ATTACHMENT 5.

Kingdom of Saudi Arabia

The National Commission for Academic Accreditation & Assessment

T6. Course Specifications
(CS)

Separation and Method Validation

(402612–3)

Course Specifications

Institution: **Umm Al-qura University**	Date: **2017**
College/Department: **Faculty of Applied Science / Department of Chemistry**	

A. Course Identification and General Information

1. Course title and code: **Separation and Method Validation / 402612–3**
2. Credit hours: **3 hrs. (Theoretical)**
3. Program(s) in which the course is offered: **M. Sc. in Chemistry**
4. Name of faculty member responsible for the course: **Dr. Mohammed Ahmed Kassem**
5. Level/year at which this course is offered: **2nd / 1st**
6. Pre-requisites for this course (if any): **not applicable**
7. Co-requisites for this course (if any): **not applicable**
8. Location if not on main campus: **El-Abedyah, El-Azizya, and El-Zaher**
9. Mode of Instruction (mark all that apply)

a. Traditional classroom		What percentage?	
b. Blended (traditional and online)	■	What percentage?	80%
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? By the end of this course, the students will be familiar with: **a-** The physical and chemical principles of separations **b-** The new tools in separation as isoelectric focusing; 2D gel electrophoresis and electrochromatography. **c-** The regulations, standards, and guidelines, risk-based validation and qualification, validation of analytical methods, data review and validation and evaluation of uncertainty
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) • Increased use of IT or web based reference material. • The use of smart teaching halls for lectures. • Encourage students to carry out research reports in the course subjects using the library, data base services, and/or websites. • Changes in content as a result of new research in the field.

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

Course Description:

1. Topics to be Covered		
List of Topics	No. of Weeks	Contact hours
a- Physical and chemical principles of separations	**1**	**3**
b- Column technology for gas, liquid, and supercritical fluid chromatography: Theory, principles, and instrumentation;	**2**	**6**
c- Estimation of the quality of a separation system and Van Deemter equation.	**1**	**3**

d- Applications of ion chromatography, gel permeation, packing material, elution gradients, retention index, gas chromatography (gas-solid, gas-liquid, capillary gas).	**2**	**6**
e- Electrophoresis; Capillary electrophoresis (CE); Zone electrophoresis.	**1**	**3**
f- Isoelectric focusing; 2D gel electrophoresis; Electrochromatography; Sodium dodecyl sulphate polyacrylamide gel electrophoresis (SDS-PAGE).	**1**	**3**
g- Supercritical fluid chromatography (SCFC); Physical processes, modern instrumentation, and response characteristics of detectors relevant to these methods.	**2**	**6**
h- Regulations, standards, and guidelines, risk-based validation and qualification.	**2**	**6**
i- Validation of analytical methods, data review and validation and evaluation of uncertainty.	**1**	**3**

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

	Lecture	Tutorial	Laboratory or Studio	Practical	Other:	Total
Contact Hours	**39**	---	---	---	---	**39**
Credit	**3**	---	---	---	---	**3**

3. Additional private study/learning hours expected for students per week. **2 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 And Course Learning Outcomes**	**Course Teaching Strategies**	**Course Assessment Methods**
1.0	**Knowledge**		
1.1	• Understand the physical and chemical principles of separations.	• Lectures • Scientific discussion • Use the library to work duties and a small research on separation and method validation. • Use of the internet to carry out some reports on course subjects.	• Written mid-term and final exams. • Long and short essays.
1.2	• Describe the column technology for gas, liquid, and supercritical fluid chromatography.		
1.3	• Identify the quality of a separation system and Van Deemter equation.		
1.4	• Recording the applications of ion chromatography, gel permeation, packing material and elution gradients.		
1.5	• Explain the electrophoresis; Capillary electrophoresis (CE) as well as Zone electrophoresis.		
1.6	• Compare between isoelectric focusing and 2D gel electrophoresis.		
1.7	• Outline the regulations, standards, and guidelines in addition to risk-based validation and qualification.		

1.8	• Write about data review and validation and evaluation of uncertainty.		
2.0	**Cognitive Skills**		
2.1	• Modify the quality of a separation system.	• Lectures • Scientific discussion • Library visits • Web-based study • Using brain storming at the beginning of each lecture in order to stimulate the students towards the new topic of the course. • Enhancing open discussion during the lecture.	• Mid-term and final exams. • Measuring the response to the assignments. • Through assignments and homework
2.2	• Explain the application of sodium dodecyl sulphate in polyacrylamide gel electrophoresis (SDS-PAGE).		
2.3	• Construct the supercritical fluid chromatography (SCFC).		
2.4	• Report the characteristics of detectors relevant to Supercritical fluid chromatography (SCFC).		
2.5	• Interpret the validation of analytical methods.		
3.0	**Interpersonal Skills & Responsibility**		
3.1	• Operate in team work and accept his college's opinions.	• Dividing students into groups to carry out collective scientific reports. • Periodic individual duties to develop the skill of taking responsibility and self-reliance.	• Evaluate the results of collective works and duties as well as knowing the contribution of each individual through dialogue and discussion.
3.2	• Choose the suitable method to solve problems.		
3.3	• Develop the student's ability in self-reliance and responsibility.		

			• Assessment of individual tasks and duties to determine the student's ability to self-reliance.
4.0	**Communication, Information Technology, Numerical**		
4.1	Use computers and the international information network (the Internet) to perform calculations and to identify recent research relevant to decision sources.	• Visiting research centers. • The use of computers in the training room of the department. • Using the internet for collecting data.	• Evaluation of the duties associated with the proper use of numerical and communication skills. • Web-based student performance systems. • Individual and group presentations.
4.2	Communicate effectively in oral and written forms.		
4.3	Use basic mathematical and statistical techniques to perform data analysis.		
5.0	**Psychomotor**		
5.1	Not applicable.		

5. Schedule of Assessment Tasks for Students During the Semester			
	Assessment task (e.g. essay, test, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment
1	Activities and Assignments.	--	10 %

2	Midterm Exam.	8	30 %
3	Final Exam.	15-16	60 %
4	**Total**	**100 %**	

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: During the working hours weekly.
- Academic advising for students.
- Availability of Staff members to provide counseling and advice.

E Learning Resources

1. List Required Textbooks

1- *Validation and Qualification in Analytical Laboratories*, Ludwig Huber, 2ed edition, New York, NY 10017, 2007 by Informa Healthcare USA, Inc.

2- *Bioanalysis of Pharmaceuticals, Sample Preparation, Separation Techniques, and Mass Spectrometry*, STEEN HONORÉ HANSEN, 2015 John Wiley & Sons, Ltd.

3- *Green ChromatographicTechniques Separation and Purification of Organic and Inorganic Analytes*, Inamuddin, Ali Mohammad, 2014, Springer Dordrecht Heidelberg London New York

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

1- Faure K, Bouju E, Suchet P, Berthod A (2013) Use of limonene in CCC: a green alkane substitute. Anal Chem 85:4644-4650. doi:10.1021/ac4002854

2- Lee J, Gupta S, Huang J, Jayathilaka LP, Lee B (2013) HPLC-MTT assay: anti-cancer activity of aqueous garlic extract is from allicin. Anal Biochem 436:187–189

3. List Recommended Textbooks and Reference Material (Journals, Reports, etc)

1- *Analytical Method Validation and Instrument Performance Verification*, Chung Chow Chan, 2004, John Wiley & Sons, Inc., Hoboken, New Jersey.
4. List Electronic Materials, Web Sites, Facebook, Twitter, etc. • http://nsdl.niscair.res.in/jspui/ • http://www.chemistry.uoc.gr/ • http://www.chemie.uni-hamburg.de/
5. Other learning material such as computer-based programs/CD, professional standards or regulations and software. : None.

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.) • Equipped lecture hall specializing in separation and method validation.
2. Computing resources (AV, data show, Smart Board, software, etc.) • Room equipped with computers, data show and TV.
3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list) : No other requirements.

G Course Evaluation and Improvement Processes

1 Strategies for Obtaining Student Feedback on Effectiveness of Teaching • Student representation on staff-student committees and institutional bodies. • Structured group discussions and/or focus groups. • Questionnaires can be used to collect student feedback.
2 Other Strategies for Evaluation of Teaching by the Instructor or by the Department • Colleagues have the expertise to evaluate the quality of a course as evidenced by its content and format (peer reviewers). • The instructor's statement of his/her goals for the course, teaching methods and philosophy,

student outcomes, and plans for improvement are a critical source of information. • A systematic self-review has the potential for contributing significantly to the instructor's teaching improvement by focusing on the strengths and weaknesses of the course in light of his/her original course objectives. • Visits by other faculty can provide information about the process of teaching.
3 Processes for Improvement of Teaching • Exchange of experiences internal and external. • Training programs and workshops for Staff member. • The application of e-learning.
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) • 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. • Hosting a visiting staff to evaluate of the course. • Periodic review of the contents of the syllabus and modify the negatives. • Consult other staff of the course.

Name of Instructor: **Dr. Mohammed Ahmed Kassem**
Signature: _____Date Report completed: **2017**
Name of Field Experience Teaching Staff _____
Program Coordinator:_____
Signature: _____ Date Received:_____