

SPRING 2024

Pharmaceutical Analysis

PHA 6416 (3 cr.)

Class Meeting Times: Lecture: Wednesdays 12-1:30 pm and Fridays 12-1:30 2 pm

Professors: Dr. Mei He (contact), Dr. Fan Zhang,
 Dr. Abhisheak Sharma, Dr. Jinmai Jiang, Dr. Thomas Schmittgen

Meeting Location: Gainesville MSB P4-20; Lake Nona Conference room 462

Email: mhe@cop.ufl.edu, UF CGRC 458

Office Hours: Flexible, preferentially after appointment via e-mail

Textbooks:

Pharmaceutical analysis: a textbook for pharmacy students and pharmaceutical chemists

Watson, David G., 2005

Available online through UF Library

Method validation in pharmaceutical analysis: a guide to best practice.

Ermer, Joachim, editor.; Nethercote, Phil W., editor. 2015

UF Health Science Center Library - Reserves

Available, RESV; QV25 .W338m 2005

Chromatographic Analysis of Pharmaceuticals. Adamovics, John A., editor. 2017

Available eBook at UF HSC library

<https://ufl->

[flvc.primo.exlibrisgroup.com/discovery/fulldisplay?docid=alma99384145034306597&context=L&vid=01FALSC_UFL:UFL&lang=en&search_scope=MyInstitution&adaptor=Local%20Search%20Engine&tab=LibraryCatalog&query=sub,exact,Drugs%20--%20Analysis&offset=0](https://ufl-flvc.primo.exlibrisgroup.com/discovery/fulldisplay?docid=alma99384145034306597&context=L&vid=01FALSC_UFL:UFL&lang=en&search_scope=MyInstitution&adaptor=Local%20Search%20Engine&tab=LibraryCatalog&query=sub,exact,Drugs%20--%20Analysis&offset=0)

Handbook of pharmaceutical analysis by HPLC, Ahuja, Satinder; Dong, M. W. 2005

<https://ufl->

[flvc.primo.exlibrisgroup.com/discovery/fulldisplay?docid=alma990343963890306597&context=L&vid=01FALSC_UFL:UFL&lang=en&search_scope=MyInstitution&adaptor=Local%20Search%20Engine&tab=LibraryCatalog&query=any,contains,Pharmaceutical%20Analysis&sortby=rank&offset=0](https://ufl-flvc.primo.exlibrisgroup.com/discovery/fulldisplay?docid=alma990343963890306597&context=L&vid=01FALSC_UFL:UFL&lang=en&search_scope=MyInstitution&adaptor=Local%20Search%20Engine&tab=LibraryCatalog&query=any,contains,Pharmaceutical%20Analysis&sortby=rank&offset=0)

UF Canvas System will be used for announcements and posting files such as assignments, notes, solutions, and supplementary materials.

COURSE OBJECTIVES

The primary goals for Pharmaceutical Analysis I are for students to:

1. Learn the fundamentals and theory for practical use of pharmaceutical analysis methods and instruments.
2. Be able to rationally choose analytical approaches for determining drugs and endogenous substances in biological fluids.
3. Learn examples of current research activities in academic or pharma industry using pharmaceutical analysis methods.
4. Develop skills in analyzing and presenting research data both in writing and orally.

COURSE OUTCOMES

1. Students should understand fundamental sample preparation, gas and liquid chromatography, mass spectroscopy, screening, sequencing and omic study, immunological and spectroscopic approaches for pharmaceutical analysis.
2. Students should be able to understand substance quality and its specifications that derived from pharmaceutical analysis approaches for used in quality control (QC) during full-scale production in a real-world setting.
3. Students should be able to derive methodologies for informing rational drug development and characterizing active components, particulates, and impurities.
4. Students should be able to solve problems involving pharmaceutical analysis methods.

COURSE PRE-REQUISITES

Grad standing and permission of instructors.

Students not majoring in Pharmaceutical Sciences degrees may be allowed for this course.

Prior to taking CHM 3120 Quantitative Chemical Analysis would be preferred.

COURSE ORGANIZATION

Lectures are held on Wednesdays and Fridays. Homework assignments will be assigned monthly approximately (total three assignments). Two exams will be given during the lecture period, approximately every 1.5 months, *tentatively* scheduled for March 8th and April 19th. A research case study will also be assigned for a report and an oral presentation as the final exam format given on April 17.

CLASS ATTENDANCE AND ETIQUETTE

- Regular class attendance is required. All pre-existing conflicts with lectures must be communicated in person to the instructor(s) responsible for the lecture(s) at least two weeks prior to the scheduled lecture. The decision on granting an absence from class is at the sole discretion of the responsible instructor. Students who are ill or indisposed on a lecture date must contact the instructor(s) responsible for the lecture(s) prior to the lecture(s). The post fact communications are not accepted. Each unexcused absence from a lecture will result in deduction of 1/3 of a full grade (for example: "A" to "A-", or "A-" to "B+" or "B+" to "B").
- It is expected that lectures may not closely follow a textbook. Some of the lecture notes will be posted to Canvas, and it is the responsibility of the student to learn of any changes in material coverage, assignments or due dates announced in class.
- Homework and exam solutions are made available immediately after the due date. Thus, late homework is not accepted, nor will exams be given outside of the scheduled times.
- As a professional practiced within organizations of diverse individuals, professional decorum and attitude is expected at all times in the classroom. During class, all cell phones and pagers must be turned off, and talking, if any, must not interfere with classroom activities. Ethical behavior, attentiveness, courtesy and respect for others, promptness in arrival for class and completion of assignments, are required for meeting the expectations.
- As professionals, must be able to work in groups of diverse individuals - including peers, subordinates, and superiors - and to exchange technical information clearly and effectively both orally and in writing. Effective interactive communication such as asking and responding to questions is a skill to be developed and is therefore strongly encouraged. This will be formally graded as part of the research project/case study, and be considered in assessing points for class participation.
- Requirements for class attendance and make-up exams, assignments, and other work are consistent with university policies that can be found at <https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>

EXAMS

During the exams, students are allowed to bring a basic calculator capable of handling common mathematical operations. The exam sessions are close book, paper based, so students must completely independently.

If you will miss an exam due to serious doctor-treated illness or emergency, **YOU MUST CONTACT INSTRUCTOR PRIOR TO THE EXAM** if at all possible to discuss the situation. If the absence is excused, your total points will be re-weighted proportionally. Unexcused absences will earn a zero for the exam.

HOMEWORK

Homework is assigned to aid comprehension of the material covered. As much of your learning takes place as you work to understand the problem and organize your approach to solving the problem, it is always important to spend time on each problem by yourself before consulting with others. However, any work turned in for a grade must be individual work, and not a common "group" solution, unless otherwise directed. Students who turn in identical work may be assigned zeros for the assignment. The person who allows copying of their homework will be penalized the same as the person doing the copying.

Homework will be posted via Canvas. Please complete in a word file following below format:

- Write your name, HW #, course number, and date on page 1. Initial all other pages.
- Report an appropriate number of significant figures in your answer as needed.
- Following standard formats and making clear presentation of solutions is an important professional skill.
- Turn in electronically on time via Canvas

GRADING

Final letter grades will be awarded in accordance with the qualitative descriptions. Grades will be based upon three homework assignments, two exams, participation, case study and final report, and oral presentation. *Regular class attendance and participation and completion of all required assignments is expected of all students.*

Points will be awarded as follows:

30 pts. -	Homework (10 pts each)
30 pts. -	Semester Exams (15 pts each)
15 pts. -	Research Project/Case Study Report (following NIH proposal format guidelines which will be provided after spring break)
15 pts. -	Research Project/Case Study Oral Presentation
10 pts. -	Course Participation and In-class Discussion
100 pts. -	Total

All graded work should be saved until the final grades for the course are posted in case it becomes necessary to recall assignments for re-grading or to correct any mis-recorded grades.

Grading Scale

Grade	Scale	Grade	Scale
A	94-100%	C	73-76%
A-	90-93%	C-	70-72%
B+	87-89%	D+	67-69%
B	83-86%	D	63-66%

B-	80-82%	D-	60-62%
C+	77-79%	E	< 60%

For greater detail on the meaning of letter grades and university policies related to them, see the Registrar’s Grade Policy regulations at <http://www.registrar.ufl.edu/staff/grades.html> and for information on current UF grading policies for assigning grade points, see the following: <https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspxGrading>

DISABILITIES

The University of Florida seeks to provide accommodations for all qualified students with disabilities. The university adheres to all applicable federal, state, and local laws, regulations, and guidelines with respect to providing reasonable accommodations as required to afford equal educational opportunity. Students requesting classroom accommodation must first contact the Disability Resource Center located in Room 0020 Reid Hall, phone 392-8565 (www.dso.ufl.edu/drc). See the following webpage for a detailed checklist of procedures to follow in this process:

The Dean of Students Office will provide documentation to students who must then provide this documentation to the instructor when requesting accommodations. Please contact instructor privately as soon as possible to arrange for the appropriate accommodations no later than at least 2 weeks prior to the first exam.

ACADEMIC MISCONDUCT

All students registered at the University of Florida have agreed to comply with the following statement: “I understand that the University of Florida expects its students to be honest in all their academic work. I agree to adhere to this commitment to academic honesty and understand that my failure to comply with this commitment may result in disciplinary action up to and including expulsion from the University.” In addition, on all work submitted for credit the following pledge is either required or implied: “On my honor I have neither given nor received unauthorized aid in doing this assignment.” If you witness any instances of academic dishonesty in this class, please notify the instructor or contact the Student Honor Court (392-1631) or Cheating Hotline (392-6999). For additional information on Academic Honesty, please refer to the University of Florida Academic Honesty Guidelines at <http://www.dso.ufl.edu/judicial/honorcode.php>. Cheating, lying, misrepresentation, or plagiarism (that is “quoting oral or written materials, whether published or unpublished, without proper attribution to the author or submitting a document or assignment which in whole or in part is identical or substantially identical to a document or assignment not authored by the student”) is unacceptable and inexcusable behavior and may result in a reduction of course grade and a report to university officials. It is assumed that students will be honorable, trustworthy, and honest in their academic coursework, but violations of the honor code have occurred. In keeping with the seriousness of such violations, their description and sanctions are presented at the following website <http://www.dso.ufl.edu/sccr/honorcodes/conductcode.php>

Please consider them carefully. By engaging in such conduct, a student violates the Honor Code and becomes subject to the Student Conduct Code (6C1-4.016). All papers must be written independently. If a paper is submitted in whole or in part that is not your own work, the paper will receive a grade of zero. Also use of another author's exact words without including them in quotation marks and without noting the page numbers of the citation constitutes plagiarism and will result in a grade of zero for the paper. All students will be held to UF's Academic Honesty Code. Matters in potential violation of this code will be referred to the Office of Student Judicial Affairs.

Tentative Schedule of Topics

WEEK	TOPICS	NOTES
1	<ul style="list-style-type: none"> ▪ Quantitative Analytical Methodology (overview of quantitative analysis: precision, accuracy, sensitivity, dynamic range, resolution, detection limit, reproducibility, t test, etc.) ▪ Sample Preparation for handling biological samples and drug compounds and formulations 	Lecturer: Dr. He
2	Chromatographic Separation (Peak-asymmetry, Retention, Resolution)	Lecturer: Dr. Sharma
3	Chromatographic Separation (Reverse phase chromatography)	Lecturer: Dr. Sharma
4	Normal phase, ion exchange/enantiomers	<ul style="list-style-type: none"> ▪ Lecturer: Dr. Sharma ▪ Assignment #1
5	HPLC Mass Spectrometry Proteomic Seminar (Invited Speaker)	Lecturer: Dr. Sharma
6	HPLC Mass Spectrometry NMR Seminar (Invited Speaker)	Lecturer: Dr. Sharma
7	UV, Fluorescence spectrometry, Mass spectrometry	Lecturer: Dr. Sharma
8	UV, Fluorescence spectrometry, Mass spectrometry Metabolomics Seminar (Invited Speaker)	Lecturer: Dr. Sharma Assignment #2
9	Nanoparticle analysis (sizing, zeta potential, morphology, stability)	<ul style="list-style-type: none"> ▪ Lecturer: Dr. Zhang ▪ EXAM #1
10	SPRING BREAK	
11	Nanoparticle purification and separation	Lecturer: Dr. Zhang
12	Electrophoresis/capillary electrophoresis and flow cytometry	Lecturer: Dr. He
13	High throughput analysis and screening	<ul style="list-style-type: none"> ▪ Lecturer: Dr. Zhang ▪ Assignment #3
14	PCR and sequencing	Lecturer: Dr. Jinmai Jiang Dr. Schmittgen
15	Immune assays	<ul style="list-style-type: none"> ▪ Lecturer: Dr. He ▪ EXMA 2 (take home)
16	Research project/case study oral presentation	Judgers: Drs. He, Sharma, Zhang, Jiang
17	Final week, buffer room for more Research project/case study oral presentations if needed	Judgers: Dr. He, Sharma, Zhang, Jiang

Guidelines for the final report

The case study paper will be posted around April 12th. The final report will be based on the paper that you picked to review and criticize. The due date will be on April 29th @5pm, after your presentation report. After presentation and question session, you may have some thoughts and feedback to update your final report during the week of April 29th.

Requirements for final report:

--Try to keep your writing no more than two pages, Font Arial or Times New Roman, 11pt, single space, margin 0.5 all over.

--The final report will include three sections: Significance, Innovation, and Research Approach

Significance: describe the importance and impact of this paper on the both aspects of strengths and weaknesses.

Innovation: describe the technical innovation and knowledge innovation on the both aspects of strengths and weaknesses

Research approach: describe the methodology used in this paper on the both aspects of strengths and weaknesses

Note: be sure to include the rationale with your critiques.

--Submit either as the word file or PDF file. Feel free to cite or insert references to support your statement or critiques. The references do not subject to the two-page limitation.

Reference Reading:

A good grasp of reading and analytical skills is needed for students to understand how their research project contributes to the field that they are working in.



[How to read and critique a scientific research article by Foong May Yeong](#)

Publication Date: 2014

This guidebook provides a structured approach to reading a research article, guiding the reader step-by-step through each section, with tips on how to look out for key points and how to evaluate each section.

Guidelines for the final oral presentation

The final oral presentation be given on the week 15. The presentation software is PowerPoint for Windows 7 or above, so please be sure your presentation displays properly with this software prior to the oral report session. Please join ahead of time to make your slides and yourself ready.

All students are required to attend all presentations and ask at least one question during the Q&A periods following the talks. Students will also be asked to grade the reports using the presentation evaluation form provided. You should target the presentation to the portion to your classmates. Lecturers will grade the technical content of the talk while the grade for presentation skills will be based on the evaluations of the professor and students. The presentation skills report grade assigned to each person will be weighted equally between technical quality and the overall quality of the presentation, including the style.

You should also review the list of tips for giving effective presentations by below resources:

How to give a dynamic scientific presentation: <https://www.elsevier.com/connect/how-to-give-a-dynamic-scientific-presentation>

Effective presentations in Engineering and Science: <https://www.engr.psu.edu/speaking/structure.html>

6 speaking tips for scientists and engineers (TED Blog): <https://blog.ted.com/6-tips-on-how-scientists-and-engineers-can-excite-rather-than-bore-an-audience/>

But the following elements should be followed in all cases:

1) The talk should last at least 10 minutes but *not* more than 15 minutes (you will be stopped at 12 minutes whether finished or not), with 2 – 3 minutes for questions. Remember: Length ≠ Quality! Because of the short time you will necessarily be explaining only the key points of your project. Focus on helping the audience understand the significance of your topic and the most important point(s), rather than showing lots of results with minimal interpretation.

2) All speakers will be expected to take questions from the audience, and everyone in the audience is expected to ask at least one question at some time. Most of the presentations given are intended to be the basis for discussion, so the Q&A session is an important, integral part of the presentation. Preparation for this session requires being well acquainted with the content of your presentation.

3) All speakers should use good quality visual aids. A good slide can help focus your audience on key points, aid retention of important information, aid verbal descriptions, and help organize the thoughts of the audience and the speaker. The audience should not be expected to sit and read slides: they should be keeping their attention focused on the speaker. Also, slides do not need to be self-explanatory: the speaker is there to explain them to the audience. Never present detailed tables or complex, cluttered figures unless absolutely necessary. Distill the results down to the key points in any given figure/table. In principle, the audience would refer to your written report for complete details. On the other hand, you should not speak for extended periods of time without a slide displayed that outlines the key points you're trying to make as you talk. Such outlines help an audience follow your talk and take notes – plus they can be a more effective way of reminding you, as the speaker, of the points you want to make than using note cards (you may use note cards while speaking if you wish, but use them subtly and do NOT read from them).

A reasonable balance among slides could be:

- 1 – title slide
- 1 – introduction
- 2-3 – background
- 1-2 – methods
- 2-4: results & discussion

1: conclusions

1: acknowledgements for anyone who helped

8 – 11 total slides, not counting the title and acknowledgement slides

5) Reports should have an introduction (*why should the audience listen to you?*), theory/technical background (*so the audience can understand the meaning of the results and what assumptions were made*), description of the methods used, if relevant (*so the audience knows what was involved in obtaining or processing data and what might be limitations in the quality or applicability of the results*), results and discussion (*so they audience understands how the calculations were done, at least in a general way, what the actual results were and most importantly, understands the significance and limitations of conclusions that were drawn*), and the conclusions and recommendations (*what can be done with the results, and what should be done in the future if this line of research was continued*).

6) No dress code is required, but presentations should be made with a professional demeanor. However, use your imagination and creativity to make your talk an enjoyable learning experience for everyone.

Scoring criteria

Organization: Presentation unfolds in a logical order with a clear statement of purpose, appropriate background and sequence of topics. The presentation moves from point to point in a focused and purposeful manner, culminating with a distinct conclusion or summary.

Coverage: Appropriate and balanced scope considering the audience and available time.

Technical Quality: Technically accurate; presented at a level of consistency.

Analysis: Presentation critically assesses the content studied and draws original and/or thoughtful conclusions: has moved beyond simply reporting information uncovered while studying the topic.

Understanding of topic evident: Material presented with merited confidence and authority.

Quality of Visual Aids: Slides are concise and clear. Graphics help communicate the speaker's points effectively. Visual aids help the audience understand the talk and follow along.

Delivery: Spoke at an appropriate pace, avoided distracting pauses. Maintained a focus on the audience (looked at the audience, not the slides; made consistent eye contact). Made distinct points on each slide. Presentation (slides and speaking style together) was effective in maintaining audience interest and helping the audience understand the points being made.

Quality of response questions: Addressed questions directly and provided a concise and focused answer ("I am not sure" is an acceptable answer, as long as that is not the answer to every question!)

Effectiveness as an audience member: Gave each speaker full attention, and asked meaningful questions that gave the speaker a chance to clarify or expand on key points, or prompted a meaningful discussion that extended beyond the specific topics raised in the presentation.

Example of Evaluation Rubric Pharmaceutical Analysis I Final Oral Presentation

Presenter: _____

Topic/Title: _____

Date: _____

Presentation Scoring:

Quality of content: Score (out of 3) _____

Organization

E VG G F P

Coverage

E VG G F P

Technical quality and accuracy: Score (out of 3) _____

Analysis

E VG G F P

Understanding of topic evident

E VG G F P

Quality of Slides: Score (out of 3) _____

Appearance

E VG G F P

Effectiveness in aiding presentation

E VG G F P

Delivery: Score (out of 3) _____

Speaking skills (voice, eye contact, etc.)

E VG G F P

Effectiveness (did audience understand?)

E VG G F P

Quality of response to questions

E VG G F P

Effectiveness as Audience Member: Score (out of 3) _____

Asked meaningful question(s)

E VG G F P

Overall Score: Score (out of 15) _____

Comments:

Appendix A

Course Schedule, Topic, and Meeting Location

Spring 2024			
PHA 6416 Pharmaceutical Analysis (3 cr.)			
Location	Gainesville MSB P4-20; Lake Nona Conference room 462		
Class Meeting Times:	Wednesdays 12-1:30pm and Fridays 12-1:30pm		Topics
			Lecturers
Classes Begin	10-Jan	Quantitative Analytical Methodology (overview of quantitative analysis: precision, accuracy, sensitivity, dynamic range, resolution, detection limit, reproducibility, t test, etc.)	Dr. He
	12-Jan	Sample Preparation for handling biological samples and drug compounds and formulations	Dr. He
	17-Jan	Chromatographic Separation (Peak-asymmetry, Retention, Resolution)	Dr. Sharma
	19-Jan	Chromatographic Separation (Peak-asymmetry, Retention, Resolution)	Dr. Sharma
	24-Jan	Chromatographic Separation (Reverse phase chromatography)	Dr. Sharma
	26-Jan	Chromatographic Separation (Reverse phase chromatography)	Dr. Sharma
	31-Jan	Normal phase, ion exchange/enantiomers	Dr. Sharma
	2-Feb	Normal phase, ion exchange/enantiomers	Dr. Sharma
		Assignment #1	Dr. Sharma & Dr. He
	7-Feb	HPLC Mass Spectrometry	Dr. Sharma
	9-Feb	Proteomics Seminar	Dr. Sixue Chen, University of

		https://olemiss.zoom.us/j/97284904536?pwd=TIJjeHAzenBrQTdweUdFSVFJUHR0dz09 Assignment #1 due @5PM	Mississippi (invited, zoom)
	14-Feb	NMR seminar	Dr. Matthew Merritt (CTSI core director)
	16-Feb	HPLC Mass Spectrometry	Dr. Sharma
	21-Feb	UV, fluorescence spectrometry, Mass Spectrometry	Dr. Sharma
	23-Feb	UV, fluorescence spectrometry, Mass Spectrometry	Dr. Sharma
	28-Feb	Metabolomics Seminar	Dr. Timothy Garrett, from School of Medicine
		Assignment #2	Dr. Sharma & Dr. He
	1-Mar	Nanoparticle analysis (sizing, zeta potential, morphology, stability)	Dr. Zhang
	6-Mar	Nanoparticle analysis (sizing, zeta potential, morphology, stability) Assignment #2 due @5PM	Dr. Zhang
	8-Mar	Exam #1	Dr. He
Spring Break	13-Mar	NO CLASS	
	15-Mar	NO CLASS	
	20-Mar	Nanoparticle purification and separation	Dr. Zhang
	22-Mar	Nanoparticle purification and separation	Dr. Zhang

	27-Mar	Electrophoresis/capillary electrophoresis	Dr. He
	29-Mar	flow cytometry	Dr. He
	3-Apr	High throughput analysis and screening	Dr. Zhang
	5-Apr	High throughput analysis and screening	Dr. Zhang
		Assignment #3	Dr. He
	10-Apr	Sequencing	Dr. Jinmai Jiang
	12-Apr	Quantitative PCR Assignment #3 due@5PM	Dr. Schmittgen
	17-Apr	Immunoassays	Dr. He
	19-Apr	Immunoassays	Dr. He
		Exam #2 (take home)	Dr. Zhang & Dr. He
	24-Apr	Research project/case study oral presentation	Judgers: Drs. He, Sharma, Zhang, Jiang
	26-Apr	Research project/case study oral presentation Exam #2 due@5PM (take home)	Judgers: Drs. He, Sharma, Zhang, Jiang
Final Week	April 27 – May 3	NO CLASS (final report due on April 29th)	