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|  FLORIDA ATLANTIC UNIVERSITY | NEW COURSE PROPOSAL Graduate Programs | | UGPC Approval _____ UFS Approval _____ SCNS Submittal _____ Confirmed _____ Banner _____ Catalog _____ |
| | Department <u>CHEMISTRY & BIOCHEMISTRY</u> College <u>C. E. SCHMIDT COLLEGE OF SCIENCES</u> <small>(To obtain a course number, contact erudolph@fau.edu)</small> | | |
| Prefix CHM Number 6279 | <small>(L = Lab Course; C = Combined Lecture/Lab; add if appropriate)</small> Lab Code _____ | Type of Course Combined Lecture/Lab | Course Title ADV. DRUG FORMULATION |
| Credits <small>(Review Provost Memorandum)</small> 3 | Grading <small>(Select One Option)</small> <u>Regular</u> Sat/UnSat _____ | Course Description <small>(Syllabus must be attached; see Guidelines)</small> This course is an advance course offering in depth coverage of drug formulation. The course will help in understanding pre-clinical formulation; pharmacokinetic, stability and compaction studies and formulation of various types of dosage forms. | |
| Effective Date <small>(TERM & YEAR)</small> <u>SPRING 2021</u> | Prerequisites <u>G. GRADUATE STANDING</u> <i>Prerequisites, Corequisites and Registration Controls are enforced for all sections of course.</i> | | |
| Prerequisites <u>G. GRADUATE STANDING</u> <i>Prerequisites, Corequisites and Registration Controls are enforced for all sections of course.</i> | | Academic Service Learning (ASL) course Academic Service Learning statement must be indicated in syllabus and approval attached to this form. | |
| | | Corequisites None | Registration Controls <small>(For example, Major, College, Level)</small> None |
| Minimum qualifications needed to teach course: Member of the FAU graduate faculty and has a terminal degree in the subject area (or a closely related field.) | | List textbook information in syllabus or here Research articles described in the syllabus | |
| Faculty Contact/Email/Phone ShailajaAllani/skesaraj@fau.edu/5612974972 | | List/Attach comments from departments affected by new course | |

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| Approved by Department Chair <u></u> College Curriculum Chair <u> 2020.03.06 11:44:51 -05'00'</u> College Dean <u></u> UGPC Chair _____ UGC Chair _____ Graduate College Dean _____ UFS President _____ Provost _____ | Date _____ <u>02/26/2020</u> _____ <u>March 9, 2020</u> _____ _____ _____ _____ |
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Email this form and syllabus to UGPC@fau.edu 10 days before the UGPC meeting.



ADV. DRUG FORMULATION | CHM 6279 | 3 Credit hours

Instructor: Dr. Shailaja Kesaraju Allani **Term:** FALL 2017 (Aug 23 –Dec 8)
Office: RF (MC-17) Rm202 **Class Meeting days:** Wednesday
Office hours: Monday, 12- 2 PM **Class Meeting Hours:** 3:00-5:50 AM
E-mail: skesaraj@fau.edu **Class Location:** RF119, Jupiter
Phone: 561-799-8224 **Campus**
VC Location: SC 141 Boca Raton

II. Course description

This course is an advance course offering in depth coverage of drug formulation. The course will help in understanding pre-clinical formulation; pharmacokinetic, stability and compaction studies and formulation of various types of dosage forms.

III. Course Prerequisites

CHM 6277; Graduate Standing

IV. Required texts

No texts required

V. Course objective/Student learning outcomes

Students must be able to evaluate specific properties such as underlying chemistry, metabolic stability, formulation and pharmacokinetics of the drug compound. The course will be heavily focused pre-formulation, formulation and analytics of the compound. The course will be primarily lecture-based but will have additional activities including hands-on laboratory sessions. Experts in drug discovery, formulation and analytical development will present lectures on these topics. A laboratory portion will cover routine formulation development and testing techniques for tablets, capsules, emulsions and injectable dosage forms.

VI. Course Evaluation

| | % course grade |
|-------------------|----------------|
| Attendance | 15% |
| Midterm | 35% |
| Oral presentation | 5% |
| Lab report | 5% |
| Term paper | 5% |
| Finals | 35% |
| TOTAL | 100% |

Oral Presentations

Topics for oral presentations include but not limited to

- Pharmacophore modeling
- Hit to lead optimization
- HLB system
- Drug formulation studies
- Hot-melt extrusion
- Drug delivery systems
- Dosage forms

Organization of the presentation can be as follows:

1. Background/Introduction of the topic
2. Objective or Hypothesis of the journal article
3. Results: In this section you could briefly discuss the methods/experiments used to obtain results. Explain how results supported or disproved the hypothesis.
4. Conclusions: Explain how results might help the cancer field; explain what are the applications from the research performed in this article.
5. Please choose only research articles as it is not possible to cover a review article in 10 -15 min of time.

Lab Reports

Lab report must include objective, methods, results and conclusions. We will have laboratory sessions on emulsions, gels, softgels, and tablets.

Term Paper:

Term paper will be on latest technologies used for tablet analysis. Topics for term paper include but not limited to:

Near Infrared spectroscopy (NIR)

Real time particle analysis

Atomic force Microscope

The term paper must be minimum 3 pages single-spaced, 12 font and a maximum of 5 pages including references. The term paper can be organized the as below:

- Introduction
- Characterization of tablet using the technique
- Advantages and Disadvantages of the method
- Conclusion

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VII. 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

VIII. 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.

IX. 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.

X. 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.

XI. Code of Academic Integrity Policy Statement

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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

XII. 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/>.

XIII. 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/>.

XIV. 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 | |

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List of tentative articles:

Article 1 : GÄ¶ke, 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.

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