



Course Specification of Pharmaceutical Biostatistics

I. Course Identification and General Information:

1	Course Title	Pharmaceutical Biostatistics				
2	Course Number & Code:	Ph2818				
3	Credit hours:	C.H				Total
		Th.	Pr.	Tr.	Seminar.	
		1				1
4	Study level/ semester at which this course is offered:	4 th level /2 nd semester				
5	Pre –requisite (if any):	-				
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 pharmaceutics				
10	Location of teaching the course:	Faculty of Pharmacy				
11	Prepared by:	Prof. Abdulwali A. Saif				
12	Date of approval:					

II. Course description:

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نائب العميد لشؤون الجودة
د.د. محمود البريهي

رئيس القسم
د.د. ماجد علوان

عميد الكلية
د. خالد الشوبية

عميدة مركز التطوير وضمان الجودة
د.د. هدى العماد

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The course is concerned with the basic knowledge about the pharmaceutical biostatistics including the basic principles for the collection, analysis, interpretation of research results and presentation of data in all fields of pharmaceutical sciences. The application of statistics program in analysis of data is also demonstrated.

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 statistics.
 2. Define the important statistical terms and parameters.
 3. Explain concepts of probability, random variation, sampling, design the experiments estimation and confidence intervals.
 4. Select appropriate statistical tests for analysis of pharmaceutical and medical data.
 5. Evaluate and interpret the statistical procedures and graphics it in a health population context.
 6. Apply assumptions and limitations of common statistical tests.
 7. Apply numerical, tabular, and graphical descriptive techniques for the pharmaceutical data.
 8. Apply some statistical program in analysis of data.
 9. Calculate appropriate sample size in different types of pharmaceutical studies.
 10. Work independently or collaboratively to prepare seminars/ presentations or write reports.
 11. Demonstrate critical thinking, decision-making abilities and life-long learning.
 12. Effectively use internet resources to search for up-to-date information to solve emerging problems.

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:
A5-	a1- Recognize principles of inferential statistics.

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Demonstrate the basic knowledge of pharmacoconomics, pharmacovigilance, policy, legislation, marketing, administration and distribution of pharmaceutical and cosmetic products as well as ethics of health care.	a2-	Define the important statistical terms and parameters.
	a3-	Explain concepts of probability, random variation, sampling, design the experiments estimation and confidence intervals

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 principles of inferential statistics.	Lecture method, computer based teaching and learning, group discussion.	Oral exam, Quizzes, Attendance, participation, Short answers, reports, homework, and Written exam.
a2- Define the statistical terms and parameters.		
a3- Explain concepts of probability, random variation, sampling, design the experiments Estimation and Confidence Intervals.		

(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:



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.	b1-	Select appropriate statistical tests for analysis of pharmaceutical and medical data.
		b2-	Evaluate and interpret the statistical procedures and graphics it in a health population context.
B5-	Interpret the prescriptions, patient and clinical data, Analysis all the encountered pharmaceutical problems and plan the strategies for their solution, to develop the health care.		
		b3-	Apply assumptions and limitations of common statistical tests.

Teaching And Assessment Methods For Achieving Learning Outcomes:

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

<i>Course Intended Learning Outcomes (CILOs) in Intellectual Skills.</i> After participating in the course, students would be able to:		Teaching strategies/methods to be used.	Methods of assessment
b1-	Select appropriate statistical tests for analysis of pharmaceutical and medical data.	Lecture method, Computer based teaching and learning Group Discussion, Problem solving sessions	Oral Exam, Quizzes, attendance, participation, Short answers, reports, and Written exam.
b2-	Evaluate and interpret the statistical procedures and graphics it in a health population context.		
b3-	Apply assumptions and limitations of common statistical tests.		

(C) Professional and Practical Skills.

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

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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:	
C4-	Provide patient-oriented pharmaceutical care by collaboration with other health care professionals to optimize therapeutic outcomes.	c1-	Apply numerical, tabular, and graphical descriptive techniques for the pharmaceutical data.
C5-	Conduct research studies and utilize the results in different pharmaceutical fields.		
		c2-	Apply some statistical program in analysis of data.
		c3-	Calculate appropriate sample size in different types of pharmaceutical studies.

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-	Apply numerical, tabular, and graphical descriptive techniques for the pharmaceutical data.	Lecture method and group discussion	Homework and reports.
c2-	Apply some statistical program in analysis of data.		
c3-	Calculate appropriate sample size in different types of pharmaceutical studies.		

(D) General / Transferable Skills:

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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 independently or collaboratively to prepare seminars/ presentations or write reports.
D3-	Develop financial, market management, writing, presentation and time management skills as well as creativity, critical thinking, problem solving and decision making abilities.	d2-	Demonstrate critical thinking, decision making abilities and life-long learning.

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D5-	Apply information and communication technology and working effectively in a team.	d3-	Effectively use internet resources to search for up-to-date information to solve emerging problems.
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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		Teaching strategies/methods to be used.	Methods of assessment
After participating in the course, students would be able to:			
d1-	Work independently or collaboratively to prepare seminars/ presentations or write reports.	Small group discussions and Tutorials.	Homework, and reports.
d2-	Demonstrate critical thinking, decision making abilities and life-long learning.		
d3-	Effectively use internet resources to search for up-to-date information to solve emerging problems.		

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	a1, c3, d1, d2	- Definitions, - Data Visualization - Stem-and-Leaf Plot - Samples and Populations	1	2
2.	Location Parameters	a1, a2, d1, d3	- Mode, Median, Mean, - Spread Parameters: range, variance, covariance, frequency distributions, bias, precision, and accuracy	1	2

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3.	Design of Experiments and Collection of Data	a1, a3, c3, b3, d1-3	<ul style="list-style-type: none"> - Sampling by questionnaire - Sampling in the chemical laboratory - Sampling in biological and clinical experiments 	1	2
4.	Design and Conduct Of Clinical Trials	a1, a3, b3, c1,d1-3	<ul style="list-style-type: none"> - Allocation of patients in randomized design - crossover design 	2	4
5.	Mid Exam	a1-3, b3		1	2
6.	The binomial and normal probability distributions	a3, b1, b3, c1,d13	<ul style="list-style-type: none"> - The binomial distribution, - The normal distribution, - Computing probabilities from the normal distribution, - Normal approximation to the binomial distribution 	1	2

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7.	Estimation and statistical inference and data transformations	a3, b1, b3, c1, d1-3	<ul style="list-style-type: none"> - Estimation and confidence intervals - Statistical inference and the T distribution t test - Construct a null hypothesis - Construct an alternative hypothesis - Choose the level of significance - Beta error and power - Choose a sample - Determine whether the test should be one- or two-sided - Make observations and construct a t test - Two independent sample T test - Paired t test 	6	12
			<ul style="list-style-type: none"> - Tests for proportions - Chi-square test - The F distribution and tests of significance - Analysis of variance (ANOVA) and experimental design - Multiple comparisons in ANOVA, other ANOVA designs common to pharmaceutical problems - Crossover design - Nonparametric tests of significance - Exact tests - Rejection of aberrant observations. 		

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8.	Applications of some statistical program	a1, b2, c2, d1-3	Using of some statistical program in analysis of pharmaceutical data	2	4
9.	Final Exam	a1-3, b1-3, c1, c3		1	2
Number of Weeks /and Units Per Semester				16	32

VI. a-Teaching strategies of the course:

Lecture method, Group Discussion, Problem solving sessions and Computer based teaching and learning, tutorials and brainstorming

b- Assessment Methods:

Oral Exam, Quizzes, Attendance, Participation, Short answers, reports, homework, and Written exam.

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark
1	Homework Assignments	a1-3, b2-3,d1-3	Sporadic through the semester	5
2	Reports	c1-3 ,d1-3		

I. 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)

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1	Attendance, Participation, Homework, Reports and quizzes	All Weeks	10	10%	a1-3, b2-3, c1-3, d1-3
2	Theoretical mid-semester exam	6th	20	20%	a1-3, b3
3	Final Exam (theoretical)	16 th	70	70%	a1-3, b1-3, c1, c3
Total			100	100%	

II. Students' Support:

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

III. Learning Resources:

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

1- Wayne W.D. 2004, Biostatistics : A foundation for Analysis in the health sciences 8th edition.

2- Essential Medical Statistics, 2003, 2nd ed. Blackwell Publishing company.

2- Recommended Books and Reference Materials.

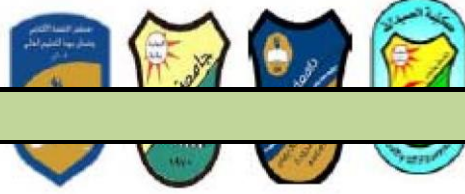
1- Linda A. Felton,, 2013, Remington Essentials of Pharmaceutics, 1st edition, Pharmaceutical Press
Lambeth High Street, London SE1 7JN, UK.

3- Electronic Materials and Web Sites etc.

[http : en. Wikipedia. Org / wiki/ Biostatistics.](http://en.Wikipedia.Org/wiki/Biostatistics)

IV. Facilities Required:

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

V. 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 th Procedures for periodically reviewing of course effectiveness and planning for improvement	
	<ul style="list-style-type: none"> ▪ Student rating and feedback ▪ Peer rating and feedback ▪ Regular meeting of the Curriculum Committee of the faculty.
6- Course development plans	
	<ul style="list-style-type: none"> ▪ Conducting regular workshops for the staff for improving their course specification skills. ▪ Regular revision of course specification and syllabus items.

VIII. Course Policies: (including plagiarism, academic honesty, attendance etc)	
The University Regulations on academic misconduct will be strictly enforced. Please refer to -----	
1	Class Attendance: <ul style="list-style-type: none"> ▪ Attendance of all lectures and practical sessions is required. Unexcused absence exceeding 25% of the lectures or practical sessions will disqualify the student from entering the final exam.
2	Tardy: <p>- 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.</p>
3	Exam Attendance/Punctuality: <ul style="list-style-type: none"> ▪ Exam attendance is obligatory unless being excused by the department and faculty. ▪ Absence from assignments or exams will be dealt with according to the general policy of the university.
4	Assignments & Projects: <ul style="list-style-type: none"> ▪ Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator. ▪ Projects: Not applicable.



5	Cheating: <ul style="list-style-type: none">Punishment of cheating will be according to the general policy of the university in this respect.
6	Plagiarism: <ul style="list-style-type: none">Plagiarism in written essays, reports, etc. is not accepted, and students who plagiarize the works of others will be punished according to the general policy of the university.
7	Other policies: <ul style="list-style-type: none">General policies of the Students' Affairs of the University and the Quality Assurance Unit.

Course Plan of Pharmaceutical Biostatistics

I- Information about Faculty Member Responsible for the Course:

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Name of Faculty Member	Prof. Abdulwali A. Saif	Office Hours					
Location & Telephone No.		SAT	SUN	MON	TUE	WED	THU
E-mail							

II- Course Identification and General Information:

1-	Course Title:	Pharmaceutical Biostatistics				
2-	Course Number & Code:	Ph2818				
3-	Credit hours:	C.H				Total
		Th.	Seminar	Pr.	F. Tr.	
		1	-	1		1
4-	Study level/year at which this course is offered:	4 th level / 2 nd semester				
5-	Pre –requisite (if any):	-				
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 is concerned with the basic knowledge about the pharmaceutical biostatistics including the basic principles for the collection, analysis, interpretation of research results and presentation of data in all fields of pharmaceutical sciences. The application of statistics program in analysis of data is also demonstrated.

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IV- 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 statistics.
2. Define the important statistical terms and parameters.
3. Explain concepts of probability, random variation, sampling, design the experiments estimation and confidence intervals.
4. Select appropriate statistical tests for analysis of pharmaceutical and medical data.
5. Evaluate and interpret the statistical procedures and graphics it in a health population context.
6. Apply assumptions and limitations of common statistical tests.
7. Apply numerical, tabular, and graphical descriptive techniques for the pharmaceutical data.
8. Apply some statistical program in analysis of data.
9. Calculate appropriate sample size in different types of pharmaceutical studies.
10. Work independently or collaboratively to prepare seminars/ presentations or write reports.
11. Demonstrate critical thinking, decision-making abilities and life-long learning.
12. Effectively use internet resources to search for up-to-date information to solve emerging problems.

13. Course Content:

1 – Course Topics/Items:

a – Theoretical Aspect

Order	Topic List / Units	CILOs (symbols)	Sub-topic List	Week Due	Contact hours
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10.	Introduction	a1, c3, d1, d2	- Definitions, - Data Visualization - Stem-and-Leaf Plot - Samples and Populations	1	2
11.	Location Parameters	a1, a2, d1, d3	- Mode, Median, Mean, - Spread Parameters: range, variance, covariance, frequency distributions, bias, precision, and accuracy	2	2
12.	Design of Experiments and Collection of Data	a1, a3, c3, b3, d1-3	- Sampling by questionnaire - Sampling in the chemical laboratory - Sampling in biological and clinical experiments	3	2
13.	Design and Conduct Of Clinical Trials	a1, a3, b3, c1,d1- 3	- Allocation of patients in randomized design - crossover design	4,5	4
14.	Mid Exam	a1-3, b3		6	2
15.	The binomial and normal probability distributions	a3, b1, b3, c1,d13	- The binomial distribution, - The normal distribution, - Computing probabilities from the normal distribution, - Normal approximation to the binomial distribution	7	2



16.	Estimation and statistical inference and data transformations	a3, b1, b3, c1, d1-3	<ul style="list-style-type: none"> - - Estimation and confidence intervals - - Statistical inference and the T distribution t test - Construct a null hypothesis - Construct an alternative hypothesis 	8-13	12
			<ul style="list-style-type: none"> - Choose the level of significance - Beta error and power - Choose a sample - Determine whether the test should be one- or two-sided - Make observations and construct a t test - Two independent sample T test - Paired t test - Tests for proportions - Chi-square test - The F distribution and tests of significance - Analysis of variance (ANOVA) and experimental design - Multiple comparisons in ANOVA, other ANOVA designs common to pharmaceutical problems - Crossover design - Nonparametric tests of significance - Exact tests - Rejection of aberrant observations. 		



17.	Applications of some statistical program	a1, b2, c2, d1-3	Using of some statistical program in analysis of pharmaceutical data	14,15	4
18.	Final Exam	a1-3, b1-3, c1, c3		16	2
Number of Weeks /and Units Per Semester				16	32

14. a-Teaching strategies of the course:

Lecture method, Group Discussion, Problem solving sessions and Computer based teaching and learning, tutorials and brainstorming

b- Assessment Methods:

Oral Exam, Quizzes, Attendance, Participation, Short answers, reports, homework, and Written exam.

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark
1	Homework Assignments	a1-3, b2-3,d1-2	Sporadic through the semester	5
2	Reports	c1-3 ,d1-2		

VI. 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)

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1	Attendance, Participation, Homework, Reports and quizzes	All Weeks	10	10%	a1-3, b2-3, c1-3,d1-2
2	Theoretical mid-semester exam	6th	20	20%	a1-3, b3,d1-2
3	Final Exam (theoretical)	16 th	70	70%	a1-3, b1-3, c1, c3
Total			100	100%	

VII. Students' Support:

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

VIII. Learning Resources:

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

- 3- Wayne W.D. 2004, Biostatistics : A foundation for Analysis in the health sciences 8th edition.
- 4- Essential Medical Statistics, 2003, 2nd ed. Blackwell Publishing company.

2- Recommended Books and Reference Materials.

- 2- Linda A. Felton,, 2013, Remington Essentials of Pharmaceutics, 1st edition, Pharmaceutical Press Lambeth High Street, London SE1 7JN, UK.

3- Electronic Materials and Web Sites *etc.*

[http://en.Wikipedia.Org/wiki/Biostatistics.](http://en.Wikipedia.Org/wiki/Biostatistics)

IX. Facilities Required:

- Well-equipped lecture halls with data show facilities, whiteboards,

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1 - Accommodation:	net connection, etc. - Well-equipped laboratories with all required equipment and reagents.
3 - Computing resources:	- Computer laboratory with internet facilities.
X. Course Improvement Processes:	
6- Strategies for obtaining student feedback on effectiveness of teaching	
	<ul style="list-style-type: none"> 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.	
	<ul style="list-style-type: none"> 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.	
	<ul style="list-style-type: none"> 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	
	<ul style="list-style-type: none"> 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.



1 ⁰ - Procedures for periodically reviewing of course effectiveness and planning for improvement	
	<ul style="list-style-type: none"> ▪ Student rating and feedback ▪ Peer rating and feedback ▪ Regular meeting of the Curriculum Committee of the faculty.
6- Course development plans	
	<ul style="list-style-type: none"> ▪ Conducting regular workshops for the staff for improving their course specification skills. ▪ Regular revision of course specification and syllabus items.

IX. Course Policies: (including plagiarism, academic honesty, attendance etc)	
The University Regulations on academic misconduct will be strictly enforced. Please refer to -----	
1	Class Attendance: <ul style="list-style-type: none"> ▪ Attendance of all lectures and practical sessions is required. Unexcused absence exceeding 25% of the lectures or practical sessions will disqualify the student from entering the final exam.
2	Tardy: <p>- 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.</p>
3	Exam Attendance/Punctuality: <ul style="list-style-type: none"> ▪ Exam attendance is obligatory unless being excused by the department and faculty. ▪ Absence from assignments or exams will be dealt with according to the general policy of the university.
4	Assignments & Projects: <ul style="list-style-type: none"> ▪ Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator. ▪ Projects: Not applicable.
5	Cheating: <ul style="list-style-type: none"> ▪ Punishment of cheating will be according to the general policy of the university in this respect.



6	Plagiarism: <ul style="list-style-type: none">Plagiarism in written essays, reports, etc. is not accepted, and students who plagiarize the works of others will be punished according to the general policy of the university.
7	Other policies: <ul style="list-style-type: none">General policies of the Students' Affairs of the University and the Quality Assurance Unit.

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