

PHBS 432  
Pharmaceutical Sciences 2 Module  
Winter 2007 - 2008

2007-2008 Catalogue Course Description

8 hours of lecture/discussion, 1 hour recitation, 3 hours laboratory

This course will emphasize the concepts of pharmacokinetics related to physiology and pathophysiology. The course continues to discuss the pharmaceutical and biopharmaceutical aspects of a variety of drug delivery systems, including solid, semisolid, and transdermal dosage forms. Novel and experimental drug delivery systems will also be examined.

The laboratory exercises are designed to introduce the student to basic pharmaceutical concepts and techniques necessary to prepare extemporaneous dosage forms, including ointments, suppositories, and gels. The chemical, physical, and biological properties of the ingredients used and their relationship to the final product will be discussed in order to facilitate preparation of elegant, stable, safe, and effective products.

Prerequisites

Completion of Pharmaceutical Sciences Module 1, Biomedical Sciences Module 1, and Patient Care Assessment Module 1.

Lecture, Recitation, Laboratory Periods

Lecture: 8:00 AM – 8:50 AM; 9:00 AM – 9:50 AM, MTRF ME 107

Recitation: To be announced weekly

Laboratory: Once every two weeks (10:00 AM – 12:50 AM) according to section schedule

Lecture Schedule

Day – Date	Week	Topic	Instructor	Lecture Hours	Laboratory title	Recitation title
Monday 11/26	1	Introduction/Lab/ New Drug Development	Kisor/Myers/ Rojeab	1	Shake Lotions & Pastes	No Recitation
Monday 11/26	1	Dosage Form Design	Rojeab	1	”	”
Tuesday 11/27	1	Powders and Granules	Rojeab	1	”	”
Tuesday 11/27	1	Tablets	Rojeab	1	”	”
Thursday 11/29	1	Tablets	Rojeab	1	”	”
Thursday 11/29	1	Capsules	Rojeab	1	”	”
Friday 11/30	1	Modified-Release Dosage Forms	Rojeab	1	”	”
Friday 11/30	1	Semisolids	Rojeab	1	”	”
Monday 12/3	2	Transdermal Drug Delivery	Rojeab	2	”	TBA

### Lecture Schedule (continued)

Tuesday 12/4	2	Suppositories and Inserts	Rojeab	1	„	„
Tuesday 12/4	2	Solutions	Rojeab	1	„	„
Thursday 12/6	2	Solutions	Rojeab	1	„	„
Thursday 12/6	2	Lab 2 prep	Myers	1	„	„
Friday 12/7	2	Ophthalmic Drug Delivery	Rojeab	1	„	„
Friday 12/7	2	Review	Rojeab	1	„	„
Monday 12/10	3	Products of Biotechnology	Rojeab	1	Ointments & Topical Applicators	TBA
Monday 12/10	3	Novel Dosage Forms	Rojeab	1	„	„
Tuesday 12/11	3	<b>Exam 1 (11/26 - 12/7)</b>	<b>Rojeab</b>	<b>2</b>	„	„
Thursday 12/13	3	PK-Physiological parameters	Kisor	2	„	„
Friday 12/14	3	PK Gastrointestinal	Kisor	2	„	„
Monday 12/17	4	PK Cardiovascular	Kisor	2	„	TBA
Tuesday 12/18	4	PK Renal	Kisor	2	„	„
Thursday 12/20	4	PK Renal	Kisor	1	„	„
Thursday 12/20	4	Lab 3 prep	Myers	1	„	„
Friday 12/21	4	Digoxin	Kisor	2	„	„
12/22 through 1/6/08	Break					
Monday 1/7	5	Aminoglycosides	Kisor	2	Gels	TBA
Tuesday 1/8	5	Aminoglycosides	Kisor	2	„	„
Thursday 1/10	5	Aminoglycoside Cases/Review	Kisor	2	„	„
Friday 1/11	5	Vancomycin	Kisor	2	„	„
Monday 1/14	6	<b>Exam 2 (12/13 – 1/10)</b>	<b>Kisor</b>	<b>2</b>	„	TBA
Tuesday 1/15	6	Vancomycin Cases	Kisor	2		
Thursday 1/17	6	Lab 4 prep	Myers	1	„	„
Thursday 01/17	6	The Cytochrome P-450 enzyme system	Christoff	1	„	„

### Lecture Schedule (continued)

Friday 01/18	6	The Cytochrome P-450 enzyme system	Christoff	2	„	„
Mon. 1/21	7	No class				
Tuesday 1/22	7	The Cytochrome P-450 enzyme system	Christoff	2	Suppositories	TBA
Thursday 1/24	7	The Cytochrome P-450 enzyme system	Christoff	2	„	„
Friday 1/25	7	The Cytochrome P-450 enzyme system	Christoff	1	„	„
Friday 1/25	7	Hepatic drug elimination	Kisor	1	„	„
Monday 1/28	8	Hepatic Drug metabolism	Kisor	2	„	CyP-450
Tuesday 1/29	8	Theophylline/Cases	Kisor	1	„	„
Tuesday 1/29	8	PK Biliary Excretion	Kisor	1	„	„
Thursday 1/31	8	PK organ Independent	Kisor	1	„	„
Thursday 1/31	8	Lab Practicum	Myers	1	„	„
Friday 2/1	8	Nonlinear Review/Phenytoin	Kisor	2	„	„
Monday 2/4	9	Phenytoin/Fosphenytoin	Kisor	2	Practical	TBA
Tuesday 2/5	9	Phenytoin/Fosphenytoin Cases	Kisor	2	„	„
Thursday 2/7	9	Review	Kisor	2	„	„
<b>Friday 2/8</b>	<b>9</b>	<b>Exam 3 (1/11 – 1/31)</b>	<b>Kisor/ Christoff</b>	<b>2</b>	„	„
Monday 2/11	10	Population PK/TDM	Kisor	1	„	TBA
Monday 2/11	10	Procainamide	Kisor	1	„	„
Tuesday 2/12	10	Special Topic	Kisor	2	„	„
Thursday 2/14	10	Special Topic	Kisor	2	„	„
Friday 2/15	10	Course review	Kisor	2	„	„

\* **Note: Modifications to lecture and laboratory schedule may be made by the faculty as need arises.**

### Laboratory Schedule

**Professional dress is required for laboratory (white lab coat, name tag, dress clothes).**

Lab #1	Shake Lotions and Pastes
Lab #2	Ointments and Topical Applicators
Lab #3	Gels
Lab #4	Suppositories

## Examination Schedule

Exam 1	Tuesday, December 11, 2007
Exam 2	Monday, January 14, 2008
Exam 3	Friday, February 8, 2008
Final Exam	TBA

## Goals/Objectives

These goals and objectives are in accordance with AACP CAPE Professional Practice-Based and General Ability-Based Outcomes and the NAPLEX Competency Statements. Copies of these competencies and outcomes are available in the department offices.

### Goals:

1. Introduce in a summary format, various pharmaceutical drug delivery systems.
2. Calculate the transport characteristics of the drug through various body compartments using kinetic methods.
3. Given a patient situation and characteristics of the drug to be used in that patient's treatment, the student should be able to recommend a particular route of administration and potential formulation for the recommended product. The student should also be able to apply pharmacokinetics to the clinical setting.
4. Have the ability to appropriately calculate pharmacokinetic parameters for drugs administered via the intravascular and extravascular routes using data from various methods of measuring clinical effectiveness.

### Objectives:

Upon the successful completion of the Pharmaceutical Sciences Module 2, the student will be able to:

1. Determine pharmacokinetic parameters from plasma or urine concentrations of a drug following an intravenous dose.
2. Estimate pharmacokinetic parameters from plasma concentration data obtained during and following constant-rate input.
3. Use pharmacokinetic parameters to predict the plasma drug concentration and the amount of drug in the body with time during and following constant-rate input with and without a loading dose.
4. Recognize and identify the sources of non-linear pharmacokinetics of drugs.
5. Accurately perform calculations involving the extemporaneous preparation of products containing small or not readily available amounts of potent medications.
6. Define the methods of sterilization utilized in the manufacture of sterile products.
7. Define the effects of physical and chemical properties of drugs and adjuvants on the design of drug delivery systems.
8. Identify and explain the influence of the route of administration on the release and absorption of drugs.
9. Identify and describe the purpose for the inclusion in a given dosage form of each of the ingredients present and, where appropriate, recommend a better ingredient for that purpose with justification for that recommendation.
10. Describe the formulation and manufacturing factors which can affect bioavailability of drugs from drug delivery systems.
11. Understand the basic concepts of topical/transdermal, rectal, and controlled release drug delivery systems.

## Textbooks

1. Basic Clinical Pharmacokinetics, 4<sup>th</sup> ed. M Winter, Editor.
2. Remington: The Science and Practice of Pharmacy, 20<sup>th</sup> ed.
3. Pharmaceutical Dosage Forms and Drug Delivery, 8<sup>th</sup> ed. by Howard Ansel *et al.*
4. Principles of Medicinal Chemistry”, 5th ed. Eds. Williams, D.A.; Lemke, T.L. Lippincott, Williams and Wilkins: Baltimore, Maryland, 2002 or if not yet purchased (Released September 2007) Principles of Medicinal Chemistry”, 6th ed. Eds. Lemke, T.L.; Williams, D.A. Lippincott, Williams and Wilkins: Baltimore, Maryland, 2008.

### Reference texts:

Principles of Sterile Product Preparation. EC Buchanan *et al.* ASHP 2002.

Physical Pharmacy, 4<sup>th</sup> ed., A Martin *et al.*

Modern Pharmaceutics, 3<sup>rd</sup> ed., G Banker *et al.*

Pharmaceutical Calculations 11<sup>th</sup> ed., HC Ansel and MJ Stoklosa or Pharmaceutical Calculations 3<sup>rd</sup> ed., J Zatz

## Grading Procedures

The final grade will be determined by the weighted average of the following\*

Exam 1 168 points

Exam 2 204 points

Exam 3 204 points

Laboratory work 240 points

Laboratory practical final 120 points

Final Exam 225 points

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TOTAL 1161 points

\*approximate

Grading Scale: Letter grades will be assigned on the following basis:

1039 points or greater = A

923 - 1038 = B

807 - 922 = C

691 - 806 = D

below 691 = failure

*Grade Review:* The student may contact the instructor to discuss, reconsider, or re-grade any returned examination / laboratory exercises within the first TWO (2) working days following the time that the examination / laboratory exercise was made available for the student to pick up. These activities must be carried out during office hours or by appointment.

*Class Expectations:* Regular class attendance is expected. If circumstances prevent the student from attending class, the burden of responsibility for obtaining missed information and/or materials lies entirely with the student.

Attendance at examinations and laboratory sessions is mandatory. An unexcused absence will result in a zero for the examination/laboratory. At the discretion of the instructors, an excused absence will permit a makeup examination (type determined by instructors). For this course, an excused absence is defined as severe illness or death in the immediate family. Documentation will be required.

**NOTE: YOU MUST HAVE A SCORE OF 70% OR HIGHER OVERALL ON THE LABORATORY WORK TO PASS THE COURSE. THAT IS, A PASSING SCORE BASED ON POINTS (807 OR GREATER) WITH A LAB OVERALL PERCENTAGE OF LESS THAN 70% WILL RESULT IN AN F.**

### Grading Procedures (continued)

Nonessential materials are NOT allowed at the students' desks during examination periods (e.g., books, coats, hats, notes, note cards, purses, etc.). Please leave all these materials either in your locker or at the front of the examination room. Possession of any such materials during an examination is considered to be evidence of dishonesty. Please note the only calculator you will be permitted to use during examinations is a Casio fx-300W. Use of any other calculator will be interpreted as evidence of cheating. DISHONESTY of any sort will absolutely NOT be tolerated. Violations will be addressed with the most severe of consequences *allowed by the established policies of the College and the University.*

*PROFESSIONAL DRESS IS REQUIRED FOR LABORATORY (white lab coat, nametag, and dress clothes)*

Students entering the Pharmaceutical Sciences class are expected to have the following mathematical skills:

- Plotting of data on numeric and semi-log graph papers.
- Use of the natural logarithmic function ( $\ln x$ ) and the inverse natural logarithmic (anti-logarithmic) function ( $e^{-x}$ ) keys on an electronic calculator.
- Convert concentration units from mg/L mg% mg/100 ml g/ml ng/ml
- Convert amounts from grams (g) milligrams (mg) micrograms (g) nanograms (ng) milliequivalents (mEq)
- Convert liters (L) milliliters (ml)
- Convert days hours minutes
- Convert pounds (lbs) kilograms (kg) grams (g)
- Given a set of x and y data points, perform a linear regression analysis and determine the correlation coefficient of the data values and the slope and intercept of the line.

### Faculty

Dr. David Kisor RE223 772-2294 [d-kisor@onu.edu](mailto:d-kisor@onu.edu) (Coordinator)

Dr. Y. Rojeab HPPEC259 772-3957 [y-rojeab@onu.edu](mailto:y-rojeab@onu.edu)

Dr. Jeff Christoff HPPEC258 772-2658 [j-christoff.1@onu.edu](mailto:j-christoff.1@onu.edu)

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### Assessment

*Internal Assessment:* Regular meetings are held during the course for faculty involved. Faculty focus groups are conducted during after completion of the module to identify strengths and weaknesses and remedies for the latter.

*External Assessment:* The College Assessment Committee arranges periodic classroom visits and student and faculty focus groups.

*Student assessment:* Students assess the module and the individual instructors at the end of the quarter by established procedures. A student focus group will also meet once weekly with the coordinator.

MODIFICATIONS TO THE SYLLABUS, INCLUDING THE LECTURE SCHEDULE MAY BE MADE BY THE FACULTY AS NEED ARISES DURING THE QUARTER.