جامعة أم القرى

كلية الصيدلة

الماجستير في الصيدلانيات





Thesis - Research Project	1	-	30	1	30 h		3		10	
Total	27	15	64	12	62	16	30	12	34	10

4. Learning and Teaching

4/1 Learning Outcomes and Graduate Specifications

4/1/1 M	lain tracks o	or specializations covered by th	e program:		
(a)	Nanotechno	logy			
(b)	Pharmacoki	netics and Biopharmaceutics			
(c)	Controlled d	lrug delivery system			
4/1/2 Cu	rriculum St	udy Plan Table			
Level	Course Code	Course Title	Required or Elective	Prerequisite Courses	Credit Hours
	1803610	Instrumental analysis	R		3
Level 1	1803611	Advanced statistics	R		2
	1803612	Research Methodology and Scientific communication	R		2
	1803613	Advanced physical pharmacy	R		3
	1803601	Chromatography and separation sciences	R		2
Level 2	1803602	Advanced Biopharmaceutics and Bioequivalence	R		3
	1803603	Advanced drug delivery systems	R		3
	1803609	Good manufacturing practice and QC	R		2
		Elective 1	E		2
Level 3		Elective 2	E		2
	1803614	Research project	R		10
Level 4	1803614	Research project	R		10

List of elective courses

Course Code	Course title	Credit units
1803604	Natural products and skin care cosmeceuticals	2
1803605	Radiopharmacy	2
1803606	Pharmaceutical biotechnology	2
1803607	Pharmaceutical applications of nanotechnology	2
1803608	Pharmaceutical microbiology	2



المملكه العربيه السعوديه وزارة التعليم جامعة أم القري عمادة الدراسات العليا

4/1/4. Course Specification:

COURSE SPECIFICATIONS Form

Course Title: Instrumental Analysis

Course Code: 1803610-3





Course Specifications

Institution: Umm AlQura University	Date:	
College/Department : College of Pharmacy		

A. Course Identification and General Information

1. Course title and code: Instrumental	Analysis (1	803610-3)	
2. Credit hours: 3			
3. Program(s) in which the course is of	fered: MSc	in Pharmaceutics	
4. Name of faculty member responsible	e for the co	urse:	
5. Level/year at which this course is off	fered:		
6. Pre-requisites for this course (if any)	1		
7. Co-requisites for this course (if any):	:		
8. Location if not on main campus:			
9. Mode of Instruction (mark all that ap	oply):		
a. traditional classroom	X	What percentage?	90%
b. blended (traditional and online)		What percentage?	
c. e-learning	X	What percentage?	10%
d. correspondence		What percentage?	
Comments:			





B Objectives

1. What is the main purpose for this course?

The aim of this course is to provide the students with the necessary knowledge and skills that will enable them to determine the arrangement of atoms, chemical bonds, and geometry of chemical compounds. This module will further provide the students with the tools to elucidate chemical structures for compounds by interpretation of different types of spectra.

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web based reference material, changes in content as a result of new research in the field)

The course will be introduced for the first time

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

The course provides a systematic introduction to basic theoretical concepts in spectroscopy for student. Successful completion of this course will provide the students with a working knowledge of analytical instrumentations widely employed in pharmaceutical, chemical and biochemical laboratories. The course will enable the students to apply these techniques to elucidate the structure of known and unknown drugs and related chemicals.

1. Topics to be Covered		
List of Topics	No. of Weeks	Contact hours
Basic theory of NMR	2	8
1D NMR techniques (¹ H, ¹³ C, DEPT, INEPT)	2	8
2D NMR techniques (COSY, HMBC, HSQC, TOCSY)	2	8
Ultraviolet and visible light spectroscopy	2	8
Fluorescence spectroscopy	1	4
Infrared spectroscopy	2	8
X-ray diffraction	1	4
Differential scanning calorimeter (DSC)	2	8

2. Course components (total contact hours and credits per semester):

		Lecture	Tutorial	Laboratory/ Studio	Practical	Other:	Total
Contact	Planed	28	14		14		56
Hours	Actual						
Credit	Planed	2	0.5		0.5		3.0
	Actual						

3. Additional private study/learning hours expected for students per week: 4 hrs.



4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Code	NQF Learning Domains	Course Teaching	Course Assessment
#	And Course Learning Outcomes	Strategies	Methods
1.0	Knowledge	T	1
1.1	Explain the general principles and theory of spectroscopy	Lectures	Written exam
1.2	Describe the specificities and applications of various types of spectroscopic methods	Lectures supported by tutorial	Written and exam and practical sessions
1.3	Relate NMR parameters to chemical structure	Lectures Tutorials	
2.0	Cognitive Skills		
2.1	Elucidate molecular structure from NMR and spectrophotometric experiments.	Self-study In class discussion	On-line exercise Assignments
2.2			
3.0	Interpersonal Skills & Responsibility		
3.1	Employ scientific literature usage skills for life-long learning	Take home homework	Prepare one literature review regarding one an application of NMR or MS in the biomedical field
3.2	Solve analytical problems in spectrophotometry	Practical, case study Self-learning	Practical report, assignment and presentation
4.0	Communication, Information Technology, Numeric	al	
4.1	Solve analytical science problems involving spectroscopic techniques	Lectures supported by tutorial, case study	Written exam and assignment
5.0	Psychomotor		
5.1	Perform the most common used spectroscopic experiments	Practical and tutorials	Practical reports

5.1	5. Schedule of Assessment Tasks for Students During the Semester				
	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment		



1	Written exam	16 th	65%
2	Practical exam	15 th	15%
3	On-line exercises	6 &11 th	10%
4	Prepare one literature review regarding one drug development process	13 th	10%

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

Students can contact the academic staff for one-to-one consultation regarding specific academic matters from time to time. Information on academic staff contact details are available and appropriately publicized to students.

Additionally, students are able to contact staff members directly with questions and requests for assistance via telephone, email or the online environment when available. Consultation times can be used to proactively work with students over the course of the semester.

E Learning Resources

1. List Required Textbooks

- Understanding NMR Spectroscopy, 2nd Edition, 2010, James Keeler, Wiley, ISBN: 978-0-470-74608-0
- Introduction to Spectroscopy, Donald L. Pavia, 2014, 5th edition, Cengage Learning
- Molecular Spectroscopy, Jeanne L. McHale, 2nd Edition, 2017, CRC Press
- 2. List Essential References Materials (Journals, Reports, etc.)
 - Pharmaceutical Analysis. DG Watson. Churchill Livingstone. ISBN0443059861
- 3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.
 - http://www.cis.rit.edu/htbooks/nmr/nmr-main.htm. Basics of NMR, online interactive textbook by Joseph P. Hornak, PhD
 - Bruker User's Guide: Basic 1D and 2D NMR Experiments
 - Bruker User's Guide: Advanced 1D and 2D NMR Experiments

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.

F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

- Classroom with 20 seats at least, projector and whiteboard.
- Laboratory for 20 students at least and equipped with glassware.

2. Technology resources (AV, data show, Smart Board, software, etc.)



Classroom should be equipped with data show and smart board

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

NMR 500 MHz, UV spectrophotometer, FT-IR, fluorescence spectrophotometer, X-ray diffractometer. Differential scanning calorimeter (DSC)

G Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching

- Online survey at the end of the course.
- Online staff member evaluation survey

2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department Mid semester survey

3. Processes for Improvement of Teaching

Vice deanship for postgraduate studies and postgraduate studies committee provide guidelines for teaching and assessment that are flexible and variable.

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.

To be decided by the vice deanship of postgraduate studies and research

Name of Course Instructor: Ziad Omran

Signature:

Date Specification Completed: 17/03/2019

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah

Date Received: 17/03/2019



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COURSE SPECIFICATIONS

Form

Course Title: Advanced Statistics

Course Code: 1803611-2





Course Specifications

Institution: Umm Al Qura University

Date:

College/Department: College of Pharmacy/ Pharmaceutics/Clinical Pharmacy

A. Course Identification and General Information

1. Course title and code: Advanced Sta	Course title and code: Advanced Statistics (803611-2)				
2. Credit hours: 2 hrs.	. Credit hours: 2 hrs.				
3. Program(s) in which the course is of	ffered.: Master of Pharmaceutics				
4. Name of faculty member responsibl	e for the course: Mohamed Zakaria				
5. Level/year at which this course is of	ffered:				
6. Pre-requisites for this course (if any):				
7. Co-requisites for this course (if any)): None				
8. Location if not on main campus:					
9. Mode of Instruction (mark all that a	pply):				
a. traditional classroom	Ves 50 What percentage?				
b. blended (traditional and online)	ves 30 What percentage?				
c. e-learning	What percentage?				
d. correspondence	What percentage?				
f. Group Discussion	ves What percentage? 20				
Comments:					





B Objectives

- 1. What is the main purpose for this course?
 - 1. To ensure that students are familiar with basic statistical methods.
 - 2. To explain key terms in statistics that are used in pharmacy such as statistical significance, p-value, confidence interval, and power.
 - 3. To give students an appreciation of the analyses of the paired& unpaired data and estimation criteria for hypothesis testing.
 - 4. To provide students with the basic principles of the Bayesian statistics and its application.
 - 5. To ensure students understanding of the principles of survival analysis.
 - 6. To give students randomization methods for experimental design.
 - 7. Describe how findings are summarized in published reports and apply them appropriately in decision- making.
 - 8. To evaluate the statistical portions of most research articles and be able to interpret and apply data when presented in figures and graphs of publications.

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field)

Blended Learning Techniques are added

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

In this course, students will learn how to describe different kinds of data, how to apply various methods for the statistical analysis of data, how to estimate confidence intervals, test hypotheses and interpret P values. Both parametric and non-parametric methods will be examined. In addition, students will learn about different experimental design.

Advanced statistics provides students with statistical foundation of the various research problems. Students will learn to recognize the main features of the processes under investigation that could be analyzed in terms of survival analysis, meta-analysis, Bayesian statistics or general analysis of the paired data. Grading this course will help the future specialist to analyze the observed phenomena in advanced statistical level.

1. Topics to be Covered		
List of Topics	No. of Weeks	Contact hours
Descriptive STAT, Hypothesis testing	1	2





Analysis of the independent data	2	4
- Independent, variables - Normality - t-test, Mann Whitney		
Analysis of the paired data	2	4
- Paired, repeated and matched variables - Normality - Paired t-test,		
Wilcoxson		
Analysis of variance (ANOVA)	2	4
The F-criterion and comparison of variances - 1-way ANOVA -		
Generalizations of ANOVA		
Randomization and randomization-based analysis	1	2
- Randomized experiment		
Survival Analysis	2	4
- Common terms - Cox regression analysis - Tree-structure models		
The basic Bayesian statistics	2	4
Bayesian probability - Likelihood - Prior and posterior - Empirical Bayes		
models - Bayesian information criterion		
Sample size calculation	2	4

2. Course components (total contact hours and credits per semester):							
		Lecture	Tutorial	Team Work/Project	Practical	Other:	Total
Contact	Planed	14		2	10		26
Hours	Actual						
Credit	Planed	1		0.2	0.8		2
	Actual						

3. Additional private study/learning hours expected for students per week. (2 hours)

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert





appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Cod	NQF Learning Domains	Course Teaching	Course
e	And Course Learning Outcomes	And Course Learning Outcomes Strategies	
#	Methods		Methods
1.0	Knowledge		
1.1	Familiarize the students with basic statistical methods.	Lecture	Final Exam
1.2	Explain key terms in statistics that are used in pharmacy such as statistical significance, p- value, confidence interval, and power.	Lecture	Final Exam
2.0	Cognitive Skills		
2.1	Explain the analyses of the paired& unpaired data and estimate the criteria for hypothesis testing.	Lecture/practical with SPSS	Final Exam/Practical SPSS exam
2.2	Explain the basic principles of the Bayesian statistics and its application.	Lecture/practical with SPSS	Final Exam/Practical SPSS exam
2.3	Describe the principles of survival analysis.	Lecture/practical with SPSS	Final Exam/Practical SPSS exam
2.4	Evaluate the statistical portions of most research articles and be able to interpret and apply clinical data when presented in figures and graphs of publications.	Project/ Team Work presentation	Project/ Team Work presentation
3.0	Interpersonal Skills & Responsibility		
3.1	Evaluate published medical literature for use in clinical decision- making and understand scientific reasoning and the research process in this context.	Discussion/Team Work	Journal Club Presentation
4.0	Communication, Information Technology,	Numerical	





4.1	Describe how findings are summarized in published reports and apply them appropriately in decision- making.	Participate in a proposal using the appropriate statistical tests.	Project/ Team Work presentation
5.0	Psychomotor		
	none		

-						
5.1	5. Schedule of Assessment Tasks for Students During the Semester					
	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment			
1	1. Final exam (40%): The final exam will consist of 50 MCQ questions and 10 SQ.	Exam weeks	50%			
2	2. SPSS exam (30%):	Week 12	20%			
3	3. Project: Designing and analyzing a statistical project.	Week 10	15%			
4	Journal Club Presentation/Team Work Evaluation	Throughout the course	15%			





D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

Office Hours

E Learning Resources

1. List Required Textbooks

- 1. Rosner, B. (2015). Fundamentals of Biostatistics (8 ed.): Cengage Learning.
- 2. Indrayan, A., & Malhotra, R. K. (2017). Medical Biostatistics (4 ed.): CRC Press.
- 3. Jackson, S. L. (2015). Research methods and statistics: A critical thinking approach. Cengage Learning.

2. List Essential References Materials (Journals, Reports, etc.)

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

Remind app, Poll Everywhere

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.

Laptops computers

SPSS statistics software v. 23, IBM corporation

G*Power: Statistical Power Analyses for Windows version 3.1.9.4





F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

Classroom with round tables

2. Technology resources (AV, data show, Smart Board, software, etc.)

Data Show

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

No

G Course Evaluation and Improvement Processes

- 1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching
- 1. A post midterm. open-ended questionnaire will be distributed to students to draw the instructor's attention to the weaknesses and strengths of his presentations
- 2. End-of-term evaluation of course by students through course survey
- 3. Periodical open discussion with students to survey their opinions on the degree of achievement of course, goals and objectives
- 2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department

Peer review process

3. Processes for Improvement of Teaching

According to the feedback form and the internal peer review process within the department

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

check marking by an independent member teaching staff of a sample of student work

5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.

1.Compare syllabi and course description to those found in other universities

2. Compare course objectives and goals to students' achievement





- 3. Try to contact other professors in different universities who are teaching similar courses (including well-known institutions) to exchange views regarding the optimal ways to improve the course
- 4. The course content are reviewed annually by the curriculum committee

Name of Course Instructor: Mohamed Zakaria

Signature:

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah

Date Received:



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COURSE SPECIFICATIONS Form

Course Title: Research Methodology and Scientific Communication

Course Code: 1830612-2





Course Specifications

Institution: Umm Al-Qura University	Date:	
College/Department: College of Pharmac	y/ Department of Pharmaceutical C	hemistry
A. Course Identification and General Info	ormation	
1. Course title and code: Research Metho	odology and Scientific Communicat	ion (1830612-2)
2. Credit hours: 2 CU		
3. Program(s) in which the course is offer	red.	
(If general elective available in many prog	grams indicate this rather than list p	rograms)
4. Name of faculty member responsible f	for the course:	
5. Level/year at which this course is offer	red: Master degree/First Year	
6. Pre-requisites for this course (if any):		
7. Co-requisites for this course (if any):		
8. Location if not on main campus:		
9. Mode of Instruction (mark all that app	ly):	
a. traditional classroom	X What percentage?	40%
b. blended (traditional and online)	What percentage?	
c. e-learning	X What percentage?	40%
d. correspondence	What percentage?	
f. other	What percentage?	20%
Oral presentation		
Assignment, presentation and case studies	S	





Comments:





B Objectives

1. What is the main purpose for this course?

The main purpose of this course is to introduce the students with research methods, data analysis, and to enable them to implicate qualitative and quantitative methods for conducting manipulative as well as interoperative research. The students will gain an insight of research intent and design, methodology and technique, format and presentation, and data management and analysis informed by commonly used statistical methods. The focal point of this course will not to search the mystery of statistics but to develop each student's ability to use this knowledge to become more effective in research after going through important concepts of research design, data collection, statistical and interpretative analysis, and final report presentation.

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field)

The change is inevitable to make progress either in academic or research provided that it is properly facilitated and managed. This course is introduced for the first time so the progress of the course in terms of input and output would be critically evaluated with the passage of time during or after the completion of course for the master program. However, the implementation of online activities (i.e., online assignments) along with traditional lectures, tutorials and case studies will be used in the most teaching classes for this course.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

- Overall, the course will work through the weekly plan lessons related to research and/or statistics-related concepts to the students with real-life research examples to understand them how research changes the life in academics, industries and profession.
- This course will provide knowledge about methods in research design, preparation a preliminary research project in their subject matter areas.
- The course will also explicit how to accurately collect data, its interpretation and presentation for dissertation, research papers, seminars and conferences.
- The course will also focus to empirically review, judge, and analyze findings which may affect their areas of research and communication.

1. Topics to be Covered





List of Topics	No. of Weeks	Contact hours
The process of conducting research: An overview	1	2
Introduction to research integrity and ethics	1	2
How to read different scientific articles (review or research) paraphrasing, planning for writing and writing research proposal.	2	4
Research design introduction	1	2
Experimental design	1	2
 Introduction to Qualitative Research Interpreting Qualitative Data 	2	4
Introduction to Quantitative Research	1	2
Sampling Concepts	1	2
Quantitative Data Collection Instruments	1	2
Data Mining – Finding the Patterns and Problems in the World of Data	1	2
Reporting results: Writing About Qualitative and Quantitative Findings	1	2

2. Course	2. Course components (total contact hours and credits per semester):						
		Lecture	Tutorial	Laboratory/ Studio	Practical	Other:	Total
Contact	Planed	16	10				26
Hours	Actual						
Credit	Planed	1.2	0.8				2.0
	Actual						

3. Additional private study/learning hours expected for students per week.

3





4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Cod	NQF Learning Domains	Course Teaching	Course
e	And Course Learning Outcomes	Strategies	Assessment
#	And Course Learning Outcomes	Strategies	Methods
1.0	Knowledge		
1.1	Evaluate the use of research methodology and oral communication in academics and research	Lectures supported by tutorial	Written Exam
1.2	Judge the reliability and validity of methodology and experiment design	Lectures supported by tutorial	Written Exam
2.0	Cognitive Skills		
2.1	Optimize and able to perform exploratory data analysis	Lectures supported by tutorial and research papers data	Written Exam and assignment
2.2	Manage to interpret data by writing in accurate scientific way.	Lectures supported by tutorial and research papers data	Written Exam and assignment
3.0	Interpersonal Skills & Responsibility		
3.1	Draw inference/ conclusions from categorical data	Lectures supported by tutorial and research papers data	Assignment and presentation





3.2	Present well thought research ideas in a compelling way	Lectures supported by tutorial and research papers data	Oral presentation
4.0	Communication, Information Technology, Nun	nerical	
4.1	Use of computer-intensive methods for data analysis	Lectures, self- learning and tutorial	Written Exam and assignment
4.2	To Draw conclusions from statistical test results	Lectures supported by tutorial and research papers data	Assignment and case studies
5.0	Psychomotor		
5.1	None		

5. 5	Schedule of Assessment Tasks for Students During the Semeste	r	
	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment
1	Written Exam	16	60%
2	Assignment	8-15	20%
3	Presentation	7-13	20%

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

The student communication regarding course contents, study matters and consultation for academic affairs with the academic staff is necessary for the smooth run of the course. For this purpose, the face to face consultation, by phone or email is recommended with academic staff. For this, the contact information of related academic staff would be displayed or conveyed to the students through proper channels of communication. The students' questions regarding course plan, tutorials and assignments may ask directly or via assistance of telephone, email and other social media channels provided that approved and authorize by the vice dean of student's academic affairs. The availability of oral consultation time would be factually on the jurisdiction of the academic staff, however; they would be encouraged to spare some time for this purpose.



E Learning Resources

- 1. List Required Textbooks
- Cohen, P.R., 1995. Empirical methods for artificial intelligence (Vol. 139). Cambridge, MA: MIT press.
- Research Design: Qualitative, Quantitative, and Mixed Methods Approaches, John Creswell. Publisher: SAGE Publications, Inc; Fourth Edition (March 14, 2013), Language: English, ISBN-10: 1452226105 ISBN-13: 978-145222610.
- Bryman, A., 2006. Integrating quantitative and qualitative research: how is it done?. Qualitative research, 6(1), pp.97-113.
- Research Methodology: Methods and Techniques by <u>C. R. Kothari</u>, 3rd edition. New Age International Publishers
- Kothari, C.R., 2004. Research methodology: Methods and techniques. New Age International.
- Yin, Robert K. 2003. Case Study Research Design and Methods. Third Edition, Applied Social Research Methods Series, Volume 5, SAGE Publications, Thousand Oaks, London, New Delhi, Newbury Park, CA.
- Yin, R.K., 2017. Case study research and applications: Design and methods. Sage publications.
- Maxwell, J.A. 2001. QUALITATIVE RESEARCH DESIGN. Applied Social Research Methods Series, Volume 5, SAGE Publications, Thousand Oaks, London, New Delhi.
- Maxwell, J.A., 2013. Applied social research methods series: Vol. 41. Qualitative research design: An interactive approach, 3
- Jackson, S. L. (2015). Research methods and statistics: A critical thinking approach. Cengage Learning. Third edition.
 - 2. List Essential References Materials (Journals, Reports, etc.)
- 3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.
 - <u>http://upetd.up.ac.za/authors/create/index.htm</u>
 - <u>http://www.csulb.edu/~msaintg/ppa696/696menu.htm</u>
 - <u>http://www.up.ac.za/asservices/ais/assign.pdf</u>

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.

F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

Classroom both for male and female students accommodating minimally 20 students each are required.

2. Technology resources (AV, data show, Smart Board, software, etc.)

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)





G Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching

Course evaluation questionnaires available on the faculty portal website will be used to get the students feed-back about the course. However, other channels such as group discussion, group leader assessment, staff-student committees, face-to-face interviews with students and e-mail survey form can also be used to overview overall effectiveness of the course.

- 2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department
- Peer rating
- Exit and Alumni ratings
- Employer ratings
- Self-evaluation
- 3. Processes for Improvement of Teaching
- Attending training sessions and workshops in staff development program organized by college of pharmacy and deanship of academic development and quality.
- Meeting with colleagues to discuss problems during teaching or using different teaching resources.
- Discussion about classroom challenges with colleagues and members of the department counsel.
- Review of previous teaching strategies in different courses and evaluating the student's feedback.

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

4. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.

It may be achieved by;

- Benchmarking the program with other international universities actively conferring the course.
- A direct comparison of course objectives and student achievements.
- Conversation to other professors from different universities teaching the same course to exchange ideas for the improvement of the course.
- Course revision annually by the curriculum committee.

Name of Course Instructor: Mohamed Zakaria

Signature: _____ Date Specification Completed: _____

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah

Date Received:



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COURSE SPECIFICATIONS Form

Course Title: Advanced Physical Pharmacy

Course Code: 1803601-3





Course Specifications

Institution: Umm AlQura University	Date:	November 2017
College/Department: Pharmacy/ Pharmaceutics		

A. Course Identification and General Information

1. Course title and code: Advanced Physical Pharmacy (1803601-3)				
2. Credit hours: 3CU (2+1)				
3. Program(s) in which the course is offer	red.			
(If general elective available in many prog	grams indicate this rather than list	programs)		
Master of Pharmaceutics				
4. Name of faculty member responsible faculty	or the course: staff member of Pha	armaceutics		
5. Level/year at which this course is offer	red: Post graduate level			
6. Pre-requisites for this course (if any):				
7. Co-requisites for this course (if any):				
8. Location if not on main campus: main	campus			
9. Mode of Instruction (mark all that appl	y):			
a. traditional classroom	What percentage?	50%		
b. blended (traditional and online)	What percentage?	20%		
c. e-learning	What percentage?	10%		
d. correspondence	What percentage?			
f. other as oral presentation, group d	iscussion and flipped classroom	20% percentage?		





Comments:





B. Objectives

1. What is the main purpose for this course?

This course provides the students with theories and principles to predict solubility, stability and improve critical thinking concerning industrial constrains and correlate these physical aspects with pharmaceutical problems. Beside, this course is essential for helping the students in understanding the physical chemical foundations of the pharmaceutical sciences and their Pharmaceutical applications and also update the students with the progress and new researches in the topics outlined in this . Great focusing is placed upon the application of scientific principles to practical professional problems. In this course, lectures, student oral presentation and Internet search, solving problems will be included among other instructional strategy.

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field)

The course is introduced for the first time

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

This course is considered as an interpretation of the concepts learned in undergraduate pharmaceutics courses, discussing in more depth and analyzing the physical principles that control the formulation of drugs. The presentation of this course is implemented through theoretical and physical concepts. it will provide the students with the theories, concepts and fundamental principles of disperse systems. Basic principles include thermodynamics, free energy. Equilibrium phenomena will be covered at an advanced level in this course, beside solubility in related to in/ vitro, in /vivo correlation, and effect of pH, distribution phenomena, complexation and protein binding; drug release, dissolution, surface chemistry, colloids and stability guidelines will be also discussed.

1. Topics to be Covered		
List of Topics	No. of Weeks	Contact hours
Thermodynamics	2	8
Enthalpy (Heat content and heat capacity)		
Thermodynamics laws and their uses		
Practical: problem solving		
Ionic equilibrium	2	8
Buffer, ionization Theory		
Weak acids & weak bases and pH Equations		





Solubility of sparingly soluble salts		
Practical: Determination of pH effect on ionization constant		
Determination of ionization constant		
Solubility and dissolution testing	2	8
Solutions and colligative properties		
Factors affecting solubility of weak electrolytes		
practical: Solubility study of different dosage form		
Effect of surfactant on solubility		
Effect of pH on solubility		
Surface Chemistry and Colloids	2	8
Surface behavior of atoms and molecules at Interface		
Adsorption process		
Dispersion system and colloid chemistry		
Practical: Determination of colloidal stability		
Determination of particle size and Zeta potential of different disperse		
system		
Determination of Rheology of different disperse systems		
Determination of Adsorption constant		
Complexation and drug-polymer complexes	2	8
Complexation and protein binding		
Practical: Identification of different complex using DSC, NMR, Mass		
spectra		
Diffusion and diffusion coefficient	3	12
Diffusion through a membrane		
Diffusion in a Monolithic Matrix		
Diffusion in a Matrix Swelling/Erosion		
Practical: Determination of diffusion coefficient using Franz diffusion cell		
Stability testing and guidelines	1	4
Practical: Stability study at different temperature and Humidity		
Determination of reaction rate constant of different disperse systems		
Problem solving on drug kinetics		

2. Course components (total contact hours and credits per semester):							
	Lecture Tutorial Laboratory/ Studio Practical Other: Total						Total
Contact	Planed	18	10		28		56
Hours	Actual						





Credit	Planed	1.3	0.7	1	3
	Actual				

3. Additional private study/learning hours expected for students per week.

Short discussion on a topics and oral seminar

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

The course's objective is to promote understanding of the pharmaceutical phenomena and the physicochemical principles of pharmaceutics, and the interrelations between the physical properties of the raw materials and those of the pharmaceutical formulations and final dosage forms.

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Cod e #	NQF Learning Domains And Course Learning Outcomes	Course Teaching Strategies	Course Assessment Methods
1.0	Knowledge	·	
1.1	Understand theory of thermodynamic and its use for describing energy –related change of reactions		
1.2	Understand thermodynamic laws and their use	Lecture	Midterm exam (20%).
1.3	Describe ideal solution and colligative properties of nonelectrolyte in solution	Class discussion	2- Final written exam (50%).
1.4	Understand the concept of acid- base equilibrium and dissociation constant		
	and dissociation constant		





1.5	Describe the solubility and factors affecting it		
1.6	Describe the distribution coefficient and partition coefficient and their importance in pharmaceutical system		
1.7	Define types of complexes and determine stability constant of complex formation		
1.8	Describe factor affecting protein binding and complexation		
2.0	Cognitive Skills		
2.1	Calculate free energy functions and apply them to pharmaceutical relevant issues	1- Laboratory	
2.2	Calculate colligative properties	2- Teaching students how	
2.3	Calculate solubility of weak electrolyte	to understand and explain various concepts related to	- laboratory exam +
2.4	Calculate acidity constant and pH	solubility, surface	Tutorial (15%)
2.5	Calculate the diffusion coefficient	phenomena, stability	
2.6	calculate the stability parameters as reaction rate constant, half-life and Expiry date	3- Urge students to think critically and engage in group discussion	
3.0	Interpersonal Skills & Responsibility		
3.1	Act responsibly and ethically in preparing group presentation	1- One group presentation	1- 10% for:
3.2	write assignments in due time	2- Individual assignments requiring investigation using internet and library	presentation 2- Assignment and
3.3	Show effective communication and positive relation with others and be able to work as an effective member in a team.	resources as a means of developing self-study skills.	(5%)
4.0	Communication, Information Technology,	Numerical	
4.1	Use technology in collecting data		





4.2	Perform different calculations related to ionic equilibrium, solubility, thermodynamic, diffusion, stability	Allow students to extract knowledge from materials on the web site Allow students to explore recommendation obtained from International conference of harmonization (ICH) and correlate it with the condition in pharmaceutical manufacturer	Prepare a group discussion and align marks for the use of web-based material in students' presentations, participation
5.0	Psychomotor		
5.1	Perform practical session related to stability, solubility and diffusion	Student will perform the experiments and related calculations.	laboratory exam

5. Schedule of Assessment Tasks for Students During the Semester				
	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment	
1	Midterm exam	7	20%	
2	Student presentation	13	10	
3	Assignment and group discussion	12-13	5	
4	Laboratory exam+ tutorial	13	15	
5	Final exam	16	50	

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

- Course instructors are ready to answer all students' quires during their lectures or in office hours, and they can be reached by personal meeting, phones or e-mails.





- All students have the e-mail of the course instructor through course guide distributed to the student at the beginning of each semester

- Office hours of staff members are also announced, 4 hours per week

E Learning Resources

1. List Required Textbooks

- 1- Martin''s Physical Pharmacy and Pharmaceutical Science. physical chemical and biopharmaceutical principles in the pharmaceutical sciences,7 th Edition, Patric. J. Sinko, Yashveer Singh. 2017. Wolters Kluwer, Philadelphia.
- 2- Physicochemical Principles of Pharmacy, 6 th Edition, A.T. Florence & D. Attwood, 2015, Pharmaceutical Press.
- 3- Advanced Pharmaceutics: Physicochemical principles. Chern-Ju Kim, 2007, CRC Press, New York.
- 4- Applied Physical Pharmacy by Mansoor Amiji; Thomas J. Cook; W. Cary Mobley, 2 nd Edition, McGraw-Hill , 2014.
- 2. List Essential References Materials (Journals, Reports, etc.)

journal papers and review articles on the topics recommended by instructors.

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

www.sciencedirect.com

https://online.lexi.com/

http://www.uptodate.com/contents/search

http://www.fda.gov/

http://www.ema.europa.eu/ema/

http://www.medscape.com/

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.

Students are required to use Microsoft word program, Excel program and PowerPoint programmer also they are encouraged to use some mind map computer software.





F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

-Lecture rooms should be large enough to accommodate 50 students

-Laboratories should accommodate 25 students

2. Technology resources (AV, data show, Smart Board, software, etc.)

Laptop computer - projector system, data show

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

Dissolution tester, UV spectrophotometer, pH meter, electric balance, Magnetic stirrer, Filtration set, Homogenizer Brookfield viscometer Centrifuge Particle size analyzer Zeta sizer HPLC Differential scanning colorimeter Electron microscope

G. Course Evaluation and Improvement Processes

- 1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching
- 1. A post midterm. open-ended questionnaire will be distributed to students to draw the instructor's attention to the weaknesses and strengths of his presentations
- 2. End-of-term evaluation of course by students through course survey
- 3. Periodical open discussion with students to survey their opinions on the degree of achievement of course, goals and objectives
- 2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department None
 - 3. Processes for Improvement of Teaching




1. Attending training sessions

2. Attending workshops to facilitate the exchange of experiences amongst faculty members

- 3. Scheduling regular meetings with other colleagues where problems are discussed and solutions are given
- 4. Discussing the challenges in the classroom with colleagues and members of the Department Counsel
- 5. Encouraging faculty members to attend conferences on professional development

6. Setting goals for achieving excellence in teaching at the beginning of each new semester after reviewing previous semester's teaching strategies and results and after considering students'feedback

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

- 5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.
- 1.Compare syllabi and course description to those found in other universities
- 2. Compare course objectives and goals to students' achievement
- 3. Try to contact other professors in different universities who are teaching similar courses (including well-known institutions) to exchange views regarding the optimal ways to improve the course
- 4. The course content are reviewed annually by the curriculum committee

Name of Course Instructor: Nahla S Barakat

Signature: Nahla Barakat	Date Specification Completed: 3/10/2019
Program Coordinator: Khaled Atta	llah
Signature: Khaled Attallah	Date Received:



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COURSE SPECIFICATIONS Form

Course Title: Chromatography and Separation Sciences

Course Code: 1803601-2





Course Specifications

Institution:Umm al Qura university	Date:
College/Department : College of pharmacy,	Department of pharmaceutical chemistry

A. Course Identification and General Information

1. Course title and code: Chromatography and Separation Sciences (1803601-2)				
2. Credit hours: 3 Credit hours				
3. Program(s) in which the course is offered: MSc in Pharmaceutics				
4. Name of faculty member responsible for the course				
5. Level/year at which this course is offered: Master level				
6. Pre-requisites for this course (if any):				
7. Co-requisites for this course (if any):				
8. Location if not on main campus:				
9. Mode of Instruction (mark all that apply):				
a. traditional classroom X What percentage? 80%				
b. blended (traditional and online) What percentage?				
c. e-learning X What percentage? 20%				
d. correspondence What percentage?				
f. other What percentage?				
Comments:				





B Objectives

1. What is the main purpose for this course?

The module aims to provide student with advanced knowledge of chromatographic and separation techniques (GC, LC, HPLC, TLC, (solid phase extraction) SPE and (solid phase micro extraction) SPME) and their applications in pharmaceutical sciences. The student will be exposed to the approach of on-line analytical techniques such as LC-MS. At the end of this course the student will be able to:

At the end of this course the student will be able to:

- Describe the theory of chromatographic and extraction techniques
- Apply chromatographic and electrophoretic data for qualitative and quantitative analysis
- Interpret the chromatographic spectra and identify appropriate technique for analysis
- Carry out calculations from chromatographic data and draw a valid conclusion

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web based reference material, changes in content as a result of new research in the field)

The course will be introduced for first time.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description: The course provides the concept and principles of chromatography and other separation technique, including different types of chromatography, electrophoresis, TLC, solid phase extraction (SPE) and solid phase micro extraction(SPME). Chromatographic techniques have been wildly used in separation and analysis of complex mixtures. The two principle types of chromatography are gas chromatography and liquid chromatography. This course intended for postgrad students seeking advanced knowledge in chromatography and separation technique. The topics covered are useful tools for students engaged in research.

1. Topics to be Covered			
List of Topics	No. of Wee ks	Conta ct hours	
Perspective of separation methods and their uses in pharmaceutical analysis	1	4	
Principle of chromatography	2	8	
Different types of chromatography	3	12	
Principles and theory of mass spectrometry	2	8	





Mass Spectrometry/ Chromatography Coupling	2	8
Advanced applications and detectors	1	4
Separation techniques based on extraction	2	8

2. Course	2. Course components (total contact hours and credits per semester):						
		Lectur e	Tutoria 1	Laborator y/ Studio	Practical	Othe r	Total
Conta	Planed	26	6.0		20		52
ct Hours	Actual						
Cradit	Planed	2	0.2		0.8		3.0
Ciedit	Actual						

3. Additional private study/learning hours expected for students per week.		
	4	

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

(000						
Со	NQF Learning Domains	Course Teaching	Course			
de	And Course Learning Outcomes	Strategies	Assessment			
#			Methods			
1.0	Knowledge					
1.1	Describe the theory of chromatographic and extraction techniques	Lectures supported by tutorial	Written Exam			
2.0	Cognitive Skills					
2.1	Differentiate between the various chromatographic separation techniques (GC, LC, TLC) and appreciate their applications in Pharmaceutical Sciences .	Lectures supported by tutorial Practical, case studies	Exam, practical test and Theory test			
2.2	Interpret the chromatographic spectra and identify appropriate technique for analysis					
3.0	0 Interpersonal Skills & Responsibility					





3.1	write assignments in due time	Assignments and oral presentations	Assignments and oral presentations
3.2	Show effective communication and positive relation with others and be able to work as an effective member in a team.	Assignments and oral presentations	Assignments and oral presentations
4.0	Communication, Information Technology, Numerica	al	
4.1	Carry out calculations from chromatographic data and draw a valid conclusion	Practical, case study	Practical report and assignment
5.0	Psychomotor		
5.1	Produce clear and comprehensive data by working safely in the lab.	Practical, practical cases	Practical reports and presentation

5. \$	5. Schedule of Assessment Tasks for Students During the Semester					
	Assessment task (i.e., essay, test, quizzes, group project,	Week	Proportion of			
	examination, speech, oral presentation, etc.)	Due	Total Assessment			
1	Written Exam	16	60 %			
2	Cases	5-10	15 %			

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

8-12

5-12

15 %

10 %

Students can contact the academic staff for one-to-one consultation regarding specific academic matters from time to time. Information on academic staff contact details are available and appropriately publicized to students.

Additionally, students are able to contact staff members directly with questions and requests for assistance via telephone, email or the online environment when available. Consultation times can be used to proactively work with students over the course of the semester.

E Learning Resources

Assignment

4 Practical reports

3

1. List Required Textbooks

- 1. Pharmaceutical analysis, David C. Lee and Michael L. Webb, 1st ed, 2003.
- 2. Pharmaceutical Analysis: A Textbook for Pharmacy Students and Pharmaceutical Chemists. David Watson, July 2012, CHURCHILL LIVINGSTONE.
- 3. Fundamentals of Analytical Chemistry, Douglas A. Skoog, Donald M. West, F. James Holler, Stanley R. Crouch, Publisher: Brooks Cole; 8th edition.

2. List Essential References Materials (Journals, Reports, etc.)

1. R.E.Majors and P.W.Carr, 'Glossary of liquid phase separation terms', LC.GC, 19(2)(2001)124.

2. L.S.Ettre, "Nomenclature for chromatography" Pure Appl.Chem.,65(1993)819

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

https://chem.libretexts.org/Textbook_Maps/Analytical_Chemistry.

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.

F. Facilities Required





Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

- A. Classroom with 20 seats at least, projector and whiteboard.
- B. Laboratory for 20 students at least and equipped with glassware.

2. Technology resources (AV, data show, Smart Board, software, etc.)

Classroom should be equipped with data show and smart board.

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

GC, HPLC, UV spectrophotometer, UV-Vis-NIR, LC-MS, TLC silica plates, SPE cartridges

G Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching

Course evaluation questionnaires, which will be available on the faculty portal website. Student feedback can be obtained through questionnaires which is available in website or student representation on staff-student committees, structured group discussions and/or focus groups, one to one student interviews, e-mail.

2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department

Peer rating, Exit and Alumni ratings, Employer ratings and self-evaluation.

3. Processes for Improvement of Teaching

Staff development program and Monitor for progress, which can be achieved by:

1. Provide professional learning experiences.

2. Implement strategies for improving classroom culture

3. Ensure that follow-up activities and subsequent professional learning experiences are informed by the intended learning outcomes.

4. Adjust and implement new strategies to improve education culture.

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

The exams will be reviewed by an assessment committee in the college.

The exam will be checked by course coordinator and independent person from the department regarding marking and correction.

For student Activity; there will be a rubric form to be used to assess their performance.

5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.

The course effectiveness will be reviewed through; track student progress through the semester, and long-term assessment, which includes stakeholder review and recommendations. Then the course will be improved by matching the needs with course's intending learning outcomes and program's competencies.

Name of Course Instructor: Ziad Omran

Signature:

Date Specification Completed: 17/03/2019

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah

Date Received: 17/03/2019



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COURSE SPECIFICATIONS Form

Course Title: Advanced biopharmaceutics and bioequivalence

Course Code: 1803602-3





Course Specifications

Institution: Umm Al-Qura University

Date:

College/Department: College of Pharmacy, Department of Pharmaceutics

A. Course Identification and General Information

1. Course title and code: Advanced biopharmaceutics and bioequivalence (1803602-3)				
2. Credit hours: 3 hours (2+1)				
3. Program(s) in which the course is offered	3. Program(s) in which the course is offered.			
(If general elective available in many progr	rams indicate this rather than list pr	ograms)		
MSc of Pharmaceutics				
4. Name of faculty member responsible for	r the course			
5. Level/year at which this course is offere	ed:			
Post graduate				
6. Pre-requisites for this course (if any):				
7. Co-requisites for this course (if any):				
8. Location if not on main campus:				
Main campus				
9. Mode of Instruction (mark all that apply):				
a. traditional classroom	What percentage?			
	V	50%		
b. blended (traditional and online)	What percentage?			
V 20%				
c. e-learning What percentage?				
d. correspondence	What percentage?			
		30%		





f. other (Flipped classroom and case based learning)

What percentage?



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B Objectives

1. What is the main purpose for this course?

The aim of this course is to provide the students with the principles of biopharmaceutics and pharmacokinetics, estimate the bioavailability of the drug, determine the rate of drug release and calculate drug doses. The bioequivalence part of the course will discuss the accepted limits for bioequivalence. We will contrast individual bioequivalence and population bioequivalence and present some of the arguments for and against each approach. Study designs and sample size calculations will be covered

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field)

The course will be introduced for the first time.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

This course discusses the biological and physiochemical factors affecting drug bioavailability, ADME system in the body, and individualizing dosage regimens. Individual biopharmaceutical problems treating chemical and physical properties of drugs and drug systems as they relay to drug transport systems in-vivo will be also evoked. This course includes introduction, basic principles, average, individual and population bioequivalence. Also, this course includes different types of barriers and analysis of simple 2formulation experiments.

1. Topics to be Covered		
List of Topics	No. of	Contact hours
	Week s	Contact nours
Basic pharmacokinetic relationships	2	8
Major pharmacokinetic parameters		
Absorption	2	8
1st pass effect		
Enterohepatic circulation and p Glycoprotein	1	4





Distribution, clearance, cytochrome P-450 and liver enzymes	2	8
Pharmacogenetics	1	4
Non-linear pharmacokinetics and Non-compartmental pharmacokinetics Popular pharmacokinetic in therapeutic drug monitoring and drug dosing in renal disease, Pharmacokinetic in hepatic disease	1	4
Popular pharmacokinetic in therapeutic drug monitoring and drug dosing in renal disease, Pharmacokinetic in hepatic disease	1	4
The biological factors needed in to design controlled drug delivery systems (Absorption, distribution, elimination, drug protein binding, margin of safety, disease conditions)	1	4
Introduction and basic principles of bioequivalence, Average, individual and population bioequivalence	1	4
Physical, biochemical, chemical and physicochemical barriers and methods to overcome them	1	4
Analysis of simple 2-formulation experiments, common study designs and sample size	1	4

2. Course components (total contact hours and credits per semester):							
		Lecture	Tutorial	Laboratory/ Studio	Practical	Other:	Total
Contact	Planed	22	6		28		56
Hours	Actual						
Credit	Planed	1.6	0.4		1		3
	Actual						

3. Additional private study/learning hours expected for students per week.

4

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy





On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Cod	NQF Learning Domains	Course Teaching	Course	
е #	And Course Learning Outcomes	Strategies	Assessment Methods	
1.0	Knowledge			
1.1	Demonstrate the dynamic relationships among the drug, the product, and pharmacologic effect.	Lecture Self-learning project	Written and Oral exam	
1.2	State applications of pharmacokinetics in clinical situations.	Lecture Self-learning project	Written and Oral exam	
2.0	Cognitive Skills			
2.1	Apply methods of estimation of bioavailability and principles of drug clearance	Lecture	Written and Oral	
2.2	Solve problems related to pharmacokinetics and drug dose	Self-learning project	exam	
3.0	Interpersonal Skills & Responsibility			
3.1	write assignments in due time	Assignments and oral presentations	Assignments and oral presentations	
3.2	Show effective communication and positive relation with others and his ability to work as an effective participant in a team.	Assignments and oral presentations	Assignments and oral presentations	
4.0	Communication, Information Technology, Num	nerical		
4.1	Use computer skills to present information	1. Self-learning project	Oral exam, activity and presentation	





4.2	Collect information from a variety of sources	2. Self-learning project	Activity and presentation
5.0	Psychomotor		
	Produce clear and comprehensive data	Laboratory session	End of lab report

5. 5	5. Schedule of Assessment Tasks for Students During the Semester							
	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment					
1	Activity - Project	7-15	25%					
2	Written Exam	16	60%					
3	Viva	12-14	15%					

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

- Course coordinator and teaching staff of the course are willing to answer all students' quires during or after the lectures, and they can be reached by personal meeting, phones or e-mails.
- All students will have the e-mail of the course coordinator.

E Learning Resources

1. List Required Textbooks

1- Design and Analysis of Bioavailability and Bioequivalence Studies, Shein-Chung Chow, Jen-Pei Liu and Jen-Pei Liu. BN: 9781584886686, 3rd Edition, 2008.

2- Applied Biopharmaceutics & Pharmacokinetics, Shargel, L., and Andrew B.C., VU. Seventh Edition 7th Edition . Publisher: McGraw-Hill Education / Medical; ISBN: 978-0-07-183093-5, 7 edition, 2015.
3- Handbook of bioequivalence testing, Sarfaraz K. Niazi. ISBN 9781482226379. 2nd edition, 2014.

2. List Essential References Materials (Journals, Reports, etc.)

• Scientific papers

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

• Sciencedirect, Nejm, Weily inter science





4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.





F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

• Classrooms are available in the faculty of pharmacy campus which are enough to accommodate at least 20 students.

2. Technology resources (AV, data show, Smart Board, software, etc.)

- Computing resources are available in the university library.
- Microsoft Excel

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

HPLC, GC-MS, UV spectrophotometer, USP type II dissolution tester, disintegration tester, UV-visible microplate reader.

G Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching

- Students will fill a survey about the effectiveness of teaching and the course content by the end of the semester. Information in this survey will be treated confidentially and students will not be asked to write their names in it.
- 2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department
 - Any complain from students about quality of teaching and/ or course contents will be treated confidentially, considered and discussed well to find the solutions for it. Moreover, the results of the survey will be analyzed carefully to address any shortcomings.
- 3. Processes for Improvement of Teaching
 - Departmental staff will be encouraged to update their knowledge in the field of work by attending national and international conferences and self-developments courses held inside or outside the university campus.

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

• All exams are designed to be corrected and marked by computer program to minimize the human errors. In addition, a member from an institution other from the university is asked annually to join in teaching and assessing the students

5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.

• The content of the course will be reviewed and updated annually at the beginning of each academic year by the department curriculum committee and any major changes are reported to the college curriculum committee.





Name of Course Instructor: Khaled Attallah

Signature: Khaled Attallah

Date Specification Completed: 3/10/2019

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah

Date Received:



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COURSE SPECIFICATIONS Form

Course Title: Advanced drug delivery systems

Course Code: 1803603-3





Course Specifications

Institution: Umm Al-Qura University	Date:
College/Department: College of Pharmacy , Pharmaceutics	S

A. Course Identification and General Information

1. Course title and code: Advanced drug delivery systems (1803603-3)							
2. Credit hours: 3 hours							
3. Program(s) in which the course is offere	3. Program(s) in which the course is offered.						
(If general elective available in many progr	rams indicate this rather than list p	programs)					
MSc of Pharmaceutics							
4. Name of faculty member responsible for	r the course						
5. Level/year at which this course is offere	ed:						
Post graduate							
6. Pre-requisites for this course (if any):							
7. Co-requisites for this course (if any):							
8. Location if not on main campus:							
Main campus							
9. Mode of Instruction (mark all that apply	<i>י</i>):						
a. traditional classroom	What percentage?						
b. blended (traditional and online)	✓ What percentage?	50%					
c. e-learning	✓ What percentage?	20%					
d. correspondence	What percentage?						
	- V	30%					





f. other (flipped class room)

What percentage?





B Objectives

1. What is the main purpose for this course?

The student will have an overview on different types of drug delivery systems and their therapeutic uses. The student will interact effectively and work as a member of a team.

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web based reference material, changes in content as a result of new research in the field)

The course is introduced for the first time.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

This course discusses the principles of design, properties, and mechanisms of controlled-release dosage forms. The course will enable the undertakers to propose modifications on existing formulations of controlled-release dosage forms and analyze the best method for preparation and determine the ideal character for each.

1. Topics to be Covered		
List of Topics	No. of Weeks	Contact hours
Basis and design of controlled-release drug delivery systems	1	4
Design and operation of controlled-release formulations: Physicochemical principals	1	4
Design and operation of controlled-release formulations: Biological factors	1	4
Oral Controlled-release dosage forms	1	4
Diffusion, dissolution and osmotic controlled drug delivery systems	1	4
Microencapsulation	1	4
Controlled-release dosage forms: Nanostructure-mediated	1	4
Liposomes and niosomes	2	8





Stem cell microencapsulation for therapeutic purposes	1	4
controlled-release dosage forms: Ocular	1	4
Controlled-release dosage forms: Vaginal and uterine	1	4
Release of drugs from stimuli-induced controlled-release systems	1	4
Role of nanomedicine in precision medicine	1	4

2. Course components (total contact hours and credits per semester):							
		Lecture	Tutorial	Laboratory/ Studio	Practical	Other:	Total
Contact	Planed	24	8		8	8	48
Hours	Actual						
Credit	Planed	2	0.33		0.33	0.33	3
	Actual						

3. Additional private study/learning hours expected for students per week.

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)





Cod	NQF Learning Domains	Course Teaching	Course
e	And Course Learning Outcomes	Stratogias	Assessment
#	And Course Learning Outcomes	Strategies	Methods
1.0			
1.0	Knowledge		
1.1	Describe basic design principle for controlled- release drug delivery systems	 Lecture Self-learning Open discussion 	Written and Oral exam
1.2	Discuss physicochemical factors influencing design and operation of controlled-release formulations	 Lecture Self-learning Open discussion 	Written and Oral exam
2.0	Cognitive Skills		
2.1	Modify the structure of a given dosage form to obtain the desired release duration.	 Lecture Self-learning Open discussion 	Written and Oral exam
3.0	Interpersonal Skills & Responsibility		
3.1	Identify technologies for developing transdermal dosage forms	LectureSelf-learning	Written and Oral exam
3.2			
4.0	Communication, Information Technology, Num	erical	
4.1	Use computer skills to present information	• Self-learning	Oral exam, activity and presentation
4.2	Collect information from a variety of sources	• Self-learning	Activity and presentation
5.0	Psychomotor		
5.1	Prepare and characterize plain microcapsules using coacervation, and solvent evaporation methods	• Laboratory sessions	End of lab report
5.2	Prepare and characterize plain noisome using thin film hydration method	• Laboratory session	End of lab report

5. Schedule of Assessment Tasks for Students During the Semester





	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment
1	Activity	7-15	10%
2	Written Exam	16	50%
3	Presentations	16	10%
4	End of lab report	4-6	10%
5	Oral exam	16	20%

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

- Course coordinator and teaching staff of the course are willing to answer all students' quires during or after the lectures, and they can be reached by personal meeting, phones or e-mails.
- All students will have the e-mail of the course coordinator.

E Learning Resources

1. List Required Textbooks

- 1. Advanced Drug Delivery, 1st Edition by Ashim Mitra (Author), Chi H. Lee (Author), Kun Cheng (Author), Publisher: Wiley; (2013).
- 2. Martin's Physical Pharmacy and Pharmaceutical Sciences, seventh edition by Patrick J. Sinko PhD RPh (2016)
- 3. Banker, G. S., et al. (2002). Modern Pharmaceutics, Fourth Edition, CRC Press.
- 4. Mateescu, M. A., et al. (2014). Controlled Drug Delivery: The Role of Self-Assembling Multi-Task Excipients, Elsevier Science.

2. List Essential References Materials (Journals, Reports, etc.)

• Scientific papers

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

• Sciencedirect, Weilyinterscience

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.





Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

- 1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)
 - Classrooms are available in the faculty of pharmacy campus which are enough to accommodate at least 20 students.

2. Technology resources (AV, data show, Smart Board, software, etc.)

• Computing resources are available in the university library.

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

Rotary evaporator, balance, overhead mixer, stirrer, drying oven, multisizer particle analyzer, liposome extruder

G Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching

- Students will fill a survey about the effectiveness of teaching and the course content by the end of the semester. Information in this survey will be treated confidentially and students will not be asked to write their names in it.
- 2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department
 - Any complain from students about quality of teaching and/ or course contents will be treated confidentially, considered and discussed well to find the solutions for it. Moreover, the results of the survey will be analyzed carefully to address any shortcomings.
- 3. Processes for Improvement of Teaching
 - Department teaching staff will be encourage to update their knowledge in the field of work by attending national and international conferences and self-developments courses held inside or outside the university campus.
 - Peer rating
 - Exit and Alumni ratings
 - Employer ratings
 - Self-evaluation

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

• All student's exams are designed to be corrected and marked by computer program to minimize the human errors. In addition, a member from an institution other from the university is asked annually to join in teaching and assessing the students

5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.





• The course content will be reviewed and updated annually at the beginning of each academic year by the department curriculum committee and any major changes will be reported to the college curriculum committee.

Name of Course Instructor: Khaled Attallah

Signature: Khaled Attallah

Date Specification Completed: 3/10/2019

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah

Date Received:



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COURSE SPECIFICATIONS

Form

Course Title: Good manufacturing practice and quality control

Course Code: 1803609-2





Course Specifications

Institution: Umm AlQura University	Date	
College/Department: College of Pharmacy/ De	partment of Pharmaceutics	
A. Course Identification and General Informa	tion	

1. Course title and code: Good manufacturing practice and quality control (1803609)			
2. Credit hours: 2			
3. Program(s) in which the course is offered.			
(If general elective available in many program	is indicate this rather than list programs)		
Master of Pharmaceutics			
4. Name of faculty member responsible for th	e course: staff member of Pharmaceutics		
5. Level/year at which this course is offered:	Post graduate level		
6. Pre-requisites for this course (if any):			
7. Co-requisites for this course (if any):			
8. Location if not on main campus: main campus			
9. Mode of Instruction (mark all that apply):			
Γ	50%		
a. traditional classroom	What percentage?		
	20%		
b. blended (traditional and online)	what percentage?		
c. c-icalining	what percentage?		
[





d. correspondence	What percentage?		
f. other (field experience teaching, student assipercentage?	sted learning)	30%	What
Comments:			





B. Objectives

1. What is the main purpose for this course?

Upon completion of this course the student will:

- 1- Understand the basis of Good Manufacturing Practice and the current legal guidelines and regulations
- 2- Outline the main GMP requirements related to personnel, storage facilities, and premises
- 3- Understand the principles of the GMP quality system and quality control
- 4- Recognize the important steps when dealing with complaints and recalls;

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field)

The course will improve the communication skills of students by practicing, listening, reading, writing and speaking clearly. Also. A 5-8 minutes presentations will be required. Students will discuss several challenges that face maintenance department in a pharmaceutical plant.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

This course covers the foundations of the regulations that control the manufacture and distribution of pharmaceutical, biologic and medical devices. Students will understand how knowledge of the regulations helps in efficient and cost-effective production and problem resolution. The course would include a field training in one of the pharmaceutical companies to get the hand-on experience on how the GMP is implemented in real life.

1. Topics to be Covered		
List of Topics	No. of Weeks	Contact hours
Introduction to Good manufacturing practice	1	2
Overview on the current Saudi FDA GMP requirement for pharmaceuticals	1	2
Principle and overview of Pharmaceutical quality system	1	2
Personnel (background and duties)	2	4





Premises and equipment	2	4
Documentation	2	4
Production	2	4
Quality control	2	4
Complaints and Recalls	1	2

2. Course components (total contact hours and credits per semester):							
		Lecture	Tutorial	Laboratory/ Studio	Practical	Other: (field visits)	Total
Contact	Planed	14	2			12	28
Hours	Actual						
Credit	Planed	1	0.2			0.8	2
	Actual						

3. Additional private study/learning hours expected for students per week. 2 hours

Short discussion on a topics and oral seminar

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

The main goal of the course is to familiarize the students with the principles of the GMP quality system and quality control and the important procedures when dealing with complaints and recalls;

On the table below are the five NQF Learning Domains, numbered in the left column.





First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Cod	NQF Learning Domains	Course Teaching	Course
e	And Course Learning Outcomes	Strategies	Assessment
#	And Course Loui ining Outcomes		Methods
1.0	Knowledge		
1.1	Define Good manufacturing practice		
1.2	Describe the basic requirements of good manufacturing practice	Lecture	Midterm exam (15%).
1.3	Recognize the principles of pharmaceutical quality system	Class discussion	2- Final written exam (50%).
1.4	Identify the content and implementation of process quality control		
2.0	Cognitive Skills	•	
2.1	Differentiate between different types of defects	- Lectures	
2.2	Determine the transfer protocol	-Tutorials	-
2.3	Determine the main tasks of quality control department	- group discussion -Case study	Assignment (10%)
2.4	Explain the protocol for product recall	Field visit to one of	GMP requirement
2.5		the sterile	for sterile products
		manufacturing facilities	
3.0	Interpersonal Skills & Responsibility		
3.1	Act responsibly and ethically in preparing group presentation	1- One group presentation	1- Student
3.2	write assignments in due time	2- Individual assignments requiring investigation using	presentation 25%





3.3	Show effective communication and positive relation with others and be able to work as an effective member in a team.	internet and library resources as a means of developing self- study skills.	On the GMP requirements for biological medicine
4.0	Communication, Information Technology, Nun	nerical	
4.1	Use technology in collecting data	encourage students to use materials on the web extensively	Align marks for the use of web-based material in students presentations, participation
		-	
5.0	Psychomotor		
5.1	non		

5. Schedule of Assessment Tasks for Students During the Semester					
	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment		
1	Midterm exam	Week 7	15%		
2	Student presentation	Week 12	25%		
3	Assignment report on the field visit	Week 11	10 %		
5	Final exam	Week 15	50 %		

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

- Course instructors are ready to answer all students' quires during their lectures or in office hours, and they can be reached by personal meeting, phones or e-mails.





- All students have the e-mail of the course instructor through course guide distributed to the student at the beginning of each semester

- Office hours of staff members are also announced, 4 hours per week

E Learning Resources

1. List Required Textbooks

- 1. Bunn, G. P. (2019). Good Manufacturing Practices for Pharmaceuticals, Seventh Edition, CRC Press.
- 2. Durivage, M. A. (2016). The Certified Pharmaceutical GMP Professional Handbook, Second Edition, ASQ Quality Press.
- 3. Jacobs, T. and A. A. Signore (2016). Good Design Practices for GMP Pharmaceutical Facilities, Second Edition, CRC Press.

2. List Essential References Materials (Journals, Reports, etc.)

journal papers and review articles on the topics recommended by instructors.

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

http://www.fda.gov/

https://ispe.org/initiatives/regulatory-resources/gmp

https://ispe.org/publications/guidance-documents

http://www.ich.org/products/guidelines.html

http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.

Students are required to use Microsoft word program, Excel program and PowerPoint programs also they are encouraged to use some mind map computer software.





F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

-Lecture rooms should be large enough to accommodate 50 students

2. Technology resources (AV, data show, Smart Board, software, etc.)

Laptop computer - projector system, data show

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

G. Course Evaluation and Improvement Processes

- 1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching
- 1. A post midterm. open-ended questionnaire will be distributed to students to draw the instructor's attention to the weaknesses and strengths of his presentations
- 2. End-of-term evaluation of course by students through course survey
- 3. Periodical open discussion with students to survey their opinions on the degree of achievement of course goals and objectives
- 2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department None
 - 2. Processes for Improvement of Teaching
- 1. Attending training sessions
- 2. Attending workshops to facilitate the exchange of experiences amongst faculty members
- 3. Scheduling regular meetings with other colleagues where problems are discussed and solutions are given
- 4. Discussing the challenges in the classroom with colleagues and members of the Department Counsel





5. Encouraging faculty members to attend conferences on professional development

6. Setting goals for achieving excellence in teaching at the beginning of each new semester after reviewing previous semester's teaching strategies and results and after considering students' feedback

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.

1.Compare syllabi and course description to those found in other universities

2. Compare course objectives and goals to students' achievement

3. Try to contact other professors in different universities who are teaching similar courses (including wellknown institutions) to exchange views regarding the optimal ways to improve the course

4. The course content are reviewed annually by the curriculum committee

Name of Course Instructor: Mostafa Shahin

Signature: Mostafa Shahin_____ Date Specification Completed: 3/19/2019

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah

Date Received:




COURSE SPECIFICATIONS Form

Course Title: Natural products and skin care cosmeceuticals

Course Code: 1803604-2





Course Specifications

Institution: Umm Al-Qura University	Date:	
College/Department: Pharmacy/ Pharmaceutics		

A. Course Identification and General Information

1. Course title and code: Natural products and cosmeceuticals (1803604-2)
2. Credit hours: 2h
3. Program(s) in which the course is offered.
(If general elective available in many programs indicate this rather than list programs)
4. Name of faculty member responsible for the course:
5. Level/year at which this course is offered: Post graduate level
6. Pre-requisites for this course (if any):
7. Co-requisites for this course (if any):
8. Location if not on main campus: Main campus
9. Mode of Instruction (mark all that apply):
a. traditional classroom What percentage 50%
b. blended (traditional and online) c. e-learning What percentage? 20%
d. correspondence What percentage?
f. other Peer assisted learning What percentage? 30%
Comments:





B. Objectives

1. What is the main purpose for this course?

The presentation of cosmeceuticals is an important innovation in topical skin care. This course covers all the major aspects of cosmetic formulation and technology at both fundamental and practical levels. In this regard, the course aims at broadening the students' knowledge and introduces them to the intriguing world of cosmetics and personal care products. The course can provide a basic understanding of cosmetics and personal care products, including their regulation, main characteristics, ingredients, formulation, testing.

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field)

the course is introduced for the first time.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

The course discusses the concepts of natural products, the use of essential oils and carrier oils in cosmetics products. The course designed for in-depth studies of skin, and rationale for dermatological formulations: including skin cleansing products, skin moisturizing products, products for special skin concerns, such as aging and acne, sunscreens. The course will also cover the basic principles of colloidal systems, nanotechnology, widely used for the preparation of topical products. Typical quality problems related to the formulation and/or use of products; product testing will be discussed.

1. Topics to be Covered		
	1	
	No. of	
List of Topics		Contact hours
F	Weeks	
	WCCK5	
Introduction	1	2
Comparison of cosmetics and drug		
List of products recognized as compaties		
List of products recognized as cosmetics		
Restriction on the use of ingredients in cosmetics		
	-	
Natural products in cosmetics	2	4
Animal derived natural products		





Casein, collagen, chitosan		
Herbal cosmetics:		
Seaweeds, aloe Vera, olive oil, algae, palm oil, Green tea		
vitamin A and vitamin C cosmeceuticals		
Biophysical character of the skin	2	4
Skin hydration		
Skin aging		
Skin buffering capacity		
Skin irritation		
Skin care products	1	2
Acne products		
Hair products	2	4
Formulation for increasing penetration delivery system	2	4
Hydrocolloids as Protective Colloids and Consistency Regulators		
Nanotechnology penetration enhancement:		
Nano emulsion and Liposome in Cosmetics		
Penetration enhancement device:		
Electroporation, Iontophoresis		
Transdermal patches, Galvanic current		
Development of cosmeceuticals	1	2
Regulatory, legal consideration		
Toxicology, safety and stability evaluation	2	4
Safety of finished products		
Skin tolerance and compatibility testing		
In vitro evaluation		
Cell viability/function testing		
In vivo testing in animal		



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Stem cell cosmeceuticals

Cosmeceuticals for Treating Cellulite

1	2

• ~							
2. Course	2. Course components (total contact hours and credits per semester):						
				Laboratory/			
		Lecture	Tutorial	5	Practical	Other:	Total
				Studio			
Contact	Planed	22	6		-		28
Hours	Actual						
	Planed	1.6	0.4				2
Credit							
	Actual						

3. Additional private study/learning hours expected for students per week.

-

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

The course's learning outcome is to promote the understanding of the cosmeceutical formulation and the encouragement of use of natural product as active ingredient in these products. The course correlates the use of organic, inorganic, physical, analytical and polymer science, nanotechnology, disperse systems, microbiology, lipid–nanoparticle technology in cosmetic science.

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Cod	NQF Learning Domains	Course Teaching	Course Assessment
e	And Course Learning Outcomes	Strategies	Methods
#			
1.0	Knowledge	<u>.</u>	





1.1	Record different types of natural products used		1- Midterm exam
	in formulation of cosmetics products	1- Lectures	(20%).
1.2	Describe different types of skin problems	2- Class discussion	2- Final written exam (50%).
1.3	Outline different hair care products	3- videos	
1.4	Record different evaluation test for safety and stability of cosmeceuticals		
1.5	Outline different cosmeceuticals ingredients		
2.0	Cognitive Skills		
2.1	Explain the use of natural products as	1.Urge students to	
	cosmeceuticals	explain and integrate	150/ group
2.2	Justify the use of penetration enhancement	to formulation design	presentation
2.3	Criticize the test for evaluation of	2- Encourage students to	5% class
	cosmeceuticais	think critically and	participation
2.4	Design different formulation for skin care	discussion	
3.0	Interpersonal Skills & Responsibility	I	
3.1	write assignments in due time	1.One group presentation	
3.2	Show effective communication and positive relation with others and be able to work as an effective member in a team.	2- Individual assignments requiring investigation using internet and library resources as a means of developing self-study skills.	10% assignments
4.0	Communication, Information Technology, Nun	nerical	
4.1	Use technology in collecting data		
4.2			
5.0	Psychomotor	1	
5.1			
5.2			





5. \$	Schedule of Assessment Tasks for Students During the Semeste	er	
	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment
1	Midterm exam	7	20%
2	Student presentation	7-12	15%
3	Assignment	5-12	5%
4	Final exam	16	50%
5	Tutorial	5-10	10%

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

- Course instructors are ready to answer all students' quires during their lectures or in office hours, and they can be reached by personal meeting, phones or e-mails.
- All students have the e-mail of the course instructor through course guide distributed to the student at the beginning of each semester
- Office hours of staff members are also announced, 4 hours per week

E. Learning Resources

1. List Required Textbooks

1. Cosmetics science and technology, 4 rd Edition, André O. Barel Marc Paye Howard I. Maibach. Informa healthcare, 2016.

2. Cosmetics and their relation to drug, Martin Reiger, edt. In Encyclopedia of Pharmaceutical technology, 3rd Edition, edited by: James Swarbrick, Informa Healthcar, NewYork, 2014.

3. Wenninger, J.A.; Canterbery, R.C.; McEwen, G.N., Jr. International Cosmetic Ingredient Dictionary and Handbook, 8th Ed.; The Cosmetics, Toiletries, and Fragrance Association: Washington, DC, 2010

4. Cosmeceuticals and cosmetic practice, Patricia K Farris, Editor, Willey Blackwell, 2014

2. List Essential References Materials (Journals, Reports, etc.)

1. Drug Development & Industrial Pharmacy, Informa healthcare





2. Journal of Pharmaceutical Sciences, Wiley Periodicals Inc. and the American Pharmacists

3. International Journal of Pharmaceutics, Elsevier

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

www.speciation.net

http//www.lib.utexas.edu/etd/d/2003/codyk036/codyk036.pdf

http://en.wikipedia.org/wiki/Code-switching

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.

Students are required to use Microsoft word program and PowerPoint programs also they are encouraged to use some mind map computer software

F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

Lecture rooms should be large enough to accommodate 50 students

Laboratories should accommodate 25 students

2. Technology resources (AV, data show, Smart Board, software, etc.)

Laptop computer - projector system

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

G. Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching

- 1. A post midterm. open-ended questionnaire will be distributed to students to draw the instructor's attention to the weaknesses and strengths of his presentations
- 2. End-of-term evaluation of course by students through course survey
- 3. Periodical open discussion with students to survey their opinions on the degree of achievement of course goals and objectives
- 2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department
- Peer rating





- Exit and Alumni ratings
- Employer ratings
- Self-evaluation

3. Processes for Improvement of Teaching

- 1. Attending training sessions
- 2. Attending workshops to facilitate the exchange of experiences amongst faculty members

3. Scheduling regular meetings with other colleagues where problems are discussed and solutions are given

- 4. Discussing the challenges in the classroom with colleagues and members of the Department Counsel
- 5. Encouraging faculty members to attend conferences on professional development

6. Setting goals for achieving excellence in teaching at the beginning of each new semester after reviewing previous semester's teaching strategies and results and after considering students' feedback

- 7. Keeping up to date with refereed articles and books related to the topics of the course
- 4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)
- 1. MCQs are marked by computer program to minimize the human errors.
- 2. A staff member teaching the program from another institution is asked annually to remark samples of exam papers and assignments.
- 5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.
- 1. Compare syllabi and course description to those found in other universities (including those on the Internet)
- 2. Compare course objectives and goals to students' achievement
- 3. Try to contact other professors in different universities who are teaching similar courses (including wellknown institutions) to exchange views regarding the optimal ways to improve the course
- 4. The course content are reviewed annually by the curriculum committee

Name of Course Instructor: Nahla S Barakat

Signature: Nahla barakat	Date Specification Completed: 13/3/2019

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah Date Received:



المملكه العربيه السعوديه وزارة التعليم جامعة أم القري عمادة الدراسات العليا

COURSE SPECIFICATIONS Form

Course Title: Radiopharmacy

Course Code: 1803605-2





Course Specifications

Institution: Umm Al-Qura University	Date:
College/Department: College of Pharmacy/ Pharmaceutics	

A. Course Identification and General Information

1. Course title and code: Radiopharmacy (1803605-2)
2. Credit hours: 2 hours
3. Program(s) in which the course is offered.
(If general elective available in many programs indicate this rather than list programs)
MSc of Pharmaceutics
4. Name of faculty member responsible for the course
5. Level/year at which this course is offered:
Post graduate
6. Pre-requisites for this course (if any):
7. Co-requisites for this course (if any):
8. Location if not on main campus:
Main campus
9. Mode of Instruction (mark all that apply):
a. traditional classroom What percentage?
√ 50%
b. blended (traditional and online) What percentage?
√
c. e-learning What percentage?







B Objectives

1. What is the main purpose for this course?

The aim of this course is to familiarize the student with new topics such as radioactivity, radioisotope production methods and the application of radioisotope in nuclear medicine imaging and therapy. Also, the student will acquire skills and knowledge in the theory and practice of radiopharmaceutical science.

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field)

The course is introduced for the first time.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

• This course discusses radioisotopes, nuclear pharmacy instrumentation, radiation protection. Also, it discusses different nuclear medicine imaging techniques, including PET and SPECT). Furthermore, the course will help the students to identify the process of development and preparation of sterile radiopharmaceutical products, and also the quality assurance and regulatory issues associated with ionizing radiation.

1. Topics to be Covered		
List of Topics	No. of Weeks	Contact hours
Radioactivity, radioisotopes, and the regulations controlling transport of radioactive materials.	1	2
Positron Emission Tomography (PET) imaging and the organization of a PET radio-pharmacy and list the products most commonly used therein together with their clinical indications	1	2
Radionuclide generators for Nuclear Medicine, and the principles of their design and operation, describe the Molybdenum-99/Technetium-99m generator system and give examples of other generators in routine use	1	2
Mechanisms of targeting of radiopharmaceuticals	1	2





Nuclear pharmacy instrumentation	1	2
Discuss the importance of radiation hygiene and safe working in radiopharmaceutical preparation	1	2
Radiation shielding	1	2
Methods of labeling of radiopharmaceuticals, RIA, IRMA and ELISA assays	2	4
Preparation and Quality control parameters of radiopharmaceuticals	2	4
Keeping & Disposal of Radioactive Substances	1	4
Radiation hygiene, safe working in radiopharmaceutical preparation. and Safety guidelines during dispensing of radiopharmaceuticals	2	4

2. Course components (total contact hours and credits per semester):							
Lecture Tutorial Laboratory/ Studio Practical Other: Total						Total	
Contact	Planed	18	6			4	28
Hours	Actual						
Credit Planed 1.3 0.4 0.3						2	
	Actual						

3. Additional private study/learning hours expected for students per week. 2 hours

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes,





assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Cod	NQF Learning Domains	QF Learning Domains Course Teaching	
e			Assessment
#	And Course Learning Outcomes	Strategies	Methods
1.0	Knowledge		
1.1	Define radioisotopes& radiopharmaceuticals and differentiate between different types of radioisotopes	LectureSelf-learning	Written and Oral exam
1.2	List different types of radiopharmaceuticals used in imaging or therapy	LectureSelf-learning	Written and Oral exam
2.0	Cognitive Skills		
2.1	Discuss safe and effective use of radiopharmaceuticals for diagnosis and therapy	LectureSelf-learning	Written and Oral exam
2.2			
3.0	Interpersonal Skills & Responsibility		I
3.1	Develop specialists who can solve problems and think reasonably	LectureSelf-learning	Written and Oral exam
3.2			
4.0	Communication, Information Technology, Num	erical	
4.1	Use computer skills to present information	1. Self-learning	Oral exam, activity and presentation
4.2	Collect information from a variety of sources	2. Self-learning	Activity and presentation
5.0	Psychomotor		1
5.1	None		
5.2			

5. Schedule of Assessment Tasks for Students During the Semester





	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment
1	Activity and oral presentation	7-15	15%
2	Written Exam	16	70%
3	Oral Exam	12	15%

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

- Course coordinator and teaching staff of the course are willing to answer all students' quires during or after the lectures, and they can be reached by personal meeting, phones or e-mails.
- All students will have the e-mail of the course coordinator.

E Learning Resources

1. List Required Textbooks

- 1- Radiopharmaceuticals for Therapy by F. F. Knapp, Ashutosh Dash, Publisher: Springer; 1st ed. 2016.
- 2- Essentials of Nuclear Medicine Imaging: Expert Consult Online and Print, 6e (Essentials of Nuclear Medicine Imaging (Mettler). by Fred A. Mettler Jr. MD MPH, Milton J. Guiberteau MD, Publisher: Saunders; 6 edition, 2012.
- 3- Innovative Radiopharmaceuticals in Oncology and Neurology, Denis Guilloteau, Françoise Kraeber-Bodéré, Jacques Barbet, Michel Chérel, Frontiers Media SA, 2017

2. List Essential References Materials (Journals, Reports, etc.)

- Nuclear medicine and biology
- Radiation research
- Radiochemistry
- Applied radio-isotopes

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

• Sciencedirect, Nejm, Weily inter science

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.





F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

• Classrooms are available in the faculty of pharmacy campus which is enough to accommodate at least 20 students.

2. Technology resources (AV, data show, Smart Board, software, etc.)

• Computing resources are available in the university library.

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

G Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching

• Students will fill a survey about the effectiveness of teaching and the course content by the end of the semester. Information in this survey will be treated confidentially and students will not be asked to write their names in it.

2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department

- Any complain from students about quality of teaching and/ or course contents will be treated confidentially, considered and discussed well to find the solutions for it. Moreover, the results of the survey will be analyzed carefully to address any shortcomings.
- 3. Processes for Improvement of Teaching
 - Department teaching staff will be encourage to update their knowledge in the field of work by attending national and international conferences and self-developments courses held inside or outside the university campus.

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

• All student's exam are designed to be corrected and marked by computer program to minimize the human errors. In addition, a member from an institution other from the university is asked annually to join in teaching and assessing the students

5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.

• The course content is reviewed and updated annually at the beginning of each academic year by the department curriculum committee and any major changes are reported to the college curriculum committee.





Signature: Khaled Attallah

Date Specification Completed: 3/19/2019

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah

Date Received: _____



المملكه العربيه السعوديه وزارة التعليم جامعة أم القري عمادة الدراسات العليا

COURSE SPECIFICATIONS

Form

Course Title: Pharmaceutical biotechnology

Course Code: 1803606-2





Institution: Umm AlQura University	Date:	
College/Department: Pharmacy/ Department of	Pharmaceutics	

A. Course Identification and General Information

1. Course title and code: Pharmaceutical biotechnology (1803606-2)				
2. Credit hours: 2				
3. Program(s) in which the course is offer	red.			
(If general elective available in many prog	grams indicate this rather than list	programs)		
4. Name of faculty member responsible f	for the course:			
5. Level/year at which this course is offer	red: Post graduate level			
6. Pre-requisites for this course (if any):				
7. Co-requisites for this course (if any):				
8. Location if not on main campus: main	campus			
9. Mode of Instruction (mark all that app	ly):			
a. traditional classroom	What percentage?	70%		
b. blended (traditional and online)	What percentage?	10%		
c. e-learning	What percentage?	20%		
d. correspondence	What percentage?			
f. other	What percentage?			





Comments:





B. Objectives

1. What is the main purpose for this course?

The main aim is to provide the basis of the architecture and technology of biopharmaceutical drug manufacture, and growth and use of the gene therapy, also it will amplify the practical aspects and understanding of therapeutic effects as well as of unwanted side effects of biopharmaceuticals.

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field)

Students will improve communication skills by practicing, listening, reading, writing and speaking clearly. Also. A 5-8 minutes oral presentations will be required during the class period. Students will choose Pharmaceutical Biotechnology issue and discuss it during the class time.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

This course will discus various techniques and applications of biotechnology in biopharmaceuticals and biomedical research. Also, it will explain the physicochemical aspects, pharmacology and the formulation of widely used biopharmaceuticals

1. Topics to be Covered		
List of Topics	No. of	Contact hours
	Weeks	
Introduction to biotechnology	1	2
Cloning and rDNA	2	4
Methods of gene transfer	2	4
Pharmaceutical protein production	2	4
Protein isolation and stability	1	2
Protein stability	2	4
Considerations in protein production	2	4





Formulation and delivery of protein pharmaceuticals	2	4

2. Course components (total contact hours and credits per semester):							
		Lecture	Tutorial	Laboratory/ Studio	Practical	Other:	Total
Contact	Planed	20	8				28
Hours	Actual						
Credit	Planed	1.4	0.6				2
	Actual						

3. Additional private study/learning hours expected for students per week. 2 hours

Short discussion on a topics and oral seminar

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

The main aim is to provide basis of the components and technology of biopharmaceutical drug production, and development and use of the gene therapy, also it will improve the practical aspects and understanding of therapeutic effects as well as of unwanted side effects of biopharmaceuticals.

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes,





assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Cod	NOF Learning Domains	Course Teaching	Course
e		course reacting	Assessment
#	And Course Learning Outcomes	Strategies	Methods
π			Witthous
1.0	Knowledge		
1.1	Define molecular biotechnology and biotechnology product		Midterm exam
1.2	Describe vaccine and monoclonal antibody- based pharmaceuticals	Lecture Class discussion	(15%). 2- Final written
1.3	Recognize the production of biotech product		exam (50%).
1.4	Identify ways of formulating a biotech product		
2.0	Cognitive Skills		
2.1	Differentiate biotech product and traditional medicines		
2.2	Explain the pharmacokinetics parameters of a biotech product	- Lectures -Tutorials	- Assignment (10%) (minireview on protein-based pharmaceuticals)
2.3	Determine the physical and biochemical properties of a biotech product	- group discussion	
2.4 2.5	Determine suitable technique to asses protein stability		
3.0	Interpersonal Skills & Responsibility		
3.1	Act responsibly and ethically in preparing group presentation	1- One group presentation	Student group
3.2	write assignments in due time	2- Individual assignments requiring investigation using	presentation 25% On a recently approved biotech
3.3	Show effective communication and positive relation with others and be able to work as an effective member in a team.	internet and library resources as a means of developing self- study skills.	product.
4.0	Communication, Information Technology, Nun	nerical	





4.1	Use technology in collecting data	Inspire the students to use materials on the web extensively	Align marks for the use of web-based material in presentations, participation
5.0	Psychomotor		
5.1	non		

5. \$	5. Schedule of Assessment Tasks for Students During the Semester			
	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment	
1	Midterm exam	Week 7	15%	
2	Student presentation	Week 12	25%	
3	Assignment	Week 11	10 %	
5	Final exam	Week 16	50 %	

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

- Course instructors are ready to answer all students' quires during their lectures or in office hours, and they can be reached by personal meeting, phones or e-mails.
- All students have the e-mail of the course instructor through course guide distributed to the student at the beginning of each semester
- Office hours of staff members are also announced, 4 hours per week





1. List Required Textbooks

- 1. Crommelin, D. J. A., et al. (2013). Pharmaceutical Biotechnology: Fundamentals and Applications, Springer New York.
- 2. Gad, S. C. (2007). Handbook of Pharmaceutical Biotechnology, Wiley.
- 3. Kokate, C., et al. (2016). Textbook of Pharmaceutical Biotechnology E-Book, Elsevier Health Sciences.
- 4. Walsh, G. (2013). Pharmaceutical Biotechnology: Concepts and Applications, Wiley.

2. List Essential References Materials (Journals, Reports, etc.)

journal papers and review articles on the topics recommended by instructors.

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

www.sciencedirect.com

https://online.lexi.com/

http://www.uptodate.com/contents/search

http://www.fda.gov/

http://www.ema.europa.eu/ema/

http://www.medscape.com/

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.

Students are required to use Microsoft word program, Excel program and PowerPoint programs also they are encouraged to use some mind map computer software.





F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

-Lecture rooms should be large enough to accommodate 50 students

-

2. Technology resources (AV, data show, Smart Board, software, etc.)

Laptop computer - projector system, data show

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

G. Course Evaluation and Improvement Processes

3. Strategies for Obtaining Student Feedback on Effectiveness of Teaching

- 1. A post midterm. open-ended questionnaire will be distributed to students to draw the instructor's attention to the weaknesses and strengths of his presentations
- 2. End-of-term evaluation of course by students through course survey
- 3. Periodical open discussion with students to survey their opinions on the degree of achievement of course, goals and objectives

2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department None

- 4. Processes for Improvement of Teaching
- 1. training sessions attendance

2. participation in workshops to improve the exchange of experiences amongst faculty members

3. Arrange regular meetings with other colleagues to discuss the problems and possible solutions

4. Discuss the challenges in the classroom with colleagues

5. Encourage the attendance of workshops on professional development





6. Always review students 's feedback and set goals for achieving excellence in teaching at the beginning of each new semester

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.

1.Compare syllabi and course description to those found in other universities

2. Compare course objectives and goals to students' achievement

3. Try to contact other professors in different universities who are teaching similar courses (including wellknown institutions) to exchange views regarding the optimal ways to improve the course

4. The course content are reviewed annually by the curriculum committee

Name of Course Instructor: Mostafa Shahin

Signature: _____

Date Specification Completed: 13 / 03/ 2019

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah





COURSE SPECIFICATIONS

Form

Course Title: Pharmaceutical applications of nanotechnology

Course Code: 1803607-2





Course Specifications

Institution: Umm AlQura University	Date:	
College/Department: Pharmacy/ Pharmaceutics		

A. Course Identification and General Information

1. Course title and code:Pharmaceutical applications of nanotechnology (1803607-2)					
2. Credit hours: 2					
3. Program(s) in which the course is offere	ed.				
(If general elective available in many progr	rams indicate this rather than list programs)				
Master of Pharmaceutical Sciences					
4. Name of faculty member responsible for	or the course:				
5. Level/year at which this course is offere	ed: Post graduate level				
6. Pre-requisites for this course (if any):					
7. Co-requisites for this course (if any):					
8. Location if not on main campus: main c	campus				
1. Mode of Instruction (mark all that	apply):				
a. traditional classroom	X Vhat percentage? 80				
b. blended (traditional and online)	What percentage?				
c. e-learning 20					
d. correspondence	What percentage?				
f. other	What percentage?				





Comments:





B. Objectives

1. What is the main purpose for this course?

The objective of this course is to discuss the current trends and potential applications of nanotechnology in the field of pharmaceutics. Special emphasis will be on the applications in drug delivery of small molecules, proteins, and genes.

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field)

The course is introduced for the first time.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

This course is designed for help students to acquire quality knowledge in applications of nanotechnology. Recently, we have seen unprecedented growth of applications in the area of nanoscience and nanotechnology. There is increasing optimism that nanotechnology, as applied to drug delivery, will bring significant advances in the diagnosis and treatment of many diseases. Highly efficient drug delivery, based on nanomaterials, could potentially reduce the drug dose needed to achieve therapeutic benefits, which, in turn, would lower the cost and/or reduce the side effects associated with particular drugs. This course will deal with the new and ongoing potentialities of nanotechnology applications of drug delivery. In addition, it will discuss advances in nanotechnology-based therapeutics for gene delivery systems for the treatment various illness. This course will enable students to characterize nanocarriers morphologically using SEM and through size analysis.

1. Topics to be Covered		
	No. of	
	NO. 01	$C \rightarrow 1$
List of Topics		Contact hours
	Weeks	
Introduction to Nanotechnology	1	2
Multifunctional polymeric carrier for cancer targeting	1	2
maintainetional porymente carrier for cancer augering	1	2
Nanogels as pharmaceutical carriers	1	2
Nanogers as pharmaceutical carriers	1	2
Nanotechnology based advanced therapeutics (ultrasound mediated therapy,	2	4
DNA delivery for gene therapy vaccine delivery)		
Divit derivery for gene therapy, vacenie derivery)		
nH responsive carrier for intercelluar delivery	1	2
pri responsive carrer for intarcential delivery	1	2





Functionalized dendrimers as drug carries	1	2
Biodegradable nanoconjugate for drug delivery	2	4
Functionalized carriers for mitochondrial targeting	1	2
Discussion of ethical issues and future perspective (nano-toxicity, nano-ethics)	2	4
Characterization techniques for nano-material: morphologic analysis (scanning electron microscopy)	1	2
Characterization techniques for nano-material size analysis (dynamic light scattering)	1	2

2. Course components (total contact hours and credits per semester):							
		Lecture	Tutorial	Laboratory/ Studio	Practical	Other:	Total
Contact	Planed	18	4		6		28
Hours	Actual						
Credit	Planed	1.3	0.3		0.4		2
	Actual						

3. Additional private study/learning hours expected for students per week.	3	
Short discussion on a topics and oral seminar		

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy





The objectives of this course is to provide the students with knowledge and the basic understanding of nanotechnology and its applications in pharmacy.

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Cod e #	NQF Learning Domains And Course Learning Outcomes	Course Teaching Strategies	Course Assessment Methods
1.0	Knowledge	·	
1.1	Enumerate the benefits of nanotechnology in medicine.		
1.2	Describe different techniques of drug targeting	Lecture	Midterm exam (15%).
1.3	Recognize different types of nanocarriers	Class discussion	2- Final written
1.4	Identify the tools used to fabricate novel nanocarriers		exam (50%).
1.5	Outline ethical issues related to nanocarriers		
2.0	Cognitive Skills		•
2.1	Differentiate between active and passive targeting		
2.2	Illustrate the stimuli sensitive nanocarriers	Lasturas	-
2.3	Determine the key features of multifunctional nanocarrier	- Tutorials	Writing a review
2.4	Determine variable tools used to achieve organ targeting	- group discussion -Case study	current nanoformulation of a novel anticancer
2.5	Explain different tools and techniques to characterize nanocarrier		medication.
3.0	Interpersonal Skills & Responsibility		





3.1 3.2 3.3	Act responsibly and ethically in preparing group presentation write assignments in due time Show effective communication and positive relation with others and be able to work as an effective member in a team.	 P 1- One group presentation 2- Individual assignments requiring investigation using internet and library resources as a means of developing self- study skills. 	Student group presentation 25% Group presentations on peer reviewed article with quantitative data on application of nanotechnology in different types of tumors.
4.0	Communication, Information Technology, N	umerical	
4.1	Use technology in collecting data	Promote to use materials on the web extensively	Align marks for the use of web-based material in students' presentations, participation
5.0	Psychomotor		
5.1	Characterize nanocarriers using various tools	Two laboratory sessions on scanning electron microscopy, particle size analyser	End of laboratory report 10%

5.5	5. Schedule of Assessment Tasks for Students During the Semester			
	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment	
1	Midterm exam	Week 7	15%	
2	Student presentation	Week 12	15%	
3	End of lab report	Week 7, 10	10%	





3	Assignment	Week 11	10 %
5	Final exam	Week 16	50 %

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week

- Course instructors are ready to answer all students' quires during their lectures or in office hours, and they can be reached by personal meeting, phones or e-mails.
- All students have the e-mail of the course instructor through course guide distributed to the student at the beginning of each semester
- Office hours of staff members are also announced, 4 hours per week

E Learning Resources

1. List Required Textbooks

- 1. Cornier, J., et al. (2017). Pharmaceutical Nanotechnology: Innovation and Production, 2 Volumes, Wiley.
- 2. de Villiers, M. M., et al. (2008). Nanotechnology in Drug Delivery, Springer New York.
- 3. Demetzos, C. (2016). Pharmaceutical Nanotechnology: Fundamentals and Practical Applications, Springer Singapore.
- 4. Florence, A. T. and J. Siepmann (2016). Modern Pharmaceutics, Two Volume Set, Fifth Edition, CRC Press.
- 5. Mishra, V., et al. (2017). Nanotechnology-Based Approaches for Targeting and Delivery of Drugs and Genes, Elsevier Science.
- 6. Weissig, V. and G. G. D'Souza (2011). Organelle-Specific Pharmaceutical Nanotechnology, Wiley.

2. List Essential References Materials (Journals, Reports, etc.)

journal papers and review articles on the topics recommended by instructors.

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

www.sciencedirect.com

https://online.lexi.com/

http://www.uptodate.com/contents/search

http://www.fda.gov/

http://www.ema.europa.eu/ema/

http://www.medscape.com/




4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.

Students are required to use Microsoft word program, Excel program and PowerPoint programs also they are encouraged to use some mind map computer software.





F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

-Lecture rooms should be large enough to accommodate 50 students

-

2. Technology resources (AV, data show, Smart Board, software, etc.)

Laptop computer - projector system, data show

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

Scanning electron microscope, particle size analyzer, X ray diffractometer

G. Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching

- 1. A post midterm. open-ended questionnaire will be distributed to students to draw the instructor's attention to the weaknesses and strengths of his presentations
- 2. End-of-term evaluation of course by students through course survey

3. Periodical open discussion with students to survey their opinions on the degree of achievement of course goals and objectives

- 2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department None
 - 2. Processes for Improvement of Teaching
- 1. Attending training sessions
- 2. Attending workshops to facilitate the exchange of experiences amongst faculty members
- 3. Scheduling regular meetings with other colleagues where problems are discussed and solutions are given
- 4. Discussing the challenges in the classroom with colleagues and members of the Department Counsel





- 5. Encouraging faculty members to attend conferences on professional development
- 6. Setting goals for achieving excellence in teaching at the beginning of each new semester after reviewing previous semester's teaching strategies and results and after considering students' feedback

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

- 5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.
- 1.Compare syllabi and course description to those found in other universities
- 2. Compare course objectives and goals to students' achievement
- 3. Try to contact other professors in different universities who are teaching similar courses (including well-known institutions) to exchange views regarding the optimal ways to improve the course
- 4. The course content are reviewed annually by the curriculum committee

Name of Course Instructor: Mostafa Shahin

Signature: Mostafa Shahin_____ Date Specification Completed: 13/03/2019

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah

Date Received:



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COURSE SPECIFICATIONS

Form

Course Title: Pharmaceutical Microbiology

Course Code: 1803608-2





Course Specifications

Institution: Umm Al-Qura University	Date:	10/11/2017
College/Department: College of Pharmacy/ Department	t of Pharmac	ceutics

A. Course Identification and General Information

1. Course title and code: Pharmaceutical Microbiology (1803608-2)			
2. Credit hours: 2 CU			
3. Program(s) in which the course is offe	red.		
(If general elective available in many pro	grams indicate this rather than list progra	ms)	
4. Name of faculty member responsible f	for the course:		
5. Level/year at which this course is offer	red: Post graduate level		
6. Pre-requisites for this course (if any):			
7. Co-requisites for this course (if any):			
8. Location if not on main campus: Main	Pharmacy campus		
9. Mode of Instruction (mark all that app	ly):		
a. traditional classroom	✓ What percentage?	40	
		30	
b. blended (traditional and online)	✓ What percentage?		
c. e-learning	✓ What percentage?	20	
d. correspondence	What percentage?		
f. other (student assisted learning)	✓ What perce	10 entage?	



Comments:

B Objectives

1. What is the main purpose for this course?

This course offers several topics including; contamination control, antimicrobial effectiveness testing, sterility testing, non-sterile products microbial examination, cleanrooms, preservation, ecology of microorganism and miscellaneous topics on biofilm related infection, microbiota and bacteriophage treatments. All these topics will offer skills, knowledge and competence in the field of pharmaceutical microbiology which will guide the participants to establish professional practice in pharmaceutical industry, research and clinical practice.

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field)

In this course, content will be based on advanced and recent outcomes in the field of pharmaceutical microbiology aspects, industrial microbiology and research. The implementation of online activities during traditional lectures and tutorials such as the online electronic learning applications and online interactive tools will be used in the most teaching classes for this course.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

The course provides advanced aspects in the pharmaceutical microbiology and microbiological laboratory sampling techniques which are specifically used in pharmaceutical industry and QC. The course provides also an overview of the pharmaceutical industry and regulatory affairs for the aspects of quality assurance and quality control specifically focusing on contamination control and sterility testing. This course provides comprehensive approach to microbiology practice in pharmaceutical industry. The course also covers the antimicrobial treatment, development of treatment in various approaches such as bacteriophage and biofilm infection control.

1. Topics to be Covered		
	No. of	
List of Topics	Weeks	Contact hours
1. Introduction to Pharmaceutical Microbiology: methods used in microbial	2	4
technology and microbiological aspects of pharmaceutical processing.		
2. Antimicrobials: Antimicrobial effectiveness testing, and Antibiotic	1	2
stewardship		





3. Antimicrobials: Disinfectant, Preservatives and Antiseptic	1	2
4. Antimicrobials: manufacture of antibiotics	2	4
5. Ecology of microorganisms as it affects Pharmaceutical Industry: water sampling technique, raw material, packaging and buildings.	2	4
6 . Sterile Pharmaceutical Manufacturing and Clean room: sterilization and sterility assurance and Quality Control.	2	4
7. Microbial spoilage and contamination control	2	4
8. Miscellaneous aspects in advanced pharmaceutical field interest: Biofilm, probiotic, microbiota and bacteriophage treatment	2	4

2. Course components (total contact hours and credits per semester):							
		Lecture	Tutorial	Laboratory/ Studio	Practical	Other:	Total
Contact	Planed	18	6	4			28
Hours	Actual						
Credit	Planed	1.3	0.4	0.3			2
	Actual						

3. Additional private study/learning hours expected for students per week.

3

4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

On the table below are the five NQF Learning Domains, numbered in the left column.





First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Cod	NQF Learning Domains	Course Teaching	Course
e		Stars to - to -	Assessment
#	And Course Learning Outcomes	Strategies	Methods
1.0	Knowledge	1	
1.1	Introduce the students to the concepts of antimicrobial procedures	Lecture Self-learning project Tutorial	Written exams and Oral presentation
1.2	Introduce the students to the contamination control and the concepts of sterilization and disinfection in Pharmaceutical industry and manufacturing process.	Lecture Self-learning project Tutorial	Written exams and Oral presentation
2.0	Cognitive Skills	1	
2.1	Understanding the mechanism of action of antimicrobial agents and application in Pharmaceutical industry.	Lecture Self-learning project Tutorial	Written exams and Online Discussion forum
2.2	Interpret the results of variety of pharmaceutical microbiology such as antibiotic effectiveness test and sterility testing.	Self-learning project Tutorial	Assignment and tutorial/ practical reports
3.0	Interpersonal Skills & Responsibility		
3.1	Act responsibly and ethically in preparing group presentation	Group presentation	Group presentation
3.2	Design appropriate contamination control guideline to perform GMP	Tutorial	Assignment and tutorial reports
4.0	Communication, Information Technology, Nun	nerical	





4.1	Acquire self-learning skills	Self-Learning project Flipped classroom	Presentation and group discussion
4.2			
5.0	Psychomotor		
5.1	Perform laboratory techniques related to sterility testing and antibiotic effectiveness testing.	Self-Learning project	Online Discussion forum.
5.2	Training period at microbiological testing and QC at pharmaceutical industry	Field training	Report

5.8	5. Schedule of Assessment Tasks for Students During the Semester							
	C							
		-						
	Assessment task (i.e., essay, test, quizzes, group project,		Proportion of Total					
		Week Due						
	examination, speech, oral presentation, etc.)		Assessment					
1		(14	250/					
1	Assignment and tutorial/ practical and training reports	6-14	25%					
2	Written Exemp	16	600/					
2	written Exams	10	00%					
2	Procontation	Q 15	100/					
5	rieschauon	0-15	1070					
Δ	Online Discussion forum	7-13	50/2					
4		/-15	570					





D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

a) Course coordinator and lecturers of the course are keen and available to answer all students' quires during or after the lectures. Students can contact the instructor by personal meeting or e-mails.

b) Student representative generally have the mobile number of the course instructor/ lecturer to contact him in case of any queries.

c) All students have the e-mail of the course coordinator and course instructor.

E Learning Resources

1. List Required Textbooks

1. Stephen P. Denyer, Norman A. Hodges, Sean P. Gorman, Brendan F.Gilmore (2008) Hugo and Russell's Pharmaceutical Microbiology, Blackwell Publishing company, Seventh edition.

2. Greenwood, D., Finch, R., Davey, P., & Wilcox, M. (2007). Antimicrobial chemotherapy. OUP Oxford.

3. Whyte, W. (2010). Cleanroom technology: fundamentals of design, testing and operation. John Wiley & Sons.

4. Hanlon, G., & Hodges, N. A. (2012). Essential microbiology for pharmacy and pharmaceutical science. John Wiley & Sons.

2. List Essential References Materials (Journals, Reports, etc.)

1. FDA Pharmaceutical microbiology Manual https://www.fda.gov/downloads/scienceresearch/fieldscience/ucm397228.pdf

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

1. European Committee on antimicrobial susceptibility testing (EUCAST).

https://www.eucast.org

2. https://www.lucideon.com/healthcare/pharmaceuticals/pharmaceutical-microbiology

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.





F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

Classrooms are available in the faculty of pharmacy campus for both male and female students which is enough to accommodate at least 20 students each.

2. Technology resources (AV, data show, Smart Board, software, etc.)

Data show, Wi Fi and online library access for students (such as SDL) are available for students in campus. Applications available online are helpful techniques to improve interaction with instructor and learner.

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

List of laboratory equipment and instruments for this course:

- Optical Microscopes
- Biosafety Cabinet
- Steam under pressure autoclave
- Multi-Mode Micro-plate Reader
- Pharmaceutical Refrigerator with transparent door
- Hot Air Oven
- Scanning Electron Microscope
- Basic Microbiological Incubators

G Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching

Strategies for feedback from students established by College of Pharmacy which include:

1. A post midterm, discussion with the students to draw attention to the weaknesses and strengths of students' presentations

2. End-of-term evaluation of course by students through course survey conducted and then collected in general by the College of Pharmacy Surveys committee.

3. Providing a proper and valuable written feedback on each assignment/ report and workshop to enhance the learning process as students could get feedback and improve his/her own work.

2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department

3. Processes for Improvement of Teaching





1. Attending training sessions and workshops in college of Pharmacy and in the Deanship of Academic development and quality.

2. Attending regular meetings with other colleagues and discussing problems and solutions are advised.

3. Discussing the challenges facing the instructor in the classroom with members of the Department

4. Reviewing previous semester teaching strategies and determination of the results obtained from students' feedback

4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)

5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.

1. Comprehend the course objectives and goals to students' achievement

2. Benchmark with different universities who are teaching similar courses (including well-known institutions) and contact other professors who teach these courses to exchange experiences regarding the optimal ways to improve the course

3. The course content are reviewed annually by the curriculum committee in College of Pharmacy

Name of Course Instructor: Dr. Najla Obaid

Signature: _____ Date Specification Completed: _____

Program Coordinator: Khaled Attallah

Signature: Khaled Attallah

Date Received:



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COURSE SPECIFICATIONS

Form

Course Title: Research Project

Course Code: 1803630





Course Specifications

Institution: Umm Alquara University	Date:	
College/Department: College of Pharmacy		

A. Course Identification and General Information

1. Course title and code: Research Pro	ject (1803630)						
2. Credit hours: 10 credit hours							
3. Program(s) in which the course is offered: Pharmaceutics							
4. Name of faculty member responsible	for the course TBD						
5. Level/year at which this course is offered: 2 nd year MSc							
6. Pre-requisites for this course (if any)	: Student has to complete at least a minimum of						
half of the credit hours to enroll in the	e research project.						
7. Co-requisites for this course (if any):	NA						
8. Location if not on main campus: Col	lege of Pharmacy laboratories- Abdiah Branch,						
UQU							
9. Mode of Instruction (mark all that ap	pply):						
a. traditional classroom	What percentage?						
b. blended (traditional and online)	What percentage?						
c. e-learning	What percentage?						
d. correspondence	What percentage?						
f. other	What percentage?						
Comments: This research project provides a definitive record of the main features of the program and the learning outcomes that a student may reasonably be expected to achieve and demonstrate. if s/he takes full advantage of the learning opportunities provided in the first year							



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B Objectives

1. What is the main purpose for this course?

The research project will enable student to explore one (or more) of the aspects of advance pharmaceutics aspects covered in the taught part of the program in greater depth. At the start of the third term, the specific project topic will be agreed with an academic research supervisor.

The aims of the research project are:

- 1. Development of project-specific experimental skills.
- 2. Reading and engaging with scientific literature.
- 3. Making oral presentations, writing reports, including critical evaluation.
- 4. Attending and participating in discussions with other researchers.
- 5. Implementation of planned experiments.
- 6. Recording of data and their critical analysis.
- 7. Production of a dissertation, reporting outcomes that are potentially publishable (in a peer-reviewed publication).

2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web-based reference material, changes in content as a result of new research in the field). Collaborating with some of the well-established Pharmaceutical industry and bioequivalence center in Saudi Arabia to conduct research which benefit in solving or implementing manufacturing practice or QC execution.

C. Course Description (Note: General description in the form used in Bulletin or handbook)

Course Description:

An individual research project is performed in the third term within the Pharmaceutics master program. The research project provides opportunities for students to develop and demonstrate knowledge and understanding, qualities, skills and other attributes in the pharmaceutics field. This project is performed within one of the research groups in the pharmaceutics department. Student will build on the knowledge he/she has acquired in the first year. The research project topic will be determined and finalized by student and respective supervisor. The research project and thesis constitute 10 credit hours of the total credit hours in the master degree. Research project works can start in second semester and students are expected to spend enough time to work in their research project (20 hour per week). The research project will be assessed on the

basis on the final written thesis and presentation.

Course structure

During the project preparation stage, the student will plan the project, in consultation with his/her academic supervisor. Student will carry out a preliminary literature review of the area of research before arriving at a clear judgement of the overall objectives and how they will build on the current level of knowledge in the chosen area of research. The research projects should realistically offer the opportunity of producing publishable results in peer-reviewed literature.

Student will present an overview containing of his/her research elements to the supervisor. There will be a regular meeting with supervisor to discuss and reviewed the





research progress. This will allow students' progress to be discussed and reviewed against the objectives.

At the end of the research period, Student will present a summary of the research findings to the supervisor and advisor, which will be used to plan their dissertation.

Assessment Methods

The research project will be assessed based on the practical outcomes of the project work and on student ability to communicate, and his/her background understanding, through the authorship of a scientific dissertation. The supervisor and two other academics within the department will assess this independently by verbal examination. Student has to maintain a laboratory notebook and to create a suitable archive and organization of research results. These primary sources of information will be reviewed throughout the duration of the research project.

The main procedures are:

- 1. Assign a committee comprised of the academic advisor and two other faculty members to evaluate the thesis. The chair of the committee will be a faculty member within the program.
- 2. The evaluation of the thesis credits comprises of a SATISFACTORY OR UNSATISFACTORY GRADE.
- **3.** The academic advisor is responsible for scheduling the thesis defense date with student and committee members.
- 4. The student should submit a written copy of the thesis to the thesis committee members at least two weeks prior the defense date.

1. Topics to be Covered		
List of Topics	No. of Weeks	Contact hours

2. Course components (total contact hours and credits per semester):							
		Lecture	Tutorial	Laboratory/ Studio	Practical	Other:	Total
Contact	Planed					Full time	
Hours	Actual						
Cradit	Planed					10	
Clean	Actual						

3. Additional private study/learning hours expected for students per week.





4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy

- Produce a thesis that displays competence in understanding and carrying out research in the field of pharmaceutical science devices in a research topic to investigate a particular pharmaceutical science research area
- Identify key research questions
- Select and review relevant theory and literature
- Design a study and choose appropriate methods to investigate the specific research questions
- Select appropriate modes of analysis
- Consider ethical issues involved in research
- Implement, critically appraise or apply research in a particular field
- Prepare a comprehensive written report that is professionally presented and contains all the required components of a master's thesis, including a bibliography

On the table below are the five NQF Learning Domains, numbered in the left column.

First, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table). **Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes. **Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain.)

Icariii	ing outcomes from cach domain.)				
Code	NQF Learning Domains	Course Teaching	Course Assessment		
#	And Course Learning Outcomes	Strategies	Methods		
1.0	Knowledge				
1.1	explain the core and specialized concepts in	Laboratory	Research project report, Viva		
1.1	theoretical and experimental in Pharmaceutics	Laboratory			
	Demonstrate research techniques, including		Research project report, Viva		
1.2	information retrieval, experimental design and	Laboratory			
1.2	statistics, sampling, experimental techniques,	Laboratory			
	problem solving, and laboratory safety.				
2.0	Cognitive Skills				
2.1	Perform methodological skills and understand the contemporary research, and to apply innovative	Laboratory	Dissertation		
	research concepts and practices in their professional life.	Lubblubly			
	Demonstrate independent learning and the critical	Laboratory and	Presentation, Viva		
2.2	thinking ability required for continuing	seminars			
	professional development.				
3.0	Interpersonal Skills & Responsibility				
3.1	Demonstrate self-dependence in implementing a		Viva, Dissertation		
	research project; through employ appropriate	Laboratory & workshop			
	experimental approaches and report the findings		una presentation		
4.0	Communication, Information Technology, Numerica	al			
	Develop student's ability to adapt and apply	Workshon & Formal			
4.1	methodology to the solution of unfamiliar types of	nresentation	Presentation, Viva		
	problems	presentation			





5. Schedule of Assessment Tasks for Students During the Semester							
	Assessment task (i.e., essay, test, quizzes, group project, examination, speech, oral presentation, etc.)		Week Due Pr		oportion of Total ssessment		
1	Dissertation			TBD	TBD		
2	Presentation			TBD	TBD		
3	Research project report			TBD	TBD		
4	Viv	Viva		TBD		TBD	
4.2	2	Communicate effectively across different scientific disciplines through oral presentations, computer processing and presentations and written reports	Semin present labora	nar, formal ntation & atory		Viva, Presentation and Dissertation	
5.0	5.0 Psychomotor						
5.1		Ability to plan and carry out experiments independently and assess the significance of outcomes.	Laboratory			Dissertation	
5.2	2	Work with advanced pharmaceutical industry in new laboratories dedicated both to education and to research.	Laboratory & workshop Dissertation		Dissertation		

D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)

See Course description

E Learning Resources

1. List Required Textbooks

2. List Essential References Materials (Journals, Reports, etc.)

Saudi Digital library (SDL)

3. List Electronic Materials, Web Sites, Facebook, Twitter, etc.

SDL

4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.





F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access, etc.)

1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)

2. Technology resources (AV, data show, Smart Board, software, etc.)

3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

Laboratory facilities are listed below: Scanning Electron Microscope

X-Ray Diffractometer

NMR 500 MHz

FT-IR Spectroscopy

DIFFERENTIAL SCANNING CALORIMETER (DSC)

Analytical HPLC (Auto-sampler)

FREEZE-DRYER

SPRAY DRYER

Nano Spray Dryer

WATER DEIONIZER (Water Purification)

Compact Auto-Titrator

GC-MS

Tablet Hardness Tester

TABLET DISSOLUTION TESTER

TABLET DISINTEGRATION TESTER

Multi-station TABLET PRESS

Single Punch Single Station Tablet Press

Optical Microscope

Vacuum Oven





UV/Vis-Spectrophotometer (Double Beam)

Ultrasonic Processor

WATER BATH

Water Distillator (Double-Distillator)

Rotary Evaporator

Centrifuge

Cooling Centrifuge

SHAKING WATER BATH

Furnace Oven

Herb Grinder

2 Channel Oscillograph

Isotonic Transducer

Laboratory Refrigerator

Lab. Freezer

Hot Air Oven

Suppository Dissolution Tester

HOMOGENIZER

MOISTURE ANALYZER

Analytical Balance, 0.0001

Analytical Balance, 0.00001

SEIVE SET WITH SHAKER

Ball Mill

Multisizer Particle Analyzer

Bench top extruder with standard spheronizer

Elemental analyzer for CHNS/O





Basic Lab Egg stirrer

Pharmaceutical Refrigerator with transparent door

Mini Digital Incubator

-86°C Upright Freezer

Rotary-Pumped Sputter Coater/Carbon Coater

Stability Cabinet for Pharmaceutical Preparation

Vertical Diffusion (Franz) cell

-20 °C Freezer

Hand-held tablet hardness tester

750-Watt Ultrasonic Processor

Rotational Viscometer

CODA monitor noninvasive BP measuring system

Plethysmometer (Rat paw volume measuring system)

Texture Analyzer

UV-Vis-NIR

Orbital Shaker

Thermogravimetric Analysis (TGA)

EDAX: Energy Dispersive X-ray Spectroscopy (EDS)

Bench-Top High-Pressure Homogenizer

Liposome Extruders

Multi-Mode Micro-Plate Reader

Biosafety Cabinet

Steam-under pressure Autoclave

G Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching





2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department
3. Processes for Improvement of Teaching
4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)
5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.

Name of Course Instructor:Research project Advisor						
Signature:	Date Specification Completed:					
Program Coordinator:						
Signature:	Date Received:					