



INTRO. TO DRUG FORMULATION | CHM 4274 | 3 Credit hours

Instructor: Dr. Shailaja Kesaraju Allani Term: SPRING 2021
Office: PS 336A Class Meeting days: TBA
Office hours: TBA Class Meeting Hours: TBA
E-mail: skesaraj@fau.edu Class Location: TBA, Boca Raton
Phone: 561-297-4972

II. Course description

This course provides an introduction to drug formulation. Students will learn about drug discovery, pharmacology, toxicology and formulation. Students will be introduced to different forms of drug formulation, various routes of administration and assays to analyze these dosage forms. A laboratory portion will be included that will involve analytical assays for suspensions and solid dosage forms.

III. Course Prerequisites

CHM 2211; CHM 4270;

IV. Required texts

No texts required.

VI. Course objective

This course introduces the role of formulation in drug discovery and development. It will cover a range of topics from history of medicinal chemistry to modern rational drug design by reviewing the fundamentals of medicinal chemistry, pharmacokinetics and toxicology leading to formulation of a drug and its analysis. Experts in drug discovery, formulation and analytical development will present lectures on these topics. It will include lead identification of drugs through targeted approaches, pharmacokinetics, pre-formulation studies, formulation design and analytical approaches.

Learning outcomes:

- Understand different steps that are critical in drug discovery
- Understand the underlying chemistry of drug design
- Understanding of drug metabolism and Pharmacokinetics

- Basic understanding of the concept of toxicology in drug development
- Understand fundamentals of Pre-Formulation
- Hands on experience in laboratory sessions by various types of formulation design (tablets, emulsions, liquids etc.)
- Understand fundamentals of Analytical Development in pharmaceutical industry.

VII. Course Evaluation

The course grade is based on

- attendance 20%,
- Midterm 35%
- Final 35%
- Homework 10%

Homework assignments will be research papers given bi –weekly throughout the course. Students are required to review and analyze the research paper. Students are required to submit 1-2 page evaluation including other references of the research article how it advanced drug discovery and formulation. Assignment must include introduction to the topic, critique of methods and results and your conclusions on the article.

VIII. Course Grading Scale

A+ 93% & above

A 90-92%

B+ 87-89%

B 83-86%

B- 80-82%

C+ 77-79%

C 73-76%

C- 70-72%

D+ 67-69%

D 63-66%

D- 60-62%

F 59% & below

IX. Special Course Requirements

None

X. Policy on make-up exams, late work and incompletes

Students must be present for midterm and final exams. If there is an emergency situation, the instructor must be notified via e-mail prior to the exam with a legitimate proof. Late assignments will not be accepted and no exceptions will be made.

XI. Classroom etiquette policy

Attendance is mandatory. There are no more than 2 excused absences. University policy on electronic devices "In order to enhance and maintain productive atmosphere for education, personal communication such as cellular telephones and pagers, are to be disable in class sessions". Use of laptop or tablets and arriving late or leaving early is not permitted.

XII. Attendance Policy

Students are expected to attend all of their scheduled University classes and to satisfy all academic objectives as outlined by the instructor. The effect of absences

upon grades is determined by the instructor, and the University reserves the right to deal at any time with individual cases of non-attendance.

Students are responsible for arranging to make up work missed because of legitimate class absence, such as illness, family emergencies, military obligation, court-imposed legal obligations or participation in University- approved activities. Examples of University-approved reasons for absences include participating on an athletic or scholastic team, musical and theatrical performances and debate activities. It is the student's responsibility to give the instructor notice prior to any anticipated absences and within a reasonable amount of time after an unanticipated absence, ordinarily by the next scheduled class meeting. Instructors must allow each student who is absent for a University-approved reason the opportunity to make up work missed without any reduction in the student's final grade as a direct result of such absence.

XIII. Disability Policy Statement

In compliance with the Americans with Disabilities Act (ADA), students who require reasonable accommodations due to a disability to properly execute coursework must register with the Office of Student Accessibility Services (SAS) and follow all SAS procedures. SAS has offices across three of FAU's campuses- Boca Raton, Davie, and Jupiter, however, disability services are available for students on all campuses.

XIV. Code of Academic Integrity Policy Statement

Students at Florida Atlantic University are expected to maintain the highest ethical standards. Academic dishonesty is considered a serious breach of these ethical standards, because it interferes with the university mission to provide a high quality education in which no student enjoys an unfair advantage over any other.

Academic dishonesty is also destructive of the university community, which is grounded in a system of mutual trust and places high value on personal integrity and individual responsibility. Harsh penalties are associated with academic dishonesty. For more information, see University Regulation 4.001”.

http://www.fau.edu/ctl/4.001_Code_of_Academic_Integrity.pdf

XV. Religious Accommodations:

Students have the right to reasonable accommodations from the University in order to observe religious practices and beliefs. If a student is going to miss class due to a religious observance, they must notify the instructor no later than the second week of the term. For more information, go to:

<http://www.fau.edu/regulations/chapter2/>.

XVI. Counseling and Psychological Services (CAPS) Center

Life as a university student can be challenging physically, mentally and emotionally. Students who find stress negatively affecting their ability to achieve academic or personal goals may wish to consider utilizing FAU's Counseling and Psychological Services (CAPS) Center. CAPS provides FAU students a range of services – individual counseling, support meetings, and psychiatric services, to name a few – offered to help improve and maintain emotional well-being. For more information... <http://www.fau.edu/counseling/>.

XVII. Course Outline

*Tentative Course outline (subject to change): Drug Discovery and Formulations

#	Lecture *	Homework
1	Course Intro	
2	Overview – Drug Discovery and Formulation	Article 1
3	Drug Discovery/Medicinal Chemistry	Article 1
4	Drug Toxicology	Article 1
5	Drug Metabolism and Pharmacokinetics (DMPK)	Article 2
6	Pre-Formulation (API characterization, modifications, salt forms, solubilities, compatibilities)	Article 2
7	Semisolids and Liquids	Article 2
8	Semisolids and Liquids II	Article 3
9	Analytical Approaches for Pre-Formulation (X-ray, Raman, NMR, DSC, etc)	Article 3
10	Semisolids and Liquids (Franz Cell, viscosity, pH, assay, RC, extractables/leachables, etc)	Article 3
11	Microbial Testing in Pharmaceutical Development	Article 4
12	LAB 1: Emulsion/Suspension/Liquids Lab	Article 4
13	Review Session/Q&A	Article 4
14	Mid Term Exam	Article 5
15	Tablets I –Blending, Compression, Machine General Principles	Article 5
16	Tablets II – Granulations (Wet, HME, HMG), Roller Compaction, Fluid Beds, Coating, Sustained Release	Lab notebook/R eport
17	Soft Gel Capsules	Article 5
18	Hard Shell Capsules	Article 6
19	Analytical Procedures for Solid Dose (drug release, assay, related compounds, other performance tests)	Article 6
20	Parenterals and Inhalers (bronchial/nasal)	Article 6
21	Other dosages (suppositories, otics, ophthalmics, buccal, sublingual, etc)	Article 7
22	Analytical Procedures for specialized dosages (LC/MS, particle size, drug release, other performance tests)	Article 7
23	LAB 2: Solid Dose Lab – Tablets, Capsules	Lab notebook/R eport
24	Pharmaceutical Packaging	Article 7
25	Review Session	
	FINAL EXAM	

List of tentative articles:

Article 1 : GÃ¶tke, Katrin, Thomas Lorenz, Alexandros Repanas, Frederic Schneider, Denise Steiner, Knut Baumann, Heike Bunjes, Andreas Dietzel, Jan H. Finke, Birgit Glasmacher, and Arno Kwade. "Novel Strategies for the Formulation and Processing of Poorly Water-soluble Drugs." *European Journal of Pharmaceutics and Biopharmaceutics* (2017): n. pag. Web.

Article 2: Deininger, M. "The Development of Imatinib as a Therapeutic Agent for Chronic Myeloid Leukemia." *Blood* 105.7 (2005): 2640-653. Web.

Article 3: Hassan, Hazem E., et al. "Pharmacokinetics and Safety Assessment Of-Tetrahydropalmatine in Cocaine Users: A Randomized, Double-Blind, Placebo-Controlled Study." *The Journal of Clinical Pharmacology*, vol. 57, no. 2, Apr. 2016, pp. 151–160., doi:10.1002/jcph.789.

Article 4: Cole, Ewart T., et al. "Challenges and Opportunities in the Encapsulation of Liquid and Semi-Solid Formulations into Capsules for Oral Administration." *Advanced Drug Delivery Reviews*, vol. 60, no. 6, 2008, pp. 747–756., doi:10.1016/j.addr.2007.09.009.

Article 5: Calvo, Natalia L., et al. "Chemometrics-Assisted Solid-State Characterization of Pharmaceutically Relevant Materials. Polymorphic Substances." *Journal of Pharmaceutical and Biomedical Analysis*, 2017, doi:10.1016/j.jpba.2017.06.018.

Article 6: Zheng, Xueyun, et al. "Coupling Front-End Separations, Ion Mobility Spectrometry, and Mass Spectrometry For Enhanced Multidimensional Biological and Environmental Analyses." *Annual Review of Analytical Chemistry*, vol. 10, no. 1, Dec. 2017, pp. 71–92., doi:10.1146/annurev-anchem-061516-045212.

Article 7: Kilvington, Simon, and Anthony Lam. "Development of Standardized Methods for Assessing Biocidal Efficacy of Contact Lens Care Solutions Against *Acanthamoeba* Trophozoites and Cysts." *Investigative Ophthalmology & Visual Science*, vol. 54, no. 7, May 2013, p. 4527., doi:10.1167/iovs.13-11927.