



Course Syllabus for:
PHAR 632
BIOPHARMACEUTICS DRUG DELIVERY AND CALCULATIONS

Course Unit Value: 5

Calendar of Important Dates

Friday September 25th -----Midterm Exam I
Friday October 30th -----Midterm Exam II
December TBD -----Cumulative Final Exam

Course Coordinator, Instructors and Contact Information

Dr. Eman Atef (Co-Coordinator)

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Dr. Rania Elkeeb (Co-Coordinator)

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Classroom and Meeting Times

Room: Classroom 2A
Time: 9:15 am to 12:00 pm TUES, THUR
9:30 am to 11:30 am FRI

Course Description

This course is designed to give students an appreciation of the formulation, manufacture, and testing of dosage forms as well as an understanding of the interactions between complex drug delivery systems and biological systems. The course covers all the basic dosage forms and drug delivery systems as well as the routes of administration, absorption, and bioavailability. The course will also cover pharmaceutical calculations and some elements of compounding. It presents an overview of drug quality control and regulation.

Prerequisite Courses

- None

Prerequisite Knowledge

- Basic Physical Chemistry concepts such as pH and diffusion
- Basic physiological concepts such as absorption, stomach emptying and gastro-intestinal transit
- Basic arithmetic concepts such as fractions, decimals, percent, ratio and proportion – see first web link for a good website to review basic arithmetic operations
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Required Textbook(s) and Material(s)

1. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems (ISBN 978-1451188769) by Loyd V. Allen, Nicholas G. Popovich, and Howard C. Ansel, 10th Ed., Lippincott Williams & Wilkins.
2. Pharmaceutical Calculations, Howard C. Ansel and Mitchell J. Stoklosa, (ISBN 978-1451120363) 14th Ed, Lippincott Williams & Wilkins.

Optional Textbook(s) and Material(s)

1. Modern Pharmaceutics by Banker and Rhodes. Taylor and Francis. ISBN 9780824706746

Web Links

1. A good source for basic arithmetic information and to revise calculation skills <http://www.themathpage.com/ARITH/arithmetic.htm>
2. Electronic Orange Book.
<http://www.fda.gov/cder/ob/>
3. FDA website.
<http://www.fda.gov>

Technology

1. Computer-assisted instruction (Clickers) and SCANTRON Sheets
2. Web-based course management (ASAP)
3. Audio/Video recordings and demonstrations where applicable

Evaluation Components

In keeping with the Team Based Learning (TBL) approach, Grades will be determined as follows:

Individual Components	70%
Lab	8%
Individual Readiness Assurance Test (iRAT)	8%
Midterm Exam I	18%
Midterm Exam II	18%
Cumulative Final Exam	18%
Team Components	30%
Team Readiness Assessment Test (tRAT)	12%
Team Application Exercises	15%
Peer Evaluation	3%

Grade Legend:

90.0-100%	A
80.0-89.9%	B
70.0-79.9%	C
60.0-69.9%	D
Below 60.0%	F

Grading related policies Within the course.

- 1- Students who score 70.0% or less in any midterm are placed on Academic Alert.
- 2- Any student who scores less than 70% in any midterm **is required to** email the course coordinator to schedule a meeting within a week of the grades being posted to discuss possible plan of improvement, extra help needs and to sign off the Academic Alert form.
- 3- Grades can only be disputed within two weeks of the posting dates.
- 4- Any individual assignment that is submitted without name or team work without team number will receive a **ZERO**
- 5- Viewing any exam is allowed till the next major exam date. In other words students cannot view midterm one after midterm two is administered.

Topics and Schedule

(Subject to change, updates will be posted and announced by email)

Handouts are provided for each class along with the reading assignments from the text books

Day	Date	Topics	Text books reading assignment
*Tuesday	Aug 25	A Introduction to Course and Overview of Basic Calculation Skills	Chapter 1 (page1-7) (1)
*Thursday	Aug 27	A Routes of Drug Administration	Handout (2)
*Friday	Aug 28	A CALC ¹ : Basic Calculation Introduction: Skills and Estimation Methods for Calculations (session 1)	Chapter 1 (1) Some Applications from Chapter 6
*Tuesday	Sep 1	A CALC ¹ : Basic Calculation Introduction: Percentage, Ratio strength (session 2)	Chapter 6 (1)
*Thursday	Sep 3	A CALC ¹ : Pharmaceutical Measurements. Pharmaceutical calculations, aliquot and percentage errors	Chapter 3 (1)
Friday	Sep 4	A Workshop Percentages, ratios, ratio strength	Chapter 6
*Tuesday	Sep 8	A CALC ¹ : Concentrations, Density and SG	Chapter 5 (1)

*Thursday	Sep 10	A CALC ¹ : Calculations of doses: Patient parameters/ body surface are and chemotherapy	Chapter 8 (1)
Friday	Sep 11	A Workshop	
*Tuesday	Sep 15	E Oral Route Handout	Use the Handout (2)
*Thursday	Sep 17	E Pharmaceutical Solutions	Use the Handout (2)
Friday	Sep 18	E Workshop	
*Tuesday	Sep 22	A CALC ¹ : Isotonicity and Buffers	Chapter 11 guided reading (1)
Thursday	Sep 24	A Review	
Friday	Sep 25	Midterm Exam I	
*Tuesday	Sep 29	E Emulsions	Chapter 14 guided reading (2)
*Thursday	Oct 1	A CALC ¹ : Millimoles CALC ¹ : Milliequivalents	Chapter 12, (1)
Friday	Oct 2	E Workshop	
*Tuesday	Oct 5	E Pharmaceutical Suspensions	Handout (2)
*Thursday	Oct 8	A CALC ¹ : Osmolarity ^a	Chapter 12 (1)
Friday	Oct 9	A Workshop	
*Tuesday	Oct 13	E Pharmaceutical Powders	Handout (2)
		Granulation	Chapter 8 ² supplemented with brief notes (2)
*Thursday	Oct 15	E Tablets & Capsule	Chapter 8 ² supplemented with brief notes
		Capsule	Handout
Friday	Oct 16	E Workshop	
*Tuesday	Oct 20	E Colonic Delivery	Handout (2)
		Modified Release	Handout (2)
*Thursday	Oct 22	A CALC ¹ : Stocks, Alligation and Application to Mixtures	Chapter 15 (1)
Friday	Oct 23	A Workshop	
*Tuesday	Oct 27	E Review	

*Thursday	Oct 29	^E Buccal and Sublingual Delivery	Handout (2)
Friday	Oct 30	Midterm Exam II	
*Tuesday	Nov 3	^E Transdermal Delivery	Handout (2)
*Thursday	Nov 5	^E Vaginal and Rectal Delivery Handout	Handout (2)
Friday	Nov 6	^E Workshop	
*Tuesday	Nov 10	^A CALC ¹ : IV infusions	(1)
*Thursday	Nov 12	^A CALC ¹ : Parenteral Admixtures Dr.Atef	(1)
Friday	Nov 13	^A Workshop	
*Tuesday	Nov 17	^E Lab Group 1	Handout
*Thursday	Nov 19	^E Lab Group 2	Handout
*Friday	Nov 20	^E Lab Group 3	Handout
*Tuesday	Nov 24	^E Aerosols and Pulmonary Delivery	Chapter 14 (2) and brief notes
Thursday	Nov 26	Thanksgiving Holiday	
*Tuesday	Dec 1	^E Ophthalmic and Nasal Delivery Chapter 17 ² and Handout	Chapter17 (2) and Handout
*Thursday	Dec 3	^E Dosage Form Stability	Handout
Friday	Dec 4	^E Workshop	
Tuesday	Dec 8	^E Review	

*Indicates the days iRAT/tRAT are scheduled

(1) indicates guided reading from "Pharmaceutical Calculations, Howard C. Ansel and Mitchell J. Stoklosa, 14th Ed, Lippincott Williams & Wilkins.

(2) indicates guided reading from Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems by Loyd V. Allen, Nicholas G. Popovich, and Howard C. Ansel , 10th Ed., Lippincott Williams & Wilkins..

Labs: Groups of students rotate through the labs. Groups required to start at 9 am and finish at 12 pm will be notified. Handouts on the detailed steps of the lab will be posted

"A" Instructor for these classes are Dr. Eman Atef and "E" Dr. Rania Elkeeb .

Course Learning Outcomes

No.	Learning Outcome	CNUCOP PLO/ ILO	ACPE Standard Addressed _b	CAPE Outcomes ^c	Learning Hierarchy _d	Assessment Method ^e
1	Evaluate the utility of various dosage forms, demonstrate an understanding of their formulation and quality, and show competence in identifying problems and offering solutions.	PLO 1.1, 1.2, 2.1 ILO 1.1,1.4, 1.6, 2.1	1.1	1.1.1 1.1.2 2.2.2	1,2, 3	iRAT, tRAT, MT, BAT, RUB
2	Demonstrate the ability to accurately perform pharmaceutical calculations.	PLO1.2. 2.1,3.1 ILO 1.1,2.1, 4.3, 5.1	1.1 2.1	1.1.1 1.1.2 2.1.1	1, 2	iRAT, tRAT, MT, BAT, RUB
3	Evaluate the impact of the dosage form on the body and the impact of biological factors on the dosage form, and estimate the qualitative effects of these factors on drug absorption and bioavailability.	PLO 1.1, 1.2, 2.1, 3.6 ILO 1.1, 1.4, 1.6,2.1	1.1 2.1 3.1	1.1.1 1.1.2 2.1.1 2.2.2 3.1.1 3.1.2	1, 2,3	iRAT, tRAT, MT, BAT, RUB

^a CNUCOP (2012-present) Program Learning Outcomes (P1-5), Institution Learning Outcomes (I1-6), Co-curricular Learning Outcomes (C1-3)

^b ACPE Standard as listed in the outline for ACPE Standards and Guidelines (e.g. placing 2.B.3. in the column would represent "2. Pharmaceutical Sciences B. Pharmacology 3. Pharmacodynamics of drug action" from the ACPE Standards and Guidelines Outline);

^c CAPE Supplemental Educational Outcomes (2013) as listed in the outline; Please map to the following words as defined by CAPE:

1.1. Learner (Learner), 2.1. Patient-centered care (Caregiver), 2.2. Medication use systems management (Manager), 2.3. Health and wellness (Promoter), 2.4. Population-based care (Provider), 3.1. Problem Solving (Problem Solver), 3.2. Educator (Educator), 3.3. Patient Advocacy (Advocate), 3.4. Interprofessional collaboration (Collaborator), 3.5. Cultural sensitivity (Includer), 3.6. Communication (Communicator), 4.1. Self-awareness (Self-aware), 4.2. Leadership (Leader), 4.3. Innovation and Entrepreneurship (Innovator), 4.4. Professionalism (Professional).

^d Learning Hierarchy based on Bloom's Taxonomy with 1=Memorization and/or Comprehension; 2=Application and/or Analysis; 3=Synthesis and/or Evaluation. ^e Suggestions include (but not limited to) iRAT=Individual Readiness Assurance Test; tRAT=team Readiness Assurance Test; MT=Midterm Exams; BAT=Application Exercises; RUB=Rubrics; LAB=Laboratory.

Teaching/ Learning Methodology

1. Team-based learning (TBL)
 - a. Individual and Team Readiness Assurance Test (iRAT/tRAT)
 - b. Application exercises
 - c. class discussions
2. Directed reading
3. Labs

CLO #1: Evaluate the utility of various dosage forms, demonstrate an understanding of their formulation and quality, and show competence in identifying problems and offering solutions.

Indicators	initial	Developing	Developed	Proficient
Demonstrate a knowledge of the various dosage forms and evaluate their utility	Rarely demonstrates a knowledge of dosage forms and the ability to evaluate them	Occasionally demonstrates a knowledge of dosage forms and an ability to evaluate them	Frequently demonstrates a knowledge of all the described dosage forms and an ability to evaluate them	Consistently demonstrates a knowledge of all the described dosage forms and an ability to evaluates them
Display an understanding of the factors affecting the formulation of dosage forms including physical pharmacy concepts	Rarely demonstrates an understanding of formulation factors and physical pharmacy concepts	Occasionally demonstrates an understanding of formulation factors and physical pharmacy concepts	Frequently demonstrates an understanding of formulation factors and physical pharmacy concepts	Consistently demonstrates an understanding of formulation factors and physical pharmacy concepts
Identify potential problems in dosage forms, critically evaluate test data, and offer solutions	Rarely demonstrates an ability to identify problems, to evaluate data and to offer solutions	Occasionally demonstrates an ability to identify problems, to evaluate data, and to offer solutions	Frequently demonstrates an ability to identify problems, to evaluate data and to offer solutions	Consistently able to identify problems, to evaluate data and to offer solutions

CLO #2: Demonstrate the ability to accurately perform pharmaceutical calculations and graphically represent data.

Indicators	initial	Developing	Developed	Proficient
Displays a good understanding of the problem and the steps needed to arrive at the answer	Rarely demonstrates an understanding of the problem and the steps needed for its solution	Occasionally demonstrates an understanding of the problem and the steps required for its solution	Frequently demonstrates an understanding of the problem and the steps needed to solve the problem	Consistently demonstrates an understanding of the problem and the steps needed to solve the problem
Performs mechanical calculation steps correctly	Rarely demonstrates the ability to perform mechanical calculation steps correctly	Occasionally demonstrates the ability to perform mechanical calculation steps correctly	Frequently demonstrates the ability to perform mechanical calculation steps correctly	Consistently demonstrates the ability to perform mechanical calculation steps correctly
Draws and interprets graphs accurately	Rarely demonstrates the ability to draw graphs and interpret them accurately	Occasionally demonstrates the ability to draw graphs and interpret them accurately	Frequently demonstrates the ability to draw graphs and interpret them accurately	Consistently demonstrates the ability to draw graphs and interpret them accurately

CLO #3: Evaluate the impact of the dosage form on the body and the impact of biological factors on the dosage form, and estimate the qualitative effects of these factors on drug absorption and bioavailability.

Indicators	initial	Developing	Developed	Proficient
Displays knowledge of the interaction of the dosage form and biological systems.	Rarely demonstrates an understanding of these interactions	Occasionally demonstrates an understanding of these interactions	Frequently demonstrates an understanding of these interactions	Consistently demonstrates an understanding of these interactions
Interprets the interaction between biological and dosage form factors	Rarely demonstrates an understanding of these interactions	Occasionally demonstrates an understanding of these interactions	Frequently demonstrates an understanding of these interactions	Consistently demonstrates an understanding of these interactions
Understands the impact of the previous interaction on drug absorption and bioavailability	Rarely demonstrates an understanding of the impact of the interaction on drug absorption and bioavailability	Occasionally demonstrates an understanding of the impact of the interaction on drug absorption and bioavailability	Frequently demonstrates an understanding of the impact of the interaction on drug absorption and bioavailability	Consistently demonstrates an understanding of the impact of the interaction on drug absorption and bioavailability