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Fall 2021

CHEM 714-101: Pharmaceutical Analysis

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Chemistry: *Fall 2020 Course Syllabus*

NJIT Academic Integrity Code:

The shift to remote and converged teaching due to the COVID-19 pandemic has required that both instructors and students make changes to their normal working protocols for courses. Students are asked to practice extra care and attention in regard to academic honesty, with the understanding that all cases of plagiarism, cheating, multiple submission, and unauthorized collaboration are subject to penalty. Students must properly cite and attribute all sources used for papers and assignments. Students may not collaborate on exams or assignments, directly or through virtual consultation, unless the instructor gives specific permission to do so. Posting an exam, assignment, or answers to them on an online forum (before, during, or after the due date), in addition to consulting posted materials, constitutes a violation of the university's Honesty policy. Likewise, unauthorized use of live assistance websites, including seeking "expert" help for specific questions during an exam, can be construed as a violation of the honesty policy.

All Students should be aware that the Department of Chemistry & Environmental Science (CES) takes the University Code on Academic Integrity at NJIT very seriously and enforces it strictly. This means that there must not be any forms of plagiarism, i.e., copying of homework, class projects, or lab assignments, or any form of cheating in quizzes and exams. Under the University Code on Academic Integrity, students are obligated to report any such activities to the Instructor.

COURSE INFORMATION

Course Description:

Objective: The objective of the course is to provide an overview of instrumental technique used in pharmaceutical analysis. Physically and chemically different analytes are encountered in different sample matrices. Different sample preparation techniques and analytical instrumentation are needed for analyzing these compounds. It will not be possible to cover the whole spectrum of techniques and methods. This course will also cover the rules governing the pharmaceutical industry in the US including current Good Manufacturing Practices (cGMP), method validation, and current industry guidance.

Required Reading

Guidance for Industry

Analytical Procedures and Methods Validation for Drugs and Biologics
www.fda.gov/.../guidancecomplianceregulatoryinformation/guidances/ucm386366.pdf

Bioavailability Studies Submitted in NDAs or INDs – General Considerations

United States Pharmacopeia/National Formulary

ICH Guidelines

Suggested Text Books (Not required - for your reference only)

Principles of Instrumental Analysis, 6th edition

By: Skoog

ISBN: 9780495012016

Method Validation in Pharmaceutical Analysis: A Guide to Best Practice, 2nd Edition

By: Joachim Ermer (Editor), Phil W. Nethercote (Editor), ISBN: 978-3-527-33563-3

Term Paper

Students are responsible for submitting/presenting the term paper on or before the due date. Extenuating circumstances due to an emergency will only be considered at the discretion of the instructors with proper documentation. The paper must be 4-6 pages in length, double spaced, excluding references, tables, figures, etc, and must be formatted according to the 6th Ed. American Psychological Association (APA) format. 6th edition APA Style Format can be found at:

<http://owl.english.purdue.edu/owl/resource/560/02/> .

The term paper will be written and presented by students as a group work. Any form of plagiarism will result in a failing grade on the paper and the violation will be reported to the department.

Number of Credits: 3

Prerequisites:

Course-Section and Instructors

Course-Section	Instructor
Pharmaceutical Analysis-101	Amir K Varkouhi

Office Hours for All Chemistry & Environmental Science Instructors:

Required Textbook:

Title	
Author	
Edition	
Publisher	
ISBN #	

University-wide Withdrawal Date: The last day to withdraw with a **W** is Monday, November 11, 2019. It will be strictly enforced.

Learning Outcomes:

POLICIES

All CES students must familiarize themselves with, and adhere to, all official university-wide student policies. CES takes these policies very seriously and enforces them strictly.

Grading Policy: The final grade in this course will be determined as follows:

Homework	
Quizzes	
Midterm Exam	35%
Final Exam	35%
Term paper	30%

Your final letter grade in this course will be based on the following tentative curve:

A	C
B+	D
B	F
C+	

Attendance Policy: Attendance at classes will be recorded and is **mandatory**. Each class is a learning experience that cannot be replicated through simply “getting the notes.”

Homework Policy: Homework is an expectation of the course. The homework problems set by the instructor are to be handed in for grading and will be used in the determination of the final letter grade as described above.

Exams: There will be two midterm exams held in class during the semester and one comprehensive final exam. The following exam periods are tentative and therefore possibly subject to change:

Midterm Exam I	13 October
Term paper presentation	1-8 Dec
Final Exam	15 December

The final exam will test your knowledge of all the course material taught in the entire course.

Makeup Exam Policy: There will normally be **NO MAKE-UP QUIZZES OR EXAMS** during the semester. In the event that a student has a legitimate reason for missing a quiz or exam, the student should contact the Dean of Students office and present written verifiable proof of the reason for missing the exam, e.g., a doctor’s note, police report, court notice, etc. clearly stating the date AND time of the mitigating problem. The student must also notify the CES Department Office/Instructor that the exam will be missed so that appropriate steps can be taken to make up the grade.

Cellular Phones: All cellular phones and other electronic devices must be switched off during all class times. Such devices must be stowed in bags during exams or quizzes.

ADDITIONAL RESOURCES

Chemistry Tutoring Center: Located in the Central King Building, Lower Level, Rm. G12. Hours of operation are Monday - Friday 10:00 am - 6:00 pm. For further information please click [here](#).

Accommodation of Disabilities: Office of Accessibility Resources and Services (*formerly known as Disability Support Services*) offers long term and temporary accommodations for undergraduate, graduate and visiting students at NJIT.

If you are in need of accommodations due to a disability please contact Chantonette Lyles, Associate Director at the Office of Accessibility Resources and Services at [973-596-5417](tel:973-596-5417) or via email at lyles@njit.edu. The office is located in Fenster Hall Room 260. A Letter of Accommodation Eligibility from the Office of Accessibility Resources Services office authorizing your accommodations will be required.

For further information regarding self-identification, the submission of medical documentation and additional support services provided please visit the Accessibility Resources and Services (OARS) website at:

- <http://www5.njit.edu/studentuccess/disability-support-services/>

Important Dates See: Fall 2020 Academic Calendar, Registrar
<https://www5.njit.edu/registrar/calendars/>

Course Outline

Topics to be Covered

(This is a plan and
may be subject to
change)

Lecture	Section	Topic	Assignment
1 Sep	101	Introduction of the course, Basic Concepts	
8 Sep	101	Analytical Method Development	
15 Sep	101	Analytical Method Validation	
22 Sep	101	Good Manufacturing Practice (GMP)	
29 Sep	101	Investigational New Drug Application (IND) and New Drug Application (NDA)	
6 Oct	101	Acceptance Criteria for new drugs: chemicals	
13 Oct	101	Midterm exam	
20 Oct	101	Acceptance Criteria for Biotechnological/Biologicals Products	
27 Oct	101	Bioavailability and Bioequivalence Studies	
3 Nov	101	Stability Testing of New Drug Substances and Products	
10 Nov	101	An overview of pharmaceutical techniques (Chromatography, Spectroscopic Techniques)	
17 Nov	101	Analytical techniques for Nanotherapeutics-Gene therapeutics	
24 Nov	101	Analytical techniques for Cell-based therapeutics	
1 Dec	101	Presentation and discussion of the Term paper	
8 Dec	101	Presentation and discussion of the Term paper	
15 Dec	101	Final exam	

*Updated by Genti' Price - August, 2020
Department of Chemistry & Environmental Sciences (CES)
Course Syllabus, Fall 2020*
