

PHBS 431
Pharmaceutical Sciences Module 1
Fall 2008

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*** Note: Modifications to this syllabus, including the lecture, laboratory, and recitation schedule may be made by the faculty as need arises.**

2008-2009 Course Description

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

This course deals with the physical pharmacy, pharmaceutical and biopharmaceutical aspects of a variety of drug delivery systems, including solutions, solid dosage forms, disperse systems and aerosols. The time-course of drug substances in various body compartments (pharmacokinetics) will be treated in a quantitative manner, and delivery system formulation factors which may affect drug pharmacokinetics (biopharmaceutics) will be discussed.

The laboratory exercises are designed to introduce the student to basic pharmaceutical concepts and techniques necessary to prepare extemporaneous dosage forms, including solutions, capsules, and suspensions. 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

Standing as a P-4 student

Lecture, Recitation, Laboratory Periods

Lecture: 8:00 AM – 8:50 AM; 9:00 AM – 9:50 AM, MTRF HPPEC151

Recitation: Weekly according to section schedule

Laboratory: Once every two weeks according to section schedule

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Lecture Schedule

| Week | Day - Date | Topic | Instructor | Lecture Hours | Laboratory Title | Recitation Title |
|----------|---------------|---|---------------------------|---------------|-------------------------------|------------------|
| 1 | T 9/9 | Introduction to PHBS431/ PHBS431 Lab | Kisor / Myers | 0.2/0.5 | Lab #1 Intro Lab | No recitation |
| 1 | T 9/9 | Sterile Products | Broedel- Zaugg | 1.5 | " | " |
| 1 | R 9/11 | Sterile Products | Broedel- Zaugg | 2 | " | " |
| 1 | F 9/12 | Sterile Products | Broedel- Zaugg | 2 | " | " |
| 2 | M 9/15 | Sterile Products | Broedel- Zaugg | 2 | " | " |
| 2 | T 9/16 | Sterile Products | Broedel- Zaugg | 2 | " | " |
| 2 | R 9/18 | Sterile Products | Broedel- Zaugg | 2 | " | " |
| 2 | F 9/19 | Sterile Products | Broedel- Zaugg | 2 | " | " |
| 3 | M 9/22 | Sterile Products | Broedel- Zaugg | 2 | Lab #2 Sterile Products | " |
| 3 | T 9/23 | Sterile Products | Broedel- Zaugg | 1 | " | " |
| 3 | T 9/23 | Introduction to Pharmaceutical Sciences | Rojeab | 1 | " | " |
| 3 | R 9/25 | Exam 1 (9/9 - 9/23) | Broedel- Zaugg | 2 | " | " |
| 3 | F 9/26 | Physical Pharmacy States of Matter | Mahfouz | 2 | " | " |
| 4 | M 9/29 | Physical Pharmacy Physical properties of Drug Molecules | Mahfouz | 2 | " | " |
| 4 | T 9/30 | Physical Pharmacy Solutions of Nonelectrolytes/Electrolytes | Mahfouz | 2 | " | " |
| 4 | R 10/2 | Physical Pharmacy Ionic Equilibria 1 | Mahfouz | 1 | " | " |
| 4 | R 10/2 | Aliquot Math/Other | Myers | 1 | " | " |
| 4 | F 10/3 | Physical Pharmacy Ionic Equilibria 2 | Mahfouz | 1 | " | " |
| 4 | F 10/3 | Physical Pharmacy Buffered and Isotonic Solutions 1 | Mahfouz | 1 | " | " |
| 5 | M 10/6 | Physical Pharmacy Buffered and Isotonic Solutions 2 | Mahfouz | 1 | Lab #3 Solutions | TM* |
| 5 | M 10/6 | Physical Pharmacy Solubility and Distribution Phenomena 1 | Mahfouz | 1 | " | TM |

Lecture Schedule - PHBS431 (continued)

| | | | | | | |
|---|----------------|---|----------------------------|----------|---|-----------------------|
| 5 | T 10/7 | Physical Pharmacy Solubility and Distribution Phenomena 2 | Mahfouz | 1 | “ | TM |
| 5 | T 10/7 | Physical Pharmacy Kinetics 1 | Rojeab | 1 | “ | TM |
| 5 | R 10/9 | Physical Pharmacy Kinetics 2 & 3 | Rojeab | 2 | “ | TM |
| 5 | F 10/10 | Physical Pharmacy Diffusion / Dissolution 1&2 | Rojeab | 2 | “ | TM |
| 6 | M 10/13 | Physical Pharmacy Diffusion / Dissolution 3 | Rojeab | 1 | “ | YR* |
| 6 | M 10/13 | Physical Pharmacy Interfacial Phenomena 1 | Rojeab | 1 | “ | YR |
| 6 | T 10/14 | Physical Pharmacy Interfacial Phenomena 2 | Rojeab | 1 | “ | YR |
| 6 | T 10/14 | Physical Pharmacy Colloids | Rojeab | 1 | “ | YR |
| 6 | R 10/16 | Physical Pharmacy Coarse Dispersions 1&2 | Rojeab | 2 | “ | YR |
| 6 | F 10/17 | Physical Pharmacy Rheology | Rojeab | 1 | “ | YR |
| 6 | F 10/17 | Suspensions/ Emulsions | Myers | 1 | “ | YR |
| 7 | M 10/20 | Exam 2 (9/26 – 10/17) | Mahfouz/ Rojeab | 2 | Lab # 4 Susp/ Emulsions | TBA |
| 7 | T 10/21 | Physical Pharmacy Polymer Science | Rojeab | 1 | “ | “ |
| 7 | T 10/21 | Physical Pharmacy Micromeritics | Rojeab | 1 | “ | “ |
| 7 | R 10/23 | Physical Pharmacy Drug Product Design 1&2 | Rojeab | 2 | “ | “ |
| 7 | F 10/24 | Physical Pharmacy Protein Binding | Rojeab | 1 | “ | “ |
| 7 | F 10/24 | PK – I V Push/Bolus 1 | Kisor | 1 | “ | “ |
| 8 | M 10/27 | PK – I V Push/Bolus 2&3 | Kisor | 2 | “ | Kinetic Data Set 1 |
| 8 | T 10/28 | PK – I V Push/Bolus 4&5 | Kisor | 2 | “ | Data Set 1 |
| 8 | R 10/30 | PK – I V Push/Bolus 6 | Kisor | 1 | “ | Data Set 1 |
| 8 | R 10/30 | Capsule/Tablet Math | Myers | 1 | “ | Data Set 1 |
| 8 | F 10/31 | PK – I V Infusion 1 | Kisor | 1 | “ | Data Set 1 |
| 9 | F 10/31 | PK – I V Infusion 2 | Kisor | 1 | Lab # 5 Powders/ Capsules/ Tablets | Kinetic Data Set 2 |
| 9 | M 11/3 | Exam 3 (10/21 – 10/31) | Rojeab/ Kisor | 2 | “ | Data Set 2 |
| 9 | T 11/4 | PK – I V Infusion 3 | Kisor | 1 | “ | Data Set 2 |
| 9 | T 11/4 | PK – Drug Absorption 1 | Rojeab | 1 | “ | Data Set 2 |
| 9 | R 11/6 | Lotions/Pastes | Myers | 1 | “ | Data Set 2 |
| 9 | R 11/6 | PK – Drug Absorption 2 | Rojeab | 1 | “ | Data set 2 |

Lecture Schedule - PHBS431 (continued)

| | | | | | | |
|----|---------|--------------------------|---------|---|---|--------------------|
| 9 | F 11/7 | PK – Drug Absorption 3&4 | Rojeab | 2 | “ | Data Set 2 |
| 10 | M 11/10 | PK – Extravascular 1&2 | Rojeab | 2 | “ | Kinetic Data Set 3 |
| 10 | T 11/11 | PK – Extravascular 3 | Rojeab | 1 | “ | Data Set 3 |
| 10 | T 11/11 | PK – Multiple Dosing 1 | Kisor | 1 | “ | Data Set 3 |
| 10 | R 11/13 | PK – Multiple Dosing 2 | Kisor | 1 | “ | Data Set 3 |
| 10 | R 11/13 | PK – Nonlinear 1 | Rojeab | 1 | “ | Data Set 3 |
| 10 | F 11/14 | PK – Nonlinear 2 | Rojeab | 1 | “ | Data Set 3 |
| 10 | F 11/14 | Course Review | Faculty | 1 | “ | Data Set 3 |

*TM = Tarek Mahfouz, RY = Yousif Rojeab

Laboratory Schedule

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

| | |
|--------|---------------------------------|
| Lab #1 | Intro Lab: Check-in & Measuring |
| Lab #2 | Sterile Products |
| Lab #3 | Solutions |
| Lab #4 | Suspensions/Emulsions |
| Lab #5 | Powders/Capsules/Tablets |

Examination Schedule

| | |
|-------------|-----------------------------|
| Exam 1 | Thursday September 25, 2008 |
| Exam 2 | Monday October 20, 2008 |
| Exam 3 | Monday November 3, 2008 |
| Final exam* | To be announced |

*comprehensive

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.
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 1, 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.
12. Explain how to extemporaneously compound a sterile product (i.e., parenterals, IV admixtures, CAPD solutions, irrigating solutions) utilizing proper materials, equipment and procedure.
13. Explain the basic principles including definitions, formulations (if appropriate) and problems of:
 - a. parenteral
 - b. continuous ambulatory peritoneal dialysis
 - c. home IV therapy
 - d. chemotherapy
14. Accurately perform calculations involving the extemporaneous preparation of products containing small or not readily available amounts of potent medications.

Objectives (continued):

Upon completion of the laboratory exercises, the student will be able to:

1. Determine the necessary level of accuracy and weigh or measure to that standard.
2. Prepare a uniform mixture of solids, liquids, or a combination of these.
3. Interpret and evaluate prescription orders for:
 - a. completeness
 - b. dosage regimen
 - c. appropriateness of dosage form
 - d. compliance with legal requirements
 - e. compatibility of ingredients
4. Extemporaneously prepare the following dosage forms:
 - a. solid products: powders and capsules
 - b. solutions
 - c. suspensions
5. Select appropriate packaging for each dosage form
6. Prepare an accurate error-free label incorporating appropriate patient consultation information.

Required Textbooks

1. Basic Clinical Pharmacokinetics, 4th ed. ME Winter, Lippincott Williams & Wilkins 2004.
2. Pharmaceutical Dosage Forms and Drug Delivery. 7th ed. H.C Ansel *et al.*, Lippincott Williams & Wilkins, 1999.
3. A Practical Guide to Contemporary Pharmacy Practice. 2nd ed. JE Thompson, Lippincott Williams & Wilkins 2004.

Recommended Text:

Martin's Physical Pharmacy and Pharmaceutical Sciences, fifth edition, 2006.
Remington: The Science and Practice of Pharmacy, 21st ed.
Applied Physical Pharmacy, Amiji and Sandman, 2003.

Reference Texts:

Principles of Sterile Product Preparation. EC Buchanan *et al.* ASHP 2002.
Physical Pharmacy, 4th ed., A Martin *et al.*
Clinical Pharmacokinetics, 3rd ed., M Rowland and TN Tozer.
Pharmaceutical Calculations 11th ed., HC Ansel and MJ Stoklosa

Grading Procedures

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

Exam 1 216 points
Exam 2 204 points
Exam 3 204 points
Laboratory work 300 points
Final Exam 280 points

TOTAL 1204 points

NOTE: YOU MUST HAVE A SCORE OF 70% OR HIGHER OVERALL ON THE LABORATORY WORK TO PASS THE COURSE. I.E., A PASSING SCORE BASED ON POINTS (836 OR GREATER) WITH A LAB OVERALL PERCENTAGE OF LESS THAN 70% WILL RESULT IN AN F.

Grading Procedures (continued)

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

Above 1077points = A
957- 1077 = B
836 - 956 = C
716 - 835 = D
Below 716 = F

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. It is expected that students will be attentive in class and will not be disruptive.

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

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excused absence is defined as severe illness or death in the immediate family. Documentation will be required.

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 or fx-300MS. 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. Tarek Mahfouz HPPEC257 t-mahfouz@onu.edu (Coordinator)

Dr. David Kisor RE223 772-2294 d-kisor@onu.edu

Dr. Kim Broedel-Zaugg RE229B 772-2281 k-broedel-zaugg@onu.edu

Prof. Deirdre Myers RE108A 772-1934 d-myers@onu.edu

Dr. Yousif Rojeab HPPEC259 772-3957 y-rojeab@onu.edu

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 (BUT NOT LIMITED TO) THE LECTURE, RECITATION AND LAB SCHEDULE MAY BE MADE BY THE FACULTY AS NEED ARISES DURING THE QUARTER.