials individually. Cheating and plagiarism will not be tolerated and will be prosecuted to the fullest extent possible. The student is directed to the "College of Pharmacy Honor Code" for further explanation. All examinations are taken in accordance with the Honor Code. It is a College of Pharmacy policy that it is up to each student to ensure that their own behavior during an examination is such that no doubt could possibly exist about their honesty and integrity.
- 8.3. Errors do occur in grading and students do have the right to have any error corrected promptly. The student has **7** (seven) days after return of materials to submit an examination for reconsideration, after which time, all grades become final. In the event that a student wishes to have an examination re-graded, the full examination paper and a written request are to be submitted to Dr. Li (either directly in person or to his secretary, Ms. Sager). The written request is to identify the area of concern and to state reasons why the student believes there is an error. The more clearly this request is written out, the more rapidly the faculty member will be able to return the examination to the student. The right to re-grade the entire examination upon resubmission is hereby reserved by the faculty. Because a number of faculty members may be involved in the re-grading, the process may take a seemingly long period of time. Patience is appreciated.
- 8.4. Attendance Policy: The faculty firmly believes that regular class attendance is critical to success in the course. The faculty also believes that students are professionals who are empowered to make their own decisions. Consequently, class attendance will not be monitored. As indicated above, make-up quizzes will not be administered.

The block examination system does involve some hardships on students, most notably those with religious considerations, and every effort will be made to accommodate those individuals. Please contact Dr. Li early in the semester if a re-scheduling of an examination is necessary for religious or medical considerations. Examinations missed without notification of the faculty in advance will be graded as a zero.

- 8.5. On-line Course Evaluation Policy: Regular course and instructor evaluations are required by state, university, college and accreditation regulations. These evaluations are essential for improving student learning by providing feedback to faculty about their classroom presentations. Based on your feedback, important decisions are made about courses and how they are taught. This process **CANNOT** work without your input.

Note: Course evaluations are a part of the course requirements; therefore, if you do **not** complete an evaluation, **you will receive an incomplete grade ("I") for the semester.** When you complete the course evaluation, the incomplete grade will be changed to the grade earned in the course.

The College of Pharmacy administers these evaluations electronically through a web-based program. You will receive email notifications from the Office of

Education Innovation (OEI) about when to complete a course and/or an instructor evaluation(s) for this course. Since these evaluations are completed electronically and each survey will be posted only for a limited time, you should check your university email account regularly.

Please note that your individual responses are completely **anonymous**. However, the Office of Education Innovation can track who has or has not completed each evaluation and send reminder notices. Summary reports of aggregate data will be provided to the faculty after the semester is completed.

9. Class Schedule

TOPIC	#	CONTENT	DUE	DATE	LECTURER
Introduction to Pharmacokinetics	4	Introduction to the Course (Tonglei Li) Drug Dosing and Pharmacokinetics (2 hours total)		08/20	McNamara
		Pharmacokinetic Profiles and Parameters		08/22	
		Oral Dosing and Bioavailability		08/27	
		Catch up and Review		08/29	
		Labor Day – No Class		09/03	
Overview of Dosage Forms	3	Introduction to Dosage Forms I (2 hours)		09/05	Bummer
		Introduction to Dosage Forms II		09/10	
		Introduction to Dosage Forms III		09/12	
		Exam 1 (12:30 – 2:30 PM, Ag Auditorium)		09/15	Li
		No Class (Block Exams)		09/17	
Fundamental Concepts of Drugs in Solution	14	Gastrointestinal Physiology	Report #1 (due 09/20)	09/19	Bummer
		Solubility & Diffusion I		09/24	
		Solubility & Diffusion II		09/26	
		Solubility & Diffusion III		10/01	
		Partition and Permeation	HW #1	10/03	
		pH and Ionization		10/08	
		pH and Solubility		10/10	
		Exam 2 (10:30 AM – 12:30 PM, PH220/222/223)		10/15	Li
		Chemical Stability – Overview	Report #2 (due 10/18)	10/17	Anderson
		Stability Calculation & Info Search		10/22	
		Effect of Temperature on Reaction Rates	HW #2	10/24	
		pH Effects on Reaction Rates		10/29	
		Stabilization of Drug Products		10/31	
		Stability Review I		11/05	
Stability Review II	HW #3	11/07			
		Exam 3 (8:00 – 10:00 AM, Ag Auditorium)		11/09	Li
		No Class (Block Exams)		11/12	
Introduction to Formulation Design	5	Self Study for the Term Project	Report #3	11/14	Li
		Pharmaceutical Solids (2 hours)		11/19	
		Fall Break – No Class		11/21	
		Dissolution and Disintegration (2 hours)		11/26	
		Formulation of Solid Dosage Forms I	HW #4	11/28	
		Formulation of Solid Dosage Forms II		12/03	
		Manufacturing of Solid Dosage Forms		12/05	
		Catch up and Review (8:30 – 9:50 AM, NUR201)		12/07	
		Final Exam (4:30 – 7:30 PM, PH220/222/223)	Report #4	12/13	

THE ABOVE SCHEDULE, POLICIES, AND ASSIGNMENTS IN THIS COURSE ARE SUBJECT TO CHANGE IN THE EVENT OF EXTENUATING CIRCUMSTANCES OR BY MUTUAL AGREEMENT BETWEEN THE INSTRUCTOR AND THE STUDENTS.