MARSHALL UNIVERSITY

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School of Pharmacy

SYLLABUS
Pharmacometrics
PHAR 631
(Fall 2014)

This syllabus is not to be construed as a contract with the student and is subject to change.

The School of Pharmacy reserves the right to change the course syllabus. *The School should notify the students through the course notification system or by an email preferably through the Blackboard system.*

Materials used in this class may be copyrighted and should not be shared with individuals not enrolled in this course.

Course meeting days and time	Tuesday, Wednesday, Thursday 2 PM to 3:30 PM (Weeks 9-15; 10/21/14-12/04/14)
Location	L04
Team Leader / Instructor	Dr. Jinsong Hao
Office	CEB 201
Phone	304-696-3519
Email	haoj@marshall.edu
Office hours	Tuesday, 12 PM to 1 PM or by appointment

Faculty	Email	Office	Phone Number	Office Hours / Appointments accepted?
Dr. John V. Schloss	schloss@marshall.edu	211A	696-3094	By appointment

Student: If the instructor accepts appointments, then please email the instructor for availability. The student can expect the instructor to respond to E-mails and phone messages within 72 hours.

Course Description: Topics covered include the basic theory of pharmacokinetics and pharmacodynamics; processes and mechanisms controlling the rate and extent of drug absorption and systemic availability; bioavailability and bioequivalence

Prerequisites: P-2 Standing

Text Books:

Recommended: Applied Biopharmaceutics & Pharmacokinetics, Sixth Edition, Leon Shargel, Andrew Yu, and Susanna Wu-Pong, McGraw Hill Medical, ISBN 978-0-07-160393-5

Course Objectives:

Number	Objective	Linkage to MUSOP Abilities (list ability numbers)	How Assessed
1	Describe the physiological determinants of the primary pharmacokinetic prarameters of clearance and volume of distribution	1,10	Examination Quizzes Active Learning Exercise
2	Determine primary and secondary pharmacokinetic parameters from concentration-time data	1,10	Examination Quizzes Active Learning Exercise
3	Design a pharmacokinetically-based dosage regimen for an individual patient	1,5,6,7,10	Examination Quizzes Active Learning Exercise
4	Modify a dosage regimen for a patient based on the physiological changes brought about by disease or concomitant drug therapy	1,5,6,7,10	Examination Quizzes Active Learning Exercise
5	Apply pharmacokinetic concepts to a particular drug therapy to solve relevant problems in pharmaceutical care	1,5,6,7,10	Examination Quizzes Active Learning Exercise
6	Compare and contrast the effects of various routes of xenobiotic administration on the onset, intensity, and duration of pharmacologic effect	1,10	Examination Quizzes Active Learning Exercise
7	Describe how formulation characteristics influence the disposition and action of drugs after various routes of administration	1,10	Examination Quizzes Active Learning Exercise

Schedule of Activities:

Date	#	Meeting Format	Meeting Topic	Course Student Learning Outcomes	Instructor
10/21	**1**	**SC**	Course introduction; determinants of pharmacological effect	• Describe the factors that influence the response to xenobiotics (1,10)	Dr. Hao
10/22	**2**	**SC**	Determinants of pharmacological effect	• Compare and contrast pharmacokinetics and pharmacodynamics (1,10) • Describe the relationship between regimen specific, drug specific and patient specific factors that influence the pharmacological effect (1,10)	Dr. Hao
10/23	**3**	**SC**	One-compartment model: IV bolus administration	• Describe a one-compartment model, IV bolus injection (1,10) • Explain how drugs follow one-compartment kinetics (1,10)	Dr. Hao

10/28	**4**	**SC**	One-compartment model: IV bolus administration	• Calculate PK parameters from drug concentration-time data using a one-compartment model (1,10) • Describe the relevance of the volume of distribution and clearance to underlying processes in the body (1,10)	Dr. Hao
10/29	**5**	**SC**	Multicompartment models: IV bolus administration	• Define the PK terms used in a two- and three-compartment model (1,10)	Dr. Hao
10/30	**6**	**SC**	Multicompartment models: IV bolus administration	• Calculate PK parameters of drugs that follow two- and three-compartment models (1,10) • Explain how drug metabolic enzymes, transporters, and binding proteins modify the distribution and/or elimination phase (1,10)	Dr. Hao
10/31	**EXAM 1 (#1-4)* 8 AM**				
11/4	**7**	**SC**	Intravenous infusion	• Describe the concept of steady-state and how it relates to continuous dosing (1,10)	Dr. Hao
11/5	**8**	**SC**	Intravenous infusion	• Determine optimum dosing for an infused drug by calculating PK parameters from clinical data (1,5,7,10) • Describe the purpose of a loading dose and calculate (1,10)	Dr. Hao
11/6	**9**	**SC**	Drug elimination and clearance	• Describe the main routes of drug elimination (1,10) • Define the term "clearance" and its relationship to elimination half-life and volume of distribution (1,10) • Describe the renal clearance model based on renal blood flow, glomerular filtration and drug reabsorption (1,10)	Dr. Hao
11/7	**EXAM 2 (#5-8)* 11 AM**				
11/11	**10**	**SC**	Pharmacokinetics of oral absorption	• Discuss the oral one-compartment model and explain how this model simulates drug absorption from the GI tract (1,10) • Calculate the PK parameters of a drug that follows the oral one-compartment model (1,10)	Dr. Hao
11/12	**11**	**SC**	Pharmacokinetics of oral absorption	• Describe the model parameters that form the foundation of drug absorption and bioavailability of	Dr. Hao

				oral dosage forms (1,10)	
11/13	**12**	**SC**	Multiple dose regimens	• Define drug accumulation and drug accumulation half-life (1,10) • Calculate the steady-state C_{max} and C_{min} (1,10) • Calculate k and V_D of aminoglycosides in multiple-dose regimens and adjust regimens (1,5,6,10)	Dr. Hao
11/18	**13**	**SC**	Nonlinear pharmacokinetics	• Compare and contrast linear and nonlinear pharmacokinetics (1,10) • Discuss potential risks with drugs that follow nonlinear kinetics (1,10) • Estimate the dose for nonlinear drugs (1,5,10)	Dr. Hao
11/19	**14**	**SC**	Physiologic drug distribution and protein binding	• Discuss the physiology of drug distribution in the body (1,10) • Explain how distribution is affected by blood flow, protein and tissue binding (1,10)	Dr. Hao
11/20	**15**	**SC**	Physiologic drug distribution and protein binding	• Explain how volume of distribution, drug clearance, and half-life can be affected by protein binding (1,10) • Evaluate the impact of change in drug-protein binding or displacement on free drug concentration (1,10)	Dr. Hao
11/21	**EXAM 3 (#9-13)* 11 AM**				
12/2	**16**	**SC**	Drug elimination and hepatic clearance	• Describe the pathways for drug elimination (1,10) • Compare and contrast the clinical implications of hepatic and renal disease on drug therapy (1,5,6,7,10) • Explain the role of hepatic blood flow, drug protein binding, and intrinsic clearance on hepatic clearance (1,10)	Dr. Hao
12/3	**17**	**SC**	Drug elimination and hepatic clearance	• Discuss the biotransformation of drugs in the liver (1,10) • Explain the relationship between metabolic pathways and enzyme polymorphisms on intra-subject variability (1,10)	Dr. Hao
12/4	**18**	**SC**	Pharmacogenetics	• Define pharmacogenetics and pharmacogenomics (1,10)	Dr. Hao

				• Define genetic polymorphism and explain the difference between genotype and phenotype (1,10) • Explain with relevant examples how genetic variability influences drug response, PK and dosing regimens (1,5,6,7,10) • Discuss the genetic variability of CYP enzymes and influences on PK and dosing (1,5,6,710)	
12/5	**EXAM 4 (#14-17)* 11 AM**				
12/11	**FINAL EXAM (#1-18)* 11:00 AM**				

SC = Studio Classroom
*** - major assessments**

Course Evaluation (assessment):

At or near the end of the course, each student will have the opportunity to evaluate the instructor as well as course content via an anonymous assessment according to School of Pharmacy procedures.

Course Evaluation (grading):

Quizzes and exams will be given throughout the course. There will be a comprehensive final at the end of the course that will account for 15% of the course grade. In-class activities will be graded based on completeness and accuracy. The topic of presentations or case studies will be assigned to each group. These presentations will be subjected to peer evaluation and credit will be given for student questions and critique during the discussion period following each presentation.

Point or Percentage Distribution:

Quizzes	15%
Exams	40%
Comprehensive Final	15%
In-Class Activities	10%
Presentations	20%
Total	100%

Letter grades distribution:

A = 89.50 to 100%
B = 79.50 to less than 89.50%
C = 69.50 to less than 79.50%
F = Less than 69.50%

Assignment and examination grades will be posted in Blackboard within 7 days unless otherwise stated.

Attendance policy: *Each student is required to attend class. Attendance is mandatory at graded events. Only excused absences accepted – see university and school policies.*

UNIVERSITY POLICIES

University policies regarding **Academic Dishonesty, Students with Disabilities, University Computing Services' Acceptable Use**, **Affirmative Action, and Sexual Harassment can be found at http://www.marshall.edu/wpmu/academic-affairs/policies/.**

School of Pharmacy Policies

SOCIAL JUSTICE POLICY STATEMENT

Marshall University is committed to bringing about mutual understanding and respect among all individuals and groups at the University. As part of Marshall University, School of Pharmacy has made a commitment to social justice. Therefore, no one will be discriminated against on the basis of race, gender, ethnicity, age, sexual orientation, religion, social class, or differing viewpoints. Each student will be viewed as a valuable member of this class and as the faculty for the course, I will strive to facilitate an atmosphere/learning environment where mutual understanding and respect are actualized.

ACADEMIC, ETHICAL, AND PROFESSIONAL CONDUCT

Student expectorations for academic, ethical, and professional conduct are defined within the school's Ethical and Professional Conduct Policy and the university's Academic Dishonesty Policy.

Second Chance and Remediation Policy

Second chance and remediation are mechanisms designed to assist students who have struggled within the classroom environment in demonstrating achievement of classroom and curricular learning outcomes. These processes are described in sections 200.001.003 (Second Chance) and 200.001.004 (Remediation) of the Academic Standards for Grading, Progressions, Dismissal, and Re-admission Policy.

Test Security Policy

In order to ensure the security of all examinations, the School of Pharmacy has adopted the following policies:

1. Test Administration

A. Non-electronic testing
   a. Students may not access any electronic equipment during the exam that has not been provided by the faculty, including but not limited to calculators, cell phones, laptops and PDAs.

B. Electronic testing
   a. Only those resources (electronic or otherwise) approved by the instructor may be used or accessed during the testing session.
   b. Students enrolled within courses using electronic testing must download and install the Respondus Lockdown Browser. The installation will require an installation code that must be acquired from Computing Services.

2. Test Review

A. Students will not be allowed to view any exam without direct supervision of course faculty or site facilitator
B. Students must review tests within time specified by the course faculty.
C. Limited numbers of students may be allowed to view the exam at one time depending on office size, space, and faculty preference.
D. Students will be allowed to review the exam only one time, and time limits may be placed on review as specified by course faculty.
E. NO notes can be taken by the student while reviewing the test, and students are not allowed to access any electronics while reviewing the tests. NO copies electronic or written!
F. Individual student printouts for exams are to be retained by the faculty.
G. Faculty have the right to place further restrictions on test review as deemed necessary.