MARSHALL UNIVERSITY
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School of Pharmacy

SYLLABUS
Biopharmaceutics II
PHAR 532
(Spring 2016)

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 and Thursday 10:15-11:45
Location	CEB L04
Team Leader / Instructor	Cynthia B. Jones, Ph.D.
Office	MEB 228A/230
Phone	(304) 696-7363
Email	Jonescy@marshall.edu
Office hours	Monday and Wednesday 12:00 p.m. - 1:00 p.m. and by Appt.

Faculty	Email	Office	Phone Number	Office Hours / Appointments accepted?
Hasan Koc, Ph.D.	kocha@marshall.edu	217A	(304)696-7368	By appointment only
Brian Train, Ph.D.	trainb@marshall.edu	235	(304)696-5807	Mon & Wed 12:00 to 1:00 p.m. or by appointment
Cynthia B. Jones, Ph.D.	Jonescy@marshall.edu	228A	(304)696-7363	Tue & Thurs. 12:00 to 1:00 p.m. 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 mechanisms of both immediate and sustained drug release in formulations involving solid and semi-solid systems; introduction to novel drug delivery systems; drug pre-formulation, drug preparation, liberation, absorption and stability of dosage.

Prerequisites: P-1 status

Text Book(s)

Required:

Gibaldi's Drug Delivery Systems in Pharmaceutical Care
Editors: Archana Desai and Mary Lee
ISBN 978-1-58528-136-7

Recommended:

Physicochemical Principles of Pharmacy 5th ed.
Authors: Alexander T. Florence and David Attwood
ISBN-13: 978-0853699842

Materials:

Required

Turning Point technology ResponseCard NXT (Clicker)

Course Objectives

Number	Objective	Linkage to MUSOP Abilities	How Assessed
1	Recognize, interpret, and analyze the mechanisms of immediate and sustained release formulations	1, 10	IRAT/GRAT and exams
2	Describe the basic physiological characteristics of different routes of administration	1, 10	IRAT/GRAT and exams
3	Identify, compare and contrast the delivery systems involving oral, topical, transdermal, ocular, nasal, otic, pulmonary, rectal, vaginal, and parenteral routes of administrations	1, 10, 68	IRAT/GRAT and exams
4	Explain and interpret the technological advances in drug delivery systems	1, 10, 68	IRAT/GRAT and exams
5	Describe, compare and contrast drug delivery systems in special populations (pediatric, geriatric and veterinary)	1, 10	IRAT/GRAT and exams

Schedule of Activities:

Date	Meeting #	Meeting Format	Meeting Topic	Course Student Learning Outcomes	Instructor
1/12	1	Overview discussion (OD), In-class Activity (ICA)	Chapter 1 History of physical pharmacy, drug delivery and pharmaceutics	• Describe the role of the pharmacist in the history of drug delivery (1, 10) • Understand the impact of drug formulations on bioavailability and dosing frequency (1, 10)	Dr. Jones
1/14	2	IRAT/GRAT, OD, ICA	Chapter 2 Review LADME scheme and Pharmacokinetic Parameters	• Describe each step of the LADME scheme (1, 10) • Describe the pharmacokinetic parameters for drug disposition & input (1, 6, 10)	Dr. Jones

				• Explain the effects of dosage formulations on concentration versus time curve (1, 6, 10)	
1/19	3	IRAT/GRAT, OD, ICA	Drug Absorption and routes of administration	• Review lipophilicity, permeability and pH-Partition Hypothesis (1, 10) • Examine the various routes of administration for drug delivery (1, 10) • Describe and explain the role of biological membranes in drug transport (1, 10) • Identify and describe various factors that affect drug absorption (1, 10)	Dr. Jones
1/21	4	IRAT/GRAT, OD, ICA	Enteral Drug Delivery: Oral Delivery Systems	• Review the anatomy and physiology of the gastrointestinal tract (1, 10) • Describe the physicochemical properties of drugs (1, 10) • Compare and contrast films, gelatin capsules, bulk powder, divided powders, solutions, suspensions and emulsions (1, 10) • Define comminution, trituration, pulverization by intervention, spirits, tinctures, aromatic water, elixirs and syrups (1,10)	Dr. Jones
1/26	5	IRAT/GRAT, OD, ICA	Enteral Drug Delivery: Oral Delivery Systems (continued)	• Explain the role of excipients in tablet formulations (1,10) • Describe the process of tablet making (1,10)	Dr. Jones

				• manufacturing process (1,10) • Identify the various components of tablets (1,10) • Explain problems associated with the tablet (1,10) • Describe effervescent tablets and ODT formulations (1,10) • Describe and differentiate matrix and reservoir systems (1, 10, 68)	
1/28	6	IRAT/GRAT, OD, ICA	Enteral Drug Delivery: Rectal Delivery Systems	• Review the anatomy and physiology of the rectum (1, 10) • Describe and explain the factors that influence drug delivery to the rectum (1, 10) • Compare and contrast different types of suppository bases (1,10) • Discuss the advantages and disadvantages of various rectal delivery systems (1, 10)	Dr. Jones
2/2	7	IRAT/GRAT, OD, ICA	Parenteral Drug Delivery Systems	• Compare and contrast the common routes of parental delivery (1, 10) • Describe the general characteristics of parental delivery systems (1, 10) • Identify and explain the components of parental formulations (1, 10) • Explain drug release from injectable preparations (1, 10) • Describe the use of specialized parental	Dr. Jones

				delivery devices (1, 10)	
2/4	8	IRAT/GRAT, OD, ICA	Parenteral Drug Delivery Systems (Continued)	• See above	Dr. Jones
2/5	**EXAM 1 (MATERIAL #1-8) Friday 2:00 p.m. – 4:00 p.m.**				
2/9	9	IRAT/GRAT, OD, ICA	Topical Delivery Systems	• Review the anatomy and physiology of the skin (1, 10) • Compare and contrast topical and transdermal formulations (1, 10) • Recognize and explain the different types of commonly used topical and transdermal formulations (1, 10) • Compare and contrast ointments, creams, pastes, lotions and gels (1,10) • Describe the properties of various ointment and cream bases (1,10) • Identify and describe the components of transdermal patches (1, 10) • Indicate the appropriate handling and disposal of transdermal patches (68)	Dr. Jones
2/11	10	IRAT/GRAT, OD, ICA	Transdermal Delivery Systems (continued)	See above	Dr. Jones
2/16	11	IRAT/GRAT, OD, ICA	Ocular Delivery Systems	• Review the anatomy and physiology of the eye (1, 10) • Describe and examine the advantages and disadvantages of topical versus systemic ophthalmic formulations (1, 10)	Dr. Jones

				• Compare and contrast the three different types of ophthalmic formulations (1, 10) • Discuss the use of matrix-type implants, reservoir implants and injections to the eye (1, 10) • Describe the proper technique of administering an eye drop (10)	
2/18	12	IRAT/GRAT, OD, ICA	Nasal Delivery Systems	• Review the anatomy and physiology of the nose (1, 10) • Discuss the advantages and disadvantages of nasal delivery (1, 10) • Describe and interpret conditions and properties that affect nasal drug absorption (1, 10)	Dr. Jones
2/23	13	IRAT/GRAT, OD, ICA	Otic Delivery Systems	• Review the anatomy and physiology of the ear (1, 10) • Discuss the significance of various physicochemical properties of drugs in otic formulations (1, 10) • Describe and explain the advantages and disadvantages of system versus direct application to the inner ear (68)	Dr. Jones
2/25	14	IRAT/GRAT, OD, ICA	Pulmonary Delivery Systems	• Review the anatomy and physiology of the lungs (1, 10) • Discuss and explain the rationale for pulmonary delivery versus systemic delivery (1, 10)	Dr. Jones

				• Describe and identify the drug formulation and particle characteristics for optimal pulmonary delivery (10) • Compare and contrast the advantages and disadvantages of three pulmonary delivery devices (68) • Discuss and analyze the properties of the lung and drugs that affect retention, absorption and removal of drug from the lung (1, 10)	
3/1	15	ICA	Pulmonary Delivery Systems (Continued)	See above	Dr. Jones
3/3	16	IRAT/GRAT, OD, ICA	Vaginal and Urethral Delivery Systems	• Review the anatomy and physiology of the vagina and urethra (1, 10) • Discuss the factors influencing drug delivery and absorption from the vagina and urethra (1, 10) • Describe the types of bases used in vaginal and urethral suppositories (1,10) • Describe the advantages and disadvantages of the vaginal delivery route (1, 10)	Dr. Jones
3/7	**EXAM 2 (MATERIAL #9-16) Monday 6:00 p.m. – 8:00 p.m.**				
3/8	17	IRAT/GRAT, OD, ICA	Chemical Modification (Prodrugs)	• Identify and describe the classifications of prodrugs (1, 10) • Discuss and explain the rationale of prodrug design and development (1, 10)	Dr. Jones

				• Recognize and describe modification of functional groups in the design of prodrugs (1, 10) • Examine and describe the application of prodrugs to overcome specific drug delivery barriers (1, 10)	
3/10	18	IRAT/GRAT, OD, ICA	Chemical Modification (Prodrugs)	• See above	Dr. Jones
3/15	19	IRAT/GRAT, OD, ICA	Biotechnology	• Discuss and explain why protein-based pharmaceuticals pose unique challenges for development, production, formulation, administration, and storage compared to small molecule drugs (1, 10, 68) • Describe and examine the rationale for post-translational modification of protein pharmaceuticals (1, 10) • Discuss and distinguish the primary safety issues related to the manufacturing of protein pharmaceuticals (1, 10, 68) • Identify and describe the classes of biotechnology-derived therapeutic agents and their primary clinical function (1, 10) • Compare and contrast the formulative and clinical advantages and disadvantages of	Dr. Train Dr. Koc

				the various routes of administration of biotech drugs (1, 10)	
3/17	20	OD, ICA	Biotechnology (continued)	See above	Dr. Train Dr. Koc
03/21-03/26	**SPRING BREAK**				
3/29	21	IRAT/GRATE OD, ICA	Biotechnology (continued)	• See above	Dr. Train Dr. Koc
3/31	22	IRAT/GRAT, OD, ICA	Special Populations – Pediatric DS	• Discuss and explain the differences between adult and pediatric physiology (1, 10) • Review the role of the child as a "therapeutic orphan" (10) • Explain and analyze the importance of proper dosage formulations in children (1, 10) • Name and discuss the barriers to using specific dosage formulations in children (10)	Dr. Jones
4/5	23	IRAT/GRAT, OD, ICA	Special Populations – Geriatric Delivery Systems	• Discuss and explain medication use in older adults (10) Describe and analyze the pharmacokinetic changes in older adults (10) • Discuss and interpret the advantages and disadvantages of using alternative dosage formulations in the geriatric population (1, 10)	Dr. Jones
4/7	24	IRAT/GRAT, OD, ICA	Veterinary Delivery Systems	• Discuss and explain the differences between human and veterinary compounding (1, 10)	Dr. Jones

				• Review and examine the common veterinary dosage forms (1, 10) • Describe and distinguish the advantages and disadvantages of the various veterinary dosage forms (1, 10)	
4/12	25	IRAT/GRAT, OD, ICA	Drug delivery in Endocrine Disorders	• Compare and contrast the pharmacokinetic properties of diabetic drugs (1, 10, 67) • Describe dosage formulations available to treat patients with endocrine disorders (1, 10, 67)	Dr. Jones
4/14	26	IRAT/GRAT, OD, ICA	Drug delivery in Oncologic Disorders	• Describe how chemotherapy and immunotherapy are used to treat cancers (1, 10, 67) • Compare and contrast drug delivery of chemotherapeutic and immunologic agents by different routes of administration (1, 10, 67) • Describe and explain why different routes of administration are preferred or required in cancer treatment (1, 10, 67) • Identify the hazards when handling, preparing and administering chemotherapeutic agents (1, 10, 67)	Dr. Jones
4/15	**EXAM 3 (MATERIAL #17-24) Friday 2:00 p.m. – 4:00 p.m.**				
4/19	27	IRAT/GRAT, OD, ICA	Drug delivery in Bacterial Infections	• Identify and explain various antimicrobial dosage formulations	Dr. Jones

				based on therapeutic category (1, 10, 67) • Define dosage formulations for selected antimicrobials in the treatment of various infectious diseases (1, 10, 67) • Explain the rational for the various types of dosage formulations necessary for a given antimicrobial (1, 10, 67)	
4/21	28	IRAT/GRAT, OD, ICA	Drug delivery in Fungal, Mycobacterial and Parasitic Infections	• Identify and explain various dosage formulations for antifungals, antimycobacterials and antiparasitics (1, 10, 67) • Compare and contrast the parenteral formulations of amphotericin B (1, 10, 67) • Discuss and explain the rationale for combination drug dosage formulations of antimycobaterial drugs (1, 10, 67) • Compare and contrast indications of the cream, lotion, shampoo, and spray dosage formulation for antiscabies drugs (1, 10, 67)	Dr. Jones
4/26	Review Session				
4/28	No Class				
5/3	**FINAL EXAM (CUMULATIVE)* – Tuesday 2:00 p.m. – 4:00 p.m.**				

*** -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: IRAT/GRAT: 15%
Exams: 50%
In-class Activities: 10%
Final Exam: 25%

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.
    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.