MARSHALL UNIVERSITY

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School of Pharmacy

SYLLABUS
Biopharmaceutics I
PHAR 531
(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.*

Course meeting days and time	Monday and Wednesday – 9:45 AM to 11:15 AM (Weeks 6–15; 9/29/14–12/3/14)
Location	L04
Team Leader / Instructor	Dr. Jinsong Hao
Office	CEB 201
Phone	(304) 696-3519
Email	haoj@marshall.edu
Office hours	Monday, 12 PM to 1 PM or 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 physicochemical principles of pharmacy, such as acid-base theory, solubility, physical states of drugs, thermodynamics, drug stability, excipients, surfactants, dispersions, polymers, drug delivery, chemical compatibility and interactions of drugs in various dosage forms

Prerequisites: P-1 status

Text Books:

Required:

A Practical Guide to Contemporary Pharmacy Practice, Third Edition
Authors: Judith E. Thompson and Lawrence W. Davidow
Lippincott Williams & Wilkins
ISBN 978-0781-7839-65

Physicochemical Principles of Pharmacy, Fifth Edition
Authors: Alexander T. Florence; David Attwood
Pharmaceutical Press, Royal Pharmaceutical Society, London, UK
ISBN 978-0853-6998-42

The clicker from Turning Technologies (Model: ResponseCard RF LCD)

Course Objectives:

Number	Objective	Linkage to MUSOP Abilities	How Assessed
1	Describe, interpret and apply the physical-chemical principles of drugs and dosage forms	1, 10	IRAT/GRAT and exams
2	Identify and predict the biological principles of drugs and dosage forms	1, 25	IRAT/GRAT and exams
3	Recognize and explain considerations in drug preformulation, excipients and packaging	1, 10, 25	IRAT/GRAT and exams
4	Define and classify the principles of dosage form stability and drug degradation in dosage forms	1, 10, 25	IRAT/GRAT and exams
5	Recall, summarize and elucidate the purpose and function of the following items: surfactants, emulsifying agents, solvents, preservatives, antioxidants, colors, flavors, sweeteners, and scents	1, 10, 25	IRAT/GRAT and exams
6	Describe important concepts related to physicochemical drug interactions and incompatibilities, pharmaceutical drug development, pharmacokinetics and drug dosage form evaluation	1,10,25	IRAT/GRAT and exams

Schedule of Activities:

Date	#	Meeting Format	Meeting Topic	Course Student Learning Outcomes	Instructor
9/29	**1**	Overview discussion (OD), in-class activity (ICA)	Course introduction; physical/bulk characteristics of solids	• Define and explain the similarities and differences between amorphous solids, crystal habits, polymorphs, solvates/hydrates and co-crystals (1,10) • Describe how crystallization occurs and how crystal habits can be modified (1,10) • Compare and contrast crystal habits and polymorphs (1,10) • Discuss the formation of polymorphs and crystal hydrates by some drugs and summarize the pharmaceutical consequences (1,10)	Dr. Hao
10/1	**2**	OD, ICA	Physical/bulk characteristics of solids	• Describe how changes in parameters of the Noyes-Whitney equation modify the rate of dissolution (1,10) • Explain the importance of particle size in terms of formulation and	Dr. Hao

				biopharmaceutics (1,10) • Define spreading wetting and immersional wetting and explain the significance of the contact angle (1, 10) • Define solid dispersions, eutectic, eutectic point (1,10)	
10/6	**3**	OD, ICA	Physicochemical properties of drugs in solution	• Review molarity, molality, millieqiuvalents, energy, enthalpy, entropy and free energy (1,10) • Define and explain osmotic pressure, osmolarity, and osmolality (1,10) • Explain and calculate tonicity (1, 25) • Describe and interpret the ionization of drugs in solution (1,10)	Dr. Hao
10/8	**4**	OD, ICA	Solubility	• Define and interpret solubility expressions and terms (1, 10) • Describe the process of solubility at a molecular level (1,10) • Describe and explain how certain factors affect solubility (1,10) • Interpret the solvent effects on solubility (1,10) • Explain the importance of cosolvent systems and perform cosolvent calculations (1, 25)	Dr. Hao
10/10	**EXAM 1 (MATERIAL: #1 – 4)* 2 PM**				
10/13	**5**	OD, ICA	Drug stability	• Identify classes of drugs that are particularly susceptible to chemical breakdown (1,10) • Compare and contrast the following types of decomposition: hydrolysis, oxidation, isomerization, photochemical decomposition and polymerization (1,10) • Classify and describe the kinetics of chemical decomposition (1,10) • Calculate desired variables of decomposition kinetics (10)	Dr. Hao
10/15	**6**	OD, ICA	Drug stability	• Compare and contrast the different types of solid state decomposition (1,10) • Describe the factors that influence solid and liquid form drug stability • Explain how manufacturers evaluate drug and dosage form stability and shelf-life (1,10,25) • Calculate shelf-life with changes in	Dr. Hao

				temperature (1,10,25)	
10/20	**7**	OD, ICA	Surfactants and emulsifying agents	• Define terms associated with surfactants and emulsifying agents (1) • Explain why certain molecules have the ability to lower surface and interfacial tension (1,10) • Illustrate the concept of CMC (1,10)	Dr. Hao
10/22	**8**	OD, ICA	Surfactants and emulsifying agents	• Describe the concept of solubilization (1,10) • Identify and describe the classes of pharmacy-related surfactants (1,25)	Dr. Hao
10/24	**EXAM 2 (MATERIAL: #5 – 8)* 2 PM**				
10/27	**9**	OD, ICA	Colloids, disperse systems and rheology	• Describe and explain the various aspects of emulsions and suspensions (1,10) • Define terms associated with emulsions and suspensions (1) • Explain the elements of colloid stability theory and formulation design (1,10,25) • Compare and contrast microemulsions, emulsions and liposomes (1,10)	Dr. Hao
10/29	**10**	OD, ICA	Colloids, disperse systems and rheology	• Recognize and describe pharmaceutical viscosity-inducing agents (1,10) • Describe the concept of viscosity and rheology (1,10)	Dr. Hao
11/3	**11**	OD, ICA	Polymers and macromolecules	• Recognize polymer structures and describe the properties of polymers in solution (1,10) • Compare and contrast the properties of polymer gels (1,10) • Describe the properties and uses of commonly used polymers in pharmacy and drug delivery (10,25)	Dr. Hao
11/5	**12**	OD, ICA	Pharmaceutical solvents	• Recognize and describe commonly used pharmaceutical solvents (1,10) • Compare and contrast the properties and incompatibilities of various pharmaceutical solvents (1,10)	Dr. Hao
11/10	**13**	OD, ICA	Preservatives and antioxidants	• Recognize and describe commonly used pharmaceutical preservatives and antioxidants (1,10) • Compare and contrast the properties and incompatibilities of various pharmaceutical preservatives and	Dr. Hao

				antioxidants (1,10)	
11/12	**14**	OD, ICA	Colors, flavors sweeteners and scents	• Recognize and describe commonly used pharmaceutical colors, flavors, sweeteners and scents (1,10) • Compare and contrast the properties and incompatibilities of various pharmaceutical colors, flavors, sweeteners and scents (1,10)	Dr. Hao
11/14	**EXAM 3 (MATERIAL: #9 – 14)* 2 PM**				
11/17	**15**	OD, ICA	Physicochemical drug interactions and incompatibilities	• Describe and elucidate possible physicochemical drug-drug or drug-excipient interactions (1,10) • Explain and give examples of other possible incompatibilities, such as chelation, protein binding and adsorption issues (1,10)	Dr. Hao
11/19	**16**	OD, ICA	Drug development	• Describe the drug development process (1,10) • Compare and contrast the various stages of drug development (1,10)	Dr. Hao
11/24 - 11/28	**FALL BREAK NO CLASS**				
12/1	**17**	OD, ICA	Introduction to pharmacokinetics	• Explain the processes that occur during each of the following pharmacokinetic stages: liberation, absorption, distribution, metabolism, and excretion (1,10) • Differentiate the concepts of pharmacokinetics and pharmacodynamics (1,10)	Dr. Hao
12/3	**18**	OD, ICA	Physical assessment of dosage forms	• Describe how solid dosage forms are evaluated in terms of dissolution, rheological characteristics, and adhesivity (1,10,25) • Discuss the Biopharmaceutics Classification System (BCS), (1,10) • Compare and contrast the steps for a generic product approval versus a brand name product (1,10,25) • Create a protocol to test a hypothetical drug dosage form (1,10)	Dr. Hao
12/9	**CUMULATIVE FINAL EXAM (MATERIAL: #1 – 18)* 2 PM**				

*** -indicates major assessment**

Course Evaluation (grading): Student mastery of the material will be evaluated by quizzes and exams administered throughout the semester. The majority of testable material will originate from instructor-provided handouts (≥80%). The remaining testable material will be presented during class sessions. In-class activities will assess student understanding of the material and will be graded based on completeness and accuracy.

Point or Percentage Distribution:	Quizzes:	15%
	Exams:	45%
	In-Class Activities:	20%
	Final Exam:	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%

Course Evaluation (assessment): At or near the end of the course, students are expected to complete an evaluation of the course content, learning approaches, student assessment and instructors according to School of Pharmacy procedures.

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

Attendance policy: Each student is expected to attend class. Attendance at graded events is mandatory. Only excused absences accepted – see university and school policies. The instructor must be contacted prior to the exam, unless circumstances are prohibitory. Please note – the student is solely responsible for any materials missed.

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.

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.