Course Specification of Pharmaceutical Quality Control

I. Course Identification and General Information:

1	**Course Title**	**Pharmaceutical Quality Control**					
2	**Course Number & Code:**	Ph5913					
3	**Credit hours:**	**C.H**				**Total**	
		Th.	**Pr.**	**Tr.**	**Seminar.**		
		1	2			2	
4	**Study level/ semester at which this course is offered:**	5th level / 1st semester					
5	**Pre –requisite (if any):**	Pharmaceutical Analytical Chemistry I &II Instrumental Analysis I &II.					
6	**Co –requisite (if any):**						
7	**Program (s) in which the course is offered:**	Bachelor of Pharmacy					
8	**Language of teaching the course:**	English					
9	**The department in which the course is offered:**	Department of Medicinal Chemistry, Pharmaceutical Organic and Analytical Chemistry					
10	**Location of teaching the course:**	Faculty of Pharmacy					
11	**Prepared by:**	Dr. Yahya AL-Dokhain, Dr. Mohammed Hamid-Addeen					
12	**Date of approval:**						

II. Course description:

The course provides the students with the fundamental knowledge about the principles of pharmaceutical quality control of pharmaceutical products according to GMP and

pharmacopeial requirements. It also concerns with study statistical and validation methods used for quality control of pharmaceutical products as well as their approval and stability.

III. Intended Learning Outcomes (ILOs) of the Course:

At the end of this course the students should be able to:

1. Recognize the basic principles of quality control and steps of pharmaceutical analysis.
2. Explain statistical and validation methods used for quality control of pharmaceutical products.
3. Illustrate the GMP guidlines and steps of approval of pharmaceutical products
4. Understand the Stability indicating assays and all tests carried out on pharmaceutical products.
5. Outline the GMP requirements for all steps of quality control pharmaceutical products.
6. Distinguish between parameters of validation according to ICH and USP methods.
7. Predict the factors that affect the drug stability.
8. Operate and validate different pharmaceutical instruments and methods in the lab according to rules of GMP to minimize the errors in pharmaceutical analysis..
9. Handle and dispose the chemical and pharmaceutical preparations safely and effectively.
10. Apply the pharmacopeial methods for evaluation of drug stability as well as Q.C for different dosage forms.
11. Standardize analytical methods according to ICH and USP guidelines for pharmaceutical quality Control.
12. Work effectively in a team during applications of instrumental analysis of different pharmaceutical preparations.
13. Manage the time in an work effectively.
14. Utilize computers to get and use on-line data base and improve professional competencies

IV. Intended Learning Outcomes (ILOs) of the Course:

(A) Knowledge and Understanding:

Alignment Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: Knowledge and Understanding.

Program Intended Learning Outcomes (Sub- PILOs) in: Knowledge and Understanding	Course Intended Learning Outcomes (CILOs) in: Knowledge and Understanding
After completing this program, students would be able to:	After participating in the course, students would be able to:

A1-	Recognize the principles of physical, chemical, clinical, social, behavioral, health and pharmaceutical sciences.	**a1-**	Recognize the basic principles of quality control and steps of pharmaceutical analysis.
		a2-	Explain statistical and validation methods used for quality control of pharmaceutical products.
A2-	Recognize the physicochemical properties, preparation, structure activity relationship (SAR), toxicity and the modern methods of analysis of various substances of chemical and natural products of therapeutic potential as well as the basic principle of drug discovery, design and development	**a3-**	Illustrate the GMP guidlines and steps of approval of pharmaceutical products.
		a4-	Understand the Stability indicating assays and all tests carried out on pharmaceutical products.

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment Learning Outcomes of Knowledge and Understanding to Teaching and Assessment Methods:

Course Intended Learning Outcomes (CILOs) in Knowledge and Understanding **After participating in the course, students would be able to:**		Teaching strategies/methods to be used	Methods of assessment
a1-	Recognize the basic principles of quality control and steps of pharmaceutical analysis.	Lectures method, group discussion and brainstorming.	Oral Exam, homework, report, Quizzes, Short answers and Written exam
a2-	Explain statistical and validation methods used for quality control of pharmaceutical products.		
a3-	Illustrate the GMP guidelines and steps of approval of pharmaceutical products.		
a4-	Understand the Stability indicating assays and all tests carried out on pharmaceutical products.		

(B) Intellectual Skills:

Alignment Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: **Intellectual skills**			
Program Intended Learning Outcomes (Sub-PILOs) in Intellectual skills		**Course Intended Learning Outcomes (CILOs) of Intellectual Skills**	
After completing this program, students would be able to:		**After participating in the course, students would be able to:**	
B1-	Consolidate the chemical, biochemical and physiological principles to construct the pharmacophores of the structure and their effect on the stability, pharmacokinetic and pharmacodynamic profiles of the drug.	**b1-**	Outline the GMP requirements for all steps of quality control pharmaceutical products.
B3-	Design different types of safe and effective pharmaceutical dosage forms and develop novel methods of qualitative and quantitative analytical and biological analysis for pharmaceutical and biopharmaceutical products that support pharmaceutical research.	**b2-**	Distinguish between parameters of validation according to ICH and USP methods.
		b3-	Predict the factors that affect the drug stability.

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment Learning Outcomes of Intellectual Skills to Teaching Methods and Assessment Methods:

***Course Intended Learning Outcomes (*CILOs*) in* Intellectual Skills.** **After participating in the course, students would be able to:**		**Teaching strategies/methods to be used.**	***Methods of assessment***
b1-	Outline the GMP requirements for all steps of quality control pharmaceutical products.	Lectures method, group discussion and brainstorming.	Oral Exam, homework, report, Quizzes, Short answers and Written exam
b2-	Distinguish between parameters of validation according to ICH and USP methods.		
b3-	Predict the factors that affect the drug stability.		

(C) Professional and Practical Skills.

Alignment Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: Professional and Practical Skills

Program Intended Learning Outcomes (Sub- PILOs) in Professional and Practical Skills		Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills	
After completing this program, students would be able to:		**After participating in the course, students would be able to:**	
C1-	Operate different pharmaceutical equipments and instruments and use emerging technologies in design, synthesis, pre-formulation, formulation, packaging, storage and analysis of pharmaceutical products according to GLP, GSP and cGMP guidelines.	**c1-**	Operate and validate different pharmaceutical instruments and methods in the lab according to rules of GMP to minimize the errors in pharmaceutical analysis..
C2-	Handle and dispose chemicals and pharmaceutical preparations safely and effectively.	**c2-**	Handle and dispose the chemical and pharmaceutical preparations safely and effectively.
C3-	Extract, isolate, purify, identify and formulate the natural products and assure their rational use.	**c3-**	Apply the pharmacopeial methods for evaluation of drug stability as well as Q.C for different dosage forms.
C5-	Conduct research studies and utilize the results in different pharmaceutical fields.	**c4-**	Standardize analytical methods according to ICH and USP guidelines for pharmaceutical quality Control.

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment Learning Outcomes of Professional and Practical Skills to Teaching and Assessment Methods:

Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills After participating in the course, students would be able to:		Teaching strategies/methods to be used	Methods of assessment
c1-	Operate and validate different pharmaceutical instruments and methods in the lab according to rules of GMP to minimize the errors in pharmaceutical analysis..	Lectures method, group discussion and practical sessions	Oral Exam, homework, report, Quizzes, Short answers and Written exam
c2-	Handle and dispose the chemical and pharmaceutical preparations safely and effectively.		

c3-	Apply the pharmacopeial methods for evaluation of drug stability as well as Q.C for different dosage forms.		
c4-	Standardize analytical methods according to ICH and USP guidelines for pharmaceutical quality Control.		

(D) General / Transferable Skills:

Alignment Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: General and Transferable skills

Program Intended Learning Outcomes (PILOs) in General / Transferable skills		**Course Intended Learning Outcomes (CILOs) in General / Transferable skills**	
After completing this program, students would be able to:		**After participating in the course, students would be able to:**	
D2-	Employ proper documentation and filing systems in different pharmaceutical fields	**d1-**	Work effectively in a team during applications of Q.C of different pharmaceutical preparations.
D5-	Apply information and communication technology and working effectively in a team.	**d2-**	Manage the time in work effectively.
		d3-	Utilize computers to get and use on-line dat base and improve professional competencies.

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment Learning Outcomes of General and Transferable skills to Teaching and Assessment Methods.

Course Intended Learning Outcomes (CILOs) in General and Transferable Skills **After participating in the course, students would be able to:**		**Teaching strategies/methods to be used.**	**Methods of assessment**
d1-	Work effectively in a team during applications of instrumental analysis of different pharmaceutical preparations.	Lectures method, group discussion and practical sessions	Oral Exam, homework, report, Quizzes, Short
d2-	Manage the time in work effectively.		

d3-	Utilize computers to get and use on-line data base and improv professional competencies.		answers and Written exam

V. Course Content:

1 – Course Topics/Items:

a – Theoretical Aspect

Order	Topic List / Units	CILOs (symbols)	Sub-topic List	Number of weeks	Contact hours
1	**Introduction to Quality Control**	a1, b1, d1-3	Definitions and some terms used in quality control of drugs, basic principle of quality control. Component of Quality Control, General Quality System Requirements, The main part of the ISO standard is made up of three separate standards, Pharmaceutical Quality Control System, Control Charts	2	2
2	Steps of Pharmaceutical Analysis	a1, b1, d1-3	-Define the problem, objectives, method, calculation and report.	1	1
3	Statistics used in Quality Control of Drugs	a2, b1, d1-3	Accuracy, precision, calibration curve calculations	1	1
4	Good Manufacturing Practice	a3, b1, d1-3	Some terms in GMP, GLP, GAP, requirements of GMP	2	2
5	Method Validation	a2, b1-2, d1-3	Definition, USP and ICH parameters of validation methods	2	2
6	Midterm Exam	a1-3, b1-2		1	1
7	Pharmaceutical Products Approving	a3, b1, d1-3	Registration and drug approving requirements and tests	1	1
8	Stability of Pharmaceutical Products	a4, b1, d1-3	-Definitions, half life, shelf life - Chemical reactions and storage conditions affecting drug stability	1	1

9	Stability Indicating Assays	a4, b1, d1-3	Real time and accelerated stability indicating assays	2	2
10	Physical &Physicochemical and Biological Tests Carried out on Pharmaceutical Products	a1, a4, b1-3, d1-3	All the chemical, physicochemical and biological tests on drug products	2	2
11	**Final Exam**	a1-4, b1-3		1	1
Number of Weeks /and Units Per Semester				**16**	**32**

b - Practical Aspect

Order	Tasks/ Experiments	CILOs (symbols)	Number of Weeks	Contact Hours
1	**Study the errors of pharmaceutical analysis.**	c1, c2, d1-3	1	2
2	WHO good practices for pharmaceutical quality control laboratories**.**	c1, c2, d1-3	2	4
3	Study the parameters of validation for method used for analysis of certain dosage form according to USP.	c1, c2, c4, d1-3	3	6
4	Mid-Exam	c1,c2 , c4	1	2
5	Study the parameters of validation for method used for analysis of certain dosage form according to ICH**.**	c1, c2, d1-3	3	6
6	Study of stability indicating assays **of certain drugs.**	c1, c2, c3 , d1-3	3	6
7	Quality control tests for different Pharmaceutical dosage forms	c1-4 , d1-3	2	4
8	Final Exam	**c1-4**	1	2
Number of Weeks /and Units Per Semester			**16**	**32**

VI. Teaching Strategies of the Course:

Lectures using data show video animation, Practice session, Discussions, Small group discussions, Tutorials and Practical classes

VII. Assignments:

- Homework
- Reports

VIII. Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes (CILOs symbols)
1	**Attendance, Participation, reports and quizzes**	**All Weeks**	5	5%	a1,a3 ,b1,b3, d1-3
	Oral Tests and Homework-assignments	Sporadic through the semester	5	5%	a2, a4, b1-3, d1-3
2	**Attendance, Practical Reports and Practical mid-semester exam**	8th	30	30%	c1,c2,c3, c4
3	**Theoretical mid-semester exam**	9th	20	20%	a1-3, b1, b2
5	**Final Exam (theoretical)**	**16th**	30	30%	a1-4, b1-3
6	**Final Exam (practical)**	**16th**	20	20%	c1-4
	Total		**100**	**100%**	

IX. Students' Support:

Office Hours/week	Other Procedures (if any)

Two contact hours per week	None

X. Learning Resources:

1- Required Textbook(s) (maximum two).

1- Somenath Mitra, 2003. Sample Preparation Techniques in Analytical Chemistry, A John Wiley & Sons, Inc., Publication, Canada.
2- Satinder Ahuja, Stephen Scypinski, 2001. Handbook Of Modern Pharmaceutical Analysis, Academic Press, San Diego, USA.
3- James Swarbrick, James C. Boylan, Marcel Dekker, Encyclopedia of pharmaceutical technology: Vol 7, vol16., Inc. New York- Basel- Hongkong.

2- Recommended Books and Reference Materials.

1- J. Ermer and J. H. McB. Miller, 2005. Method Validation in Pharmaceutical Analysis, WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim.
2- Robert A. Nash, Alfred H. Wachter, Pharmaceutical Process Validation, Volume 129, Marcel Dekker Inc.
3- Andrew J Fletcher, Lionel D Edward, Anthony W Fox Peter Stonie, 2002. Principle and practice of medicine, John Wiley and Sons Ltd. London , UK.
4- Lectures Notes and Practical Manual.

3- Electronic Materials and Web Sites *etc.*

1. the Analyst;
2. J. Pharm. & Biomed. Anal.
3. J. Assoc. off Anal. Chem.
4. The Analytical Abstracts database (http://www.rsc.org/ CFAA/AASearchPage.cfm)
5. The Analytical Forum on ChemWeb (http://analytical.
6. chemweb.com/search/search.exe)

XI. Facilities Required:

1 - Accommodation:	- Well-equipped lecture halls with data show facilities, whiteboards, net connection, etc. - Well-equipped laboratories with all required equipment and reagents.

2 - Computing resources:	- Computer laboratory with internet facilities.

XII. Course Improvement Processes:

1- Strategies for obtaining student feedback on effectiveness of teaching

- Student-based assessment of the effectiveness of teaching using a questionnaire designed by the Quality Assurance Unit at the end of the semester.
- Meeting with students and faculty (once per semester).

2- Other strategies for evaluation of teaching by the instructor or by the department.

- Assessment of the course syllabus and contents by the teachers using a questionnaire designed by the Quality Assurance Unit of the university at the end of the semester.
- Regular meeting and discussion of the course content between the Head of Department and the teaching staff of the course (for theory and practice).

3- Processes for improvement of teaching.

- Revision of the course specification and its teaching strategies every three academic years after consideration of all issues raised by the teachers and/or students during regular meetings and discussions.
- Exploring any possible defects in the course that might be encountered by the teaching staff and their mitigation in subsequent improved versions of course specification.

4- Processes for Verifying Standards of Students' Achievement

- Checking of a sample of students' work by an independent faculty member.
- Periodic exchange and check marking of a sample of students' assignments with a faculty member from another institution.
- Adoption of scoring rubrics to assess the students' achievement (both for ongoing or summative assessments).
- Regular follow-up of laboratory logbooks to assess the practical achievement of students.

5- Procedures for Periodically Reviewing of Course Effectiveness and Planning for Improvement

	▪ Student rating and feedback ▪ Peer rating and feedback ▪ Regular meeting of the Curriculum Committee of the faculty.
6- Course Development Plans	
	▪ Conducting regular workshops for the staff for improving their course specification skills. ▪ Regular revision of course specification and syllabus items.

XIII. Course Policies: (including plagiarism, academic honesty, attendance etc)

The University Regulations on academic misconduct will be strictly enforced. Please refer to ----------

1	**Class Attendance:** - Attendance in all lectures and practical classes are required, except in very emergency circumstances, such as serious illness or death in the family with providing an acceptable documentation approved the university and forwarded by the chairman of the department. Otherwise the absence shall be considered unexcused. -In accordance with the university rules, if the percentage of student's absentness exceeds 25 % of the total lectures or practical classes, the student involved shall be disqualified in the final written and practical examination of the course and shall be deemed to have failed in the course.
2	**Tardy:** - Roll will be called in the very beginning of each lecture and practical class. Retardation for more than three weeks without a reasonable excursion, the student involved shall not be allowed to attend the class any longer and consequently shall be considered to be absent.
3	**Exam Attendance/Punctuality:** - It is incumbent on student to report at the examination hall for checking in and rolls calling at least 15 minutes before the commencement of examination.

	-A student is not allowed to submit answer booklet and leave the examination hall only on or after the passage of the have examination duration (equivalent to the first one hour after the commencement of the examination). -A student who comes late shall not be admitted to the examination hall, only within the first one hour of the examination. Attending after this time, the student will be considered to be missed in the examination and shall be deemed to have failed in the course. When a student misses the final examination due to a legitimate medical problems or death in the family, an acceptable documentation approved by the university medical unit for the excused absentness (hospitals medical reports along with discharge summaries or death certificate) must be provided no later than three weeks and consequently the student shall be disqualified in the examination but with the excused absentness.
4	**Assignments & Projects:** - Micro-assignments and practical reports must be submitted for the assessment on or before the due date. If a student does not submit the micro-assignments or practical reports, the student shall be allotted zero marks which will affect the final assessment of the course. -The submission date extension will not be granted only by the consent of the faculty member concerned. In the case of late submission, the student must provide a reasonable explanation to the faculty member. Otherwise 1% of the obtained marks will be subtracted for each late day, including weekends and holidays.
5	**Cheating:** -If a student is found cheating in the final and med-term examinations and quizzes(copying from un authorized materials and anther students' work or allowing other students to copy from his/her own work), the student involved shall be disqualified in the examination and shall be deemed to have failed in the course and also suspended from examinations of two more courses. If a student if found engaging in any unauthorized communications (oral,sign,call,etc.), while the examination is in progress or in possessing of any authorized materials or electronic devices before the distribution of examination papers , the student involved shall be disqualified in the examination and shall be deemed to have failed the course.
6	**Plagiarism:** - Plagiarism is the presentation of any material (text, data or figures) from any other source in preparation of micro-assignments or practical reports without clear and adequate acknowledgement of the source.

	- Plagiarism is also the use or copy of other students' work (with, or without payment) to prepare all or part of undertaken micro-assignments or practical reports of work submitted for assessment. All types of plagiarism in are unacceptable and are considered of honest practices. If a student is found using plagiarism in devoted micro-assignments or reports , the student involved shall be subjected to the same penalties as in the case of cheating as already mentioned in the sub-section (5) of the course policies.
7	**Other policies:** - - Students must switch off their mobile phones, labtops, electronic devices etc. before entering lecture room or laboratory. If a student is found using these devices while the lecture or practical work is in progress, the student involved shall be expelled out of the class and shall be considered to be absent. Note that students can submit their micro-assignments or practical reports through the e-mail address of the faculty member concerned and should be prudent to keep Photostat or electronic copies of submitted works to guard against an accidental loss.

Course Plan of Pharmaceutical Quality Control

I- Information about Faculty Member Responsible for the Course:							
Name of Faculty Member	Dr. Yahya AL-Dokhain, Dr. Mohammed Hamid-Addeen	Office Hours					
Location & Telephone No.		SAT	SUN	MON	TUE	WED	THU
E-mail			h				

II- Course Identification and General Information:

1-	Course Title:	Pharmaceutical Quality Control				
2-	Course Number & Code:	Ph5913				
3-	Credit hours:	C.H				Total
		Th.	Seminar	Pr.	F. Tr.	
		2	-	1		2
4-	Study level/year at which this course is offered:	5th Level /1st Semester				
5-	Pre –requisite (if any):	Pharmaceutical Analytical Chemistry I &II Instrumental Analysis I &II.				
6-	Co –requisite (if any):	-				
7-	Program (s) in which the course is offered	Bachelor of Pharmacy				
8-	Language of teaching the course:	English				
9-	System of Study:	Semesters				

10-	**Mode of delivery:**	Regular
11-	**Location of teaching the course:**	Faculty of Pharmacy- Sana`a university

III- Course description:

The course provides the students with the fundamental knowledge about the principles of pharmaceutical quality control of pharmaceutical products according to GMP and pharmacopeial requirements. It is also concerned with study statistical and validation methods used for quality control of pharmaceutical products as well as their approval and stability.

IV- Intended Learning Outcomes (ILOs) of the Course:

At the end of this course the students should be able to:

15. Recognize the basic principles of quality control and steps of pharmaceutical analysis.
16. Explain statistical and validation methods used for quality control of pharmaceutical products.
17. Illustrate the GMP guidelines and steps of approval of pharmaceutical products
18. Understand the Stability indicating assays and all tests carried out on pharmaceutical products.
19. Outline the GMP requirements for all steps of quality control pharmaceutical products.
20. Distinguish between parameters of validation according to ICH and USP methods.
21. Predict the factors that affect the drug stability.
22. Operate and validate different pharmaceutical instruments and methods in the lab according to rules of GMP to minimize the errors in pharmaceutical analysis..
23. Handle and dispose the chemical and pharmaceutical preparations safely and effectively.
24. Apply the pharmacopeial methods for evaluation of drug stability as well as Q.C for different dosage forms.
25. Standardize analytical methods according to ICH and USP guidelines for pharmaceutical quality Control.
26. Work effectively in a team during applications of instrumental analysis of different pharmaceutical preparations.
27. Manage the time in an work effectively.
28. Utilize computers to get and use on-line data base and improve professional competencies

V- Course Content:

1 – Course Topics/Items:

a – Theoretical Aspect

Order	Topic List / Units	CILOs (symbols)	Sub-topic List	Week Due	Contact hours
1	**Introduction to Quality control**	a1, b1, d1-3	Definitions and some terms used in quality control of drugs, basic principle of quality control. Component of Quality Control, General Quality System Requirements, The main part of the ISO standard is made up of three separate standards, Pharmaceutical Quality Control System, Control Charts	1,2	2
2	Steps of pharmaceutical analysis	a1, b1, d1-3	-Define the problem, objectives, method, calculation and report.	3	1
3	Statistics used in quality control of drugs	a2, b1, d1-3	Accuracy, precision, calibration curve calculations	4	1
4	Good manufacturing practice	a3, b1, d1-3	Some terms in GMP, GLP, GAP, requirements of GMP	5,6	2
5	Method validation	a2, b1-2, d1-3	Definition, USP and ICH parameters of validation methods	7,8	2
6	Midterm Exam	a1-3, b1-2		9	1
7	Pharmaceutical products approving	a3, b1, d1-3	Registration and drug approving requirements and tests	10	1
8	Stability of pharmaceutical products	a4, b1, d1-3	-Definitions, half life, shelf life - Chemical reactions and storage conditions affecting drug stability	11	1
9	Stability indicating assays	a4, b1, d1-3	Real time and accelerated stability indicating assays	12,13	2
10	Physical &Physicochemical and biological tests carried out on pharmaceutical products	a1, a4, b1-3, d1-3	All the chemical, physicochemical and biological tests on drug products	14,15	2

11	**Final Exam**	a1-4, b1-3		16	1
Number of Weeks /and Units Per Semester				**16**	**32**

b - Practical Aspect

Order	Tasks/ Experiments	CILOs (symbols)	Week Due	Contact Hours
1	**Study the errors of pharmaceutical analysis.**	c1, c2, d1-3	1	2
2	WHO good practices for pharmaceutical quality control laboratories**.**	c1, c2, d1-3	2,3	4
3	Study the parameters of validation for method used for analysis of certain dosage form according to USP.	c1, c2, c4, d1-3	4-6	6
4	Mid-Exam	c1,c2 , c4	7	2
5	Study the parameters of validation for method used for analysis of certain dosage form according to ICH**.**	c1, c2, d1-3	8-10	6
6	Study of stability indicating assays **of certain drugs.**	c1, c2, c3 , d1-3	11-13	6
7	Quality control tests for different Pharmaceutical dosage forms	c1-4 , d1-3	14,15	4
8	Final Exam	**c1-4**	16	2
Number of Weeks /and Units Per Semester			**16**	**32**

VI- Teaching Strategies of the Course:

Lectures using data show video animation, Practice session, Discussions, Small group discussions, Tutorials and Practical classes

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VII- Assignments:

- Homework
- Reports

VIII-Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes (CILOs symbols)
1	**Attendance, Participation, reports and quizzes**	**All Weeks**	5	5%	a1,a3 ,b1,b3, d1-3
	Oral Tests and Homework-assignments	Sporadic through the semester	5	5%	a2, a4, b1-3, d1-3
2	**Attendance, Practical Reports and Practical mid-semester exam**	8th	30	30%	c1,c2,c3, c4
3	**Theoretical mid-semester exam**	9th	20	20%	a1-3, b1, b2
5	**Final Exam (theoretical)**	**16th**	30	30%	a1-4, b1-3
6	**Final Exam (practical)**	**16th**	20	20%	c1-4
	Total		**100**	**100%**	

IX- Students' Support:

Office Hours/week	Other Procedures (if any)
Two contact hours per week	None

X- Learning Resources:

1- Required Textbook(s) (maximum two).

4- Somenath Mitra, 2003. Sample Preparation Techniques in Analytical Chemistry, A John Wiley & Sons, Inc., Publication, Canada.
5- Satinder Ahuja, Stephen Scypinski, 2001. Handbook Of Modern Pharmaceutical Analysis, Academic Press, San Diego, USA.
6- James Swarbrick, James C. Boylan, Marcel Dekker, Encyclopedia of pharmaceutical technology: Vol 7, vol16., Inc. New York- Basel- Hongkong.

2- Recommended Books and Reference Materials.

5- J. Ermer and J. H. McB. Miller, 2005. Method Validation in Pharmaceutical Analysis, WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim.
6- Robert A. Nash, Alfred H. Wachter, Pharmaceutical Process Validation, Volume 129, Marcel Dekker Inc.
7- Andrew J Fletcher, Lionel D Edward, Anthony W Fox Peter Stonie, 2002. Principle and practice of medicine, John Wiley and Sons Ltd. London , UK.
8- Lectures Notes and Practical Manual.

3- Electronic Materials and Web Sites *etc.*

7. the Analyst;
8. J. Pharm. & Biomed. Anal.
9. J. Assoc. off Anal. Chem.
10. The Analytical Abstracts database (http://www.rsc.org/ CFAA/AASearchPage.cfm)
11. The Analytical Forum on ChemWeb (http://analytical.
12. chemweb.com/search/search.exe)

XI- Facilities Required:

1 - Accommodation:	- Well-equipped lecture halls with data show facilities, whiteboards, net connection, etc. - Well-equipped laboratories with all required equipment and reagents.
3 - Computing resources:	- Computer laboratory with internet facilities.

XII- Course Improvement Processes:

6- Strategies for Obtaining Student Feedback on Effectiveness of Teaching

- Student-based assessment of the effectiveness of teaching using a questionnaire designed by the Quality Assurance Unit at the end of the semester.
- Meeting with students and faculty (once per semester).

7- Other Strategies for Evaluation Of Teaching by the Instructor or by the Department.

- Assessment of the course syllabus and contents by the teachers using a questionnaire designed by the Quality Assurance Unit of the university at the end of the semester.
- Regular meeting and discussion of the course content between the Head of Department and the teaching staff of the course (for theory and practice).

8- Processes for Improvement of Teaching.

- Revision of the course specification and its teaching strategies every three academic years after consideration of all issues raised by the teachers and/or students during regular meetings and discussions.
- Exploring any possible defects in the course that might be encountered by the teaching staff and their mitigation in subsequent improved versions of course specification.

9- Processes for Verifying Standards of Students' Achievement

- Checking of a sample of students' work by an independent faculty member.
- Periodic exchange and check marking of a sample of students' assignments with a faculty member from another institution.
- Adoption of scoring rubrics to assess the students' achievement (both for ongoing or summative assessments).

	▪ Regular follow-up of laboratory logbooks to assess the practical achievement of students.
10- Procedures for Periodically Reviewing of Course Effectiveness and Planning for Improvement	
	▪ Student rating and feedback ▪ Peer rating and feedback ▪ Regular meeting of the Curriculum Committee of the faculty.
6- Course Development Plans	
	▪ Conducting regular workshops for the staff for improving their course specification skills. ▪ Regular revision of course specification and syllabus items.

XIII-Course Policies: (including plagiarism, academic honesty, attendance etc)

The University Regulations on academic misconduct will be strictly enforced. Please refer to ----------

1	**Class Attendance:** - Attendance in all lectures and practical classes are required, except in very emergency circumstances, such as serious illness or death in the family with providing an acceptable documentation approved the university and forwarded by the chairman of the department. Otherwise the absence shall be considered unexcused. -In accordance with the university rules, if the percentage of student's absentness exceeds 25 % of the total lectures or practical classes, the student involved shall be disqualified in the final written and practical examination of the course and shall be deemed to have failed in the course.
2	**Tardy:** - Roll will be called in the very beginning of each lecture and practical class. Retardation for more than three weeks without a reasonable excursion, the student involved shall not be allowed to attend the class any longer and consequently shall be considered to be absent.
3	**Exam Attendance/Punctuality:**

	- It is incumbent on student to report at the examination hall for checking in and rolls calling at least 15 minutes before the commencement of examination. -A student is not allowed to submit answer booklet and leave the examination hall only on or after the passage of the have examination duration (equivalent to the first one hour after the commencement of the examination). -A student who comes late shall not be admitted to the examination hall, only within the first one hour of the examination. Attending after this time, the student will be considered to be missed in the examination and shall be deemed to have failed in the course. When a student misses the final examination due to a legitimate medical problems or death in the family, an acceptable documentation approved by the university medical unit for the excused absentness (hospitals medical reports along with discharge summaries or death certificate) must be provided no later than three weeks and consequently the student shall be disqualified in the examination but with the excused absentness.
4	**Assignments & Projects:** - Micro-assignments and practical reports must be submitted for the assessment on or before the due date. If a student does not submit the micro-assignments or practical reports, the student shall be allotted zero marks which will affect the final assessment of the course. -The submission date extension will not be granted only by the consent of the faculty member concerned. In the case of late submission, the student must provide a reasonable explanation to the faculty member. Otherwise 1% of the obtained marks will be subtracted for each late day, including weekends and holidays.
5	**Cheating:** -If a student is found cheating in the final and med-term examinations and quizzes(copying from un authorized materials and anther students' work or allowing other students to copy from his/her own work), the student involved shall be disqualified in the examination and shall be deemed to have failed in the course and also suspended from examinations of two more courses. If a student if found engaging in any unauthorized communications (oral,sign,call,etc.), while the examination is in progress or in possessing of any authorized materials or electronic devices before the distribution of examination papers , the student involved shall be disqualified in the examination and shall be deemed to have failed the course.
6	**Plagiarism:**

	- Plagiarism is the presentation of any material (text, data or figures) from any other source in preparation of micro-assignments or practical reports without clear and adequate acknowledgement of the source. - Plagiarism is also the use or copy of other students' work (with, or without payment) to prepare all or part of undertaken micro-assignments or practical reports of work submitted for assessment. All types of plagiarism in are unacceptable and are considered of honest practices. If a student is found using plagiarism in devoted micro-assignments or reports , the student involved shall be subjected to the same penalties as in the case of cheating as already mentioned in the sub-section (5) of the course policies.
7	**Other policies:** - - Students must switch off their mobile phones, labtops, electronic devices etc. before entering lecture room or laboratory. If a student is found using these devices while the lecture or practical work is in progress, the student involved shall be expelled out of the class and shall be considered to be absent. Note that students can submit their micro-assignments or practical reports through the e-mail address of the faculty member concerned and should be prudent to keep Photostat or electronic copies of submitted works to guard against an accidental loss.