Course Specification of Pharmacokinetics

I. Course Identification and General Information:							
1	Course Title:	Pharmacokinetics					
2	Course Number & Code:	Ph2815					
3	Credit hours: 3 hrs	C.H				Total	
		Theoretical	Practical	Training	Seminar		
		2	2			3	
4	Study level/ semester at which this course is offered:	Fourth year/ Second semester					
5	Pre –requisite (if any):	Pharmaceutics I-IV - biopharmaceutics,					
6	Co –requisite (if any):	Advanced Drug Delivery Systems					
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:	Pharmaceutics and Industrial Pharmacy					
10	Location of teaching the course:	Faculty of Pharmacy-Sana'a University					
11	Prepared by:	Prof Dr / Mahmoud Mahyoob Alburyhi					
12	Date of approval:						

II. Course description:

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This course aims to provide the students with a comprehensive theoretical foundation of estimating pharmacokinetic parameters. Mathematical background for modeling of the concentration time relationships for the different routes of administration. Designing dosing regimens by relating plasma concentration of drugs to their pharmacological and toxicological action, Individualization of therapy for patients. Designing therapeutic drug monitoring plans for drugs with narrow therapeutic index or high toxicity.

III. Intended learning outcomes (ILOs) of the course:

At the end of this course, the students will be able to:

1. Define the pharmacokinetic model of a specified drug and recognize the pharmacokinetic parameters.
2. Understand the features of elimination rates, orders of pk, one & two compartment model.
3. Demonstrate the proper dose when shift form iv to oral, nonlinear pk and nonlinear pk.
4. Demonstrate the proper dose in liver and kidney disorders.
5. Demonstrate the proper therapy and therapeutic drug monitoring for each patient and dose selection for narrow therapeutic drugs.
6. Conduct pharmacokinetic parameter protocols for the pharmacological testing of new drugs.
7. Utilization of mathematics of the time course of Absorption, Distribution, Metabolism, and Excretion (ADME) of drugs in the body for dosage optimization.
8. Developing dosing regimens for the individualization of therapy for the patient.
9. Fitting concentration time profiles and estimating pharmacokinetic parameters, drug dose and protocol of therapy.
10. Calculate practically the difference between pharmacokinetics compartment models.
11. Apply dosing regimens for specific population patients, renal and hepatic dysfunction.
12. Demonstrate bioequivalence studies
13. Assess the difference between linear & nonlinear PK.
14. Communicating the dosage adjustment with physicians, suggesting therapeutic monitoring plans for physicians and use different information sources to solve medication problems.
15. Retrieve information from a variety of sources, including libraries, databases and internet.
16. Work effectively in a team and demonstrate time management skills.

IV. Intended learning outcomes (ILOs) of the course:

(A) Knowledge and Understanding:

Alignment of 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 will be able to:		**After completing this course, students will be able to:**	
A1-	Recognize the principles of physical, chemical, clinical, social, behavioral, health and pharmaceutical sciences.	**a1-**	Define the pharmacokinetic model of a specified drug and recognize the pharmacokinetic parameters.
A3-	Describe the general cellular, biochemical and physiological aspects of human body and recognize the pharmacokinetics, pharmacodynamics, disease pathophysiology, and pharmacogenetic of therapeutic agents to provide pharmaceutical care and facilitate management of patient's medication, rationalize drug use and overall health needs.	**a2-**	Understand the features of elimination rates, orders of pk, one & two compartment model.
A4	Recognize the pharmaceutical dosage form design and the quality control of pharmaceutical formulations according to GMP and pharmacopeial requirements to support the pharmaceutical industries and research	**a3-**	Demonstrate the proper dose when shift form iv to oral, linear pk and nonlinear pk.
A5	Demonstrate the basic knowledge of pharmacoecnomics, pharmacovigilence, policy, legislation, marketing, administration and distribution of pharmaceutical and cosmetic products as well as ethics of health care	**a4-**	Demonstrate the proper dose in liver and kidney disorders.
		a5-	Demonstrate the proper therapy and therapeutic drug monitoring for each patient and dose selection for narrow therapeutic drugs.
Teaching And Assessment Methods For Achieving Learning Outcomes:			
Alignment of Learning Outcomes of Knowledge and Understanding to Teaching and Assessment Methods:			

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Course Intended Learning Outcomes (CILOs) in Knowledge and Understanding		Teaching strategies/methods to be used	Methods of assessment
completing this course, students will be able to:		Lectures, and group discussion	Attendance, Written, oral exams and small projects
a1-	Define the pharmacokinetic model of a specified drug and recognize the pharmacokinetic parameters.		
a2-	Understand the features of elimination rates, orders of pk, one & two compartment model.		
a3-	Demonstrate the proper dose when shift form iv to oral, linear pk and nonlinear pk.		
a4-	Demonstrate the proper dose in liver and kidney disorders.		
a5-	Demonstrate the proper therapy and therapeutic drug monitoring for each patient and dose selection for narrow therapeutic drugs.		

(B) Intellectual Skills:

Alignment of 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 will be able to:		**After completing this course, students will 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-**	Conduct pharmacokinetic parameter protocols for the pharmacological testing of new drugs.

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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-**	Utilization of mathematics of the time course of Absorption, Distribution, Metabolism, and Excretion (ADME) of drugs in the body for dosage optimization.
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-**	Developing dosing regimens for the individualization of therapy for the patient.

Teaching And Assessment Methods For Achieving Learning Outcomes:

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

Course Intended Learning Outcomes (CILOs) in Intellectual Skills.		Teaching strategies/methods to be used	Methods of assessment
After completing this course, students will be able to:		Lectures, solving problem brainstorming and group discussion	Project, homework, Written, oral exams and small projects
b1-	Conduct pharmacokinetic parameter protocols for the pharmacological testing of new drugs.		
b2-	Utilization of mathematics of the time course of Absorption, Distribution, Metabolism, and Excretion (ADME) of drugs in the body for dosage optimization.		
b3-	Developing dosing regimens for the individualization of therapy for the patient.		

(C) Professional and Practical Skills:

Alignment of 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

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After completing this program, students will be able to:		After completing this course, students will 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-	Fitting concentration time profiles and estimating pharmacokinetic parameters, drug dose and protocol of therapy.
C3	Extract, isolate, purify, identify and formulate the natural products and assure their rational use.	c2-	Calculate practically the difference between pharmacokinetics compartment models.
		c3-	Apply dosing regimens regimens for specific population patients, renal and hepatic dysfunction.
C4	Provide patient-oriented pharmaceutical care by collaboration with other health care professionals to optimize therapeutic outcomes.	c4-	Demonstrate bioequivalence studies
C5	Conduct research studies and utilize the results in different pharmaceutical fields.	c5-	Assess the difference between linear & nonlinear PK.

Teaching And Assessment Methods For Achieving Learning Outcomes:

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

Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills		Teaching strategies/methods to be used	Methods of assessment
After completing this course, students will be able to:		Lectures , practical, discussion and brain storm	Written, practical, oral exams, report, project and observation.
c1-	Fitting concentration time profiles and estimating pharmacokinetic parameters, drug dose and protocol of therapy.		
c2-	Calculate practically the difference between pharmacokinetics compartment models.		
c3-	Apply dosing regimens for specific population patients, renal and hepatic dysfunction.		
c4-	Demonstrate bioequivalence studies		
c5-	Assess the difference between linear & nonlinear PK.		

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(D) General / Transferable Skills:

Alignment of 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 will be able to:		**After completing this course, students will be able to:**	
D2	Employ proper documentation and filing systems in different pharmaceutical fields	**d1-**	Communicating the dosage adjustment with physicians, suggesting therapeutic monitoring plans for physicians and use different information sources to solve medication problems.
D3	Develop financial, market management, writing, presentation and time management skills as well as creativity, critical thinking, problem solving and decision making abilities.	**d2**	Retrieve information from a variety of sources, including libraries, databases and internet.
D4	Take responsibility for adaptation to change needs in pharmacy practice.	**d3**	Work effectively in a team and demonstrate time management skills.

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of 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 completing this course, students will be able to:		Lectures , practical, discussion and brain storm	Written, practical, oral exams, report, project and observation.
d1-	Communicating the dosage adjustment with physicians, suggesting therapeutic monitoring plans for physicians and use different information sources to solve medication problems.		
d2-	Retrieve information from a variety of sources, including libraries, databases and internet.		
d3	Work effectively in a team and demonstrate time management skills.		

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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 basic pharmacokinetics, elimination rates and orders PK)	**a1, b1, d1,d2,d3**	basic pharmacokinetics, ADME-system, pharmacodynamics, toxicokinetics Pharmacokinetic models	**1**	**2**
2.	Pharmacokinetic parameters models, equations and order kinetics	**a2, b3, d1,d2,d3**	Define various models representing rates and order of reactions and calculate pharmacokinetic parameters (eg, zero- and first-order) from experimental data based on these models.	**1**	**2**
3.	The one-compartment open model with an intravenous bolus dose	**a2,a3, b3, d1,d2,d3**	PK parameters after I.V. dose bolus(plasma data) and (urine data)	**1**	**2**

4.	The one-compartment open model with an intravenous infusion	**a3, b2, b3, d1,d2,d3**	PK parameters, Steady state during constant rate infusion	**1**	**2**
5.	The one-compartment open model with absorption and elimination: (Extravascular PK).	**a1, a2,a3, b2, d1,d2,d3**	Absorption rate and elimination rate PK parameters after extravascular administration, e.g. oral dose.	**1**	**2**
6.	The one-compartment open model with multiple dosing kinetics: multiple dosing	**a4,b1, b2, b3, d1,d2,d3**	volume of distribution, drug clearance, and halflife can be affected by protein binding and PK parameters after multiple dosing	**1**	**2**
7.	Mid-term exam	**a1-4, b1-3**		**1**	**2**
8.	Bioavailability and bioequivalence	**a3, b2, b3, d1,d2,d3**	PK parameters, half-life AUC, AUMC	**2**	**4**
9.	The two-compartment open model with intravenous administration	**a2,b3, d1,d2,d3**	PK parameters half-life Cp, Vd, Cl, t1/2 A, B, a, b, K12, K21, K, AUC	**1**	**2**
10.	Metabolites and urinary excretion Dose adjustment in renal disorder	**a4,a5, b2,b3, d1,d2,d3**	Clinical PK parameters Kr, Km, Clr, Clm K & Cl	**1**	**2**
11.	Distribution and drug binding	**a2,a3, b2,b3, d1,d2,d3**	Clinical PK parameters	**1**	**2**
12.	pharmacokinetic of drugs follows Michaelis–Menton kinetics and Non-linear PK model.	**a2,a3,a4,a5, b2,b3, d1,d2,d3**	PK parameters	**1**	**2**

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13.	Clinical pharmacokinetics Dosage regimen, age, and diseases state	**a3,a4,a5, b2,b3, d1,d2,d3**	Clinical PK parameters Application specific populations, the Pediatric Patients, the Obese Patients and the Geriatric Patients	**2**	**4**
14.	final-term exam	**a1-5, b1-3**		**1**	**2**
Number of Weeks /and Units Per Semester				**16**	**32**

b- Practical Aspect:

Order	Practical Tasks	CILOs (symbols)	Number of weeks	Contact hours
1.	Calculate the pharmacokinetic parameters of some drugs that follow zero order.	**c1, d1,d2,d3**	**1**	**2**
2.	Calculate the pharmacokinetic parameters of some drugs that follow first order.	**c1, d1,d2,d3**	**1**	**2**
3.	The one-compartment open model with an intravenous bolus dose: calculating pharmacokinetic parameters from plasma data	**c1,c2, d1,d2,d3**	**1**	**2**
4.	The one-compartment open model with an intravenous bolus dose: calculating pharmacokinetic parameters from urinary data	**c1,c2,c3, d1,d2,d3**	**1**	**2**
5.	The one-compartment open model with an intravenous infusion: calculating pharmacokinetic parameters from continues infusion, infusion with a bolus dose, post infusion data.	**c1,c2,c3,c4, d1,d2,d3**	**1**	**2**
6.	Calculate the steady-state C max and C min after multiple IV bolus dosing of drugs.	**c1,c2,c3, d1,d2,d3**	**1**	**2**
7.	Mid-term exam	**c1-4**	**1**	**2**
8.	The one-compartment open model with absorption and elimination: calculating	**c1,c2,c3,c4, d1,d2,d3**	**2**	**2**

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	pharmacokinetic parameters from plasma data(Extravascular PK).			
9.	The one-compartment open model with multiple dosing kinetics: multiple dosing IV	**c1,c2,c3,c4, d1,d2,d3**	**1**	**2**
10.	The one-compartment open model with multiple dosing kinetics: multiple dosing oral (Extravascular PK).	**c1,c2,c3,c4,c5, d1,d2,d3**	**1**	**2**
11.	The two-compartment open model with intravenous administration.	**c1,c2,c3,c4,c5, d1,d2,d3**	**1**	**2**
12.	Designing dosing regimens and Sources of variation in intrinsic clearance	**c1,c2,c3,c4,c5, d1,d2,d3**	**1**	**2**
13.	Calculating pharmacokinetic parameters from Michaelis–Menton kinetics and Non-linear PK model.	**c5, d1,d2,d3**	**1**	**2**
14.	Estimating clinical pharmacokinetic parameters, dosage regimen according to age, and diseases state.	**c5, d1,d2,d3**	**1**	**2**
15.	final-term exam	**c1-5**	**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**,** tutorials, brainstorming and Practical sessions.

b- Assessment Methods:

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

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark
1	Homework Assignments	**a1-5, b1-3, d1-3**	Sporadic through the semester	**10**
2	Reports	**c1-5, d1-3**		

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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 and quizzes**	**All Weeks**	10	7%	**a1-5,b1-3,** d1-3
2.	**Oral Tests and Homeworkassignments**	Sporadic through the semester	10	7%	**a1-5, b1-3,** d1-3
3.	**Attendance, Practical Reports**	**All Weeks**	15	10%	**c1-5**
4.	**Practical mid-semester exam**	7th	15	10%	**c1-4**
5.	**Theoretical mid-semester exam**	7th	30	20%	**a1-4, b1-3**
6.	**Final Exam (theoretical)**	**16th**	50	33%	**a1-5, b1-3**
7.	**Final Exam (practical)**	**16th**	20	13%	**c1-5**
	Total		**150**	**100%**	

IX. Students' Support:

Office Hours/week	Other Procedures (if any)
2 hours per week	

X. Learning Resource (MLA style or APA style)S:

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1- Required Textbook(s) (maximum two)	
	1-A book prepared by the staff members 2-Shargel, L and Yu, ABC., 2016, *Applied Biopharmaceutics & pharmacokinetics*, 7th edition,
	McGraw-Hill Education, New York. 3-Bauer, LA, 2008, *Applied clinical pharmacokinetics*, 2nd edition, McGraw-Hill Companies, Inc, New York.
2- Recommended Readings and Reference Materials	
	1-Rowland M, Tozer T, 1995, Clinical Pharmacokinetics—Concepts and Applications, 3rd ed, Lea & Febiger, Philadelphia. 2-Levine RR, 1990, Drug Actions and Reactions, 4th ed., Little, Brown, Boston. 3- Gibaldi, M. (1991) Biopharmaceutics and Clinical Pharmacokinetics, 4th edn. Lea & Febiger, Philadelphia.
3- Electronic Materials and Web Sites *etc*.	
	www.pubmed.com http://www.sciencedirect.com/
4- Other Learning Material:	
	J Pharmacokinet Biopharm J Pharm Sci Published articles related to the discussed topics United States Pharmacopeia and National Formulary (latest edition) United States Pharmacopeial Convention Inc., Rockville, MD. British Pharmacopoeia (latest edition), HMSO. London. Martindale, W. (latest edition) The Extra Pharmacopoeia., Royal Pharmaceutical Society of Great Britain, London.

XI. Facilities Required:

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

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.

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II.	Course Policies:
1	**Class Attendance:** ▪ 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	**Tardiness:** ▪ Non-reasonable frequent tardiness will be allowed and is considered as absence from the lectures/
3	**Exam Attendance/Punctuality:** ▪ Exam attendance is obligatory unless being excused by the department and faculty.
I	▪ Absence from assignments or exams will be dealt with according to the general policy of the university.
4	**Assignments & Projects:** ▪ Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator. ▪ Projects: Not applicable.
5	**Cheating:** ▪ Punishment of cheating will be according to the general policy of the university in this respect.
6	**Plagiarism:** ▪ 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:** ▪ General policies of the Students' Affairs of the University and the Quality Assurance Unit.

Course Plan of Pharmacokinetics

I. - Information about Faculty Member Responsible for the Course:							
Name of Faculty Member	Prof Dr/ Mahmoud Mahyoob Alburyhi	Office Hours					
Location & Telephone No.	777970600	SAT	SUN	MON	TUE	WED	THU
E-mail	buryhi@yahoo.com			2hrs	2hrs		

II. Course Identification and General Information:						
1-	Course Title:	Pharmacokinetics				
2-	Course Number & Code:	Ph2815				
3-	Credit hours: 3hrs	C.H				Total
		Th.	Seminar	Pr.	F. Tr.	
		2	-	2		3
4-	Study level/year at which this course is offered:	Fourth year/Second semester				
5-	Pre –requisite (if any):	Pharmaceutics I-IV, Biopharmaceutics				
6-	Co –requisite (if any):	Advanced Drug Delivery Systems				
7-	Program (s) in which the course is offered	Bachelor of Pharmacy				
8-	Language of teaching the course:	English				
9-	System of Study:	Semesters				

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

III. Course description:

This course aims to provide the students with a comprehensive theoretical foundation of estimating pharmacokinetic parameters. Mathematical background for modeling of the concentration time relationships for the different routes of administration. Designing dosing regimens by relating plasma concentration of drugs to their pharmacological and toxicological action, Individualization of therapy for patients. Designing therapeutic drug monitoring plans for drugs with narrow therapeutic index or high toxicity.

IV. Intended learning outcomes (ILOs) of the course:

At the end of this course, the students will be able to:

1. Define the pharmacokinetic model of a specified drug and recognize the pharmacokinetic parameters.
2. Understand the features of elimination rates, orders of pk, one & two compartment model.
3. Demonstrate the proper dose when shift form iv to oral, nonlinear pk and nonlinear pk.
4. Demonstrate the proper dose in liver and kidney disorders.
5. Demonstrate the proper therapy and therapeutic drug monitoring for each patient and dose selection for narrow therapeutic drugs.
6. Conduct pharmacokinetic parameter protocols for the pharmacological testing of new drugs.
7. Utilization of mathematics of the time course of Absorption, Distribution, Metabolism, and Excretion (ADME) of drugs in the body for dosage optimization.
8. Developing dosing regimens for the individualization of therapy for the patient.
9. Fitting concentration time profiles and estimating pharmacokinetic parameters, drug dose and protocol of therapy.
10. Calculate practically the difference between pharmacokinetics compartment models.
11. Apply dosing regimens for specific population patients, renal and hepatic dysfunction.
12. Demonstrate bioequivalence studies
13. Assess the difference between linear & nonlinear PK.
14. Communicating the dosage adjustment with physicians, suggesting therapeutic monitoring plans for physicians and use different information sources to solve medication problems.
15. Retrieve information from a variety of sources, including libraries, databases and internet.
16. Work effectively in a team and demonstrate time management skills.

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 basic pharmacokinetics, elimination rates and orders PK)	**a1, b1, d1,d2,d3**	basic pharmacokinetics, ADME-system, pharmacodynamics, toxicokinetics Pharmacokinetic models	**1**	**2**
2.	Pharmacokinetic parameters models, equations and order kinetics	**a2, b3, d1,d2,d3**	Define various models representing rates and order of reactions and calculate pharmacokinetic parameters (eg, zero- and first-order) from experimental data based on these models.	**1**	**2**
3.	The one-compartment open model with an intravenous bolus dose	**a2,a3, b3, d1,d2,d3**	PK parameters after I.V. dose bolus(plasma data) and (urine data)	**1**	**2**
4.	The one-compartment open model with an intravenous infusion	**a3, b2, b3, d1,d2,d3**	PK parameters, Steady state during constant rate infusion	**1**	**2**
5.	The one-compartment open model	**a1, a2,a3, b2,**	Absorption rate and	**1**	**2**

	with absorption and elimination: (Extravascular PK).	**d1,d2,d3**	elimination rate PK parameters after extravascular administration, e.g. oral dose.		
6.	The one-compartment open model with multiple dosing kinetics: multiple dosing	**a4,b1, b2, b3, d1,d2,d3**	volume of distribution, drug clearance, and halflife can be affected by protein binding and PK parameters after multiple dosing	**1**	**2**
7.	Mid-term exam	**a1-4, b1-3**		**1**	**2**
8.	Bioavailability and bioequivalence	**a3, b2, b3, d1,d2,d3**	PK parameters, half-life AUC, AUMC	**2**	**4**
9.	The two-compartment open model with intravenous administration	**a2,b3, d1,d2,d3**	PK parameters half-life Cp, Vd, Cl, t1/2 A, B, a, b, K12, K21, K, AUC	**1**	**2**
10.	Metabolites and urinary excretion Dose adjustment in renal disorder	**a4,a5, b2,b3, d1,d2,d3**	Clinical PK parameters Kr, Km, Clr, Clm K & Cl	**1**	**2**
11.	Distribution and drug binding	**a2,a3, b2,b3, d1,d2,d3**	Clinical PK parameters	**1**	**2**
12.	pharmacokinetic of drugs follows Michaelis–Menton kinetics and Non-linear PK model.	**a2,a3,a4,a5, b2,b3, d1,d2,d3**	PK parameters	**1**	**2**
13.	Clinical pharmacokinetics Dosage regimen, age, and diseases state	**a3,a4,a5, b2,b3, d1,d2,d3**	Clinical PK parameters Application specific populations, the Pediatric Patients, the Obese Patients and the Geriatric Patients	**2**	**4**

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14.	final-term exam	**a1-5, b1-3**		**1**	**2**

Number of Weeks /and Units Per Semester			**16**	**32**

b- Practical Aspect:

Order	**Practical Tasks**	**CILOs (symbols)**	**Number of weeks**	**Contact hours**
1.	Calculate the pharmacokinetic parameters of some drugs that follow zero order.	**c1, d1,d2,d3**	**1**	**2**
2.	Calculate the pharmacokinetic parameters of some drugs that follow first order.	**c1, d1,d2,d3**	**1**	**2**
3.	The one-compartment open model with an intravenous bolus dose: calculating pharmacokinetic parameters from plasma data	**c1,c2, d1,d2,d3**	**1**	**2**
4.	The one-compartment open model with an intravenous bolus dose: calculating pharmacokinetic parameters from urinary data	**c1,c2,c3, d1,d2,d3**	**1**	**2**
5.	The one-compartment open model with an intravenous infusion: calculating pharmacokinetic parameters from continues infusion, infusion with a bolus dose, post infusion data.	**c1,c2,c3,c4, d1,d2,d3**	**1**	**2**
6.	Calculate the steady-state C max and C min after multiple IV bolus dosing of drugs.	**c1,c2,c3, d1,d2,d3**	**1**	**2**
7.	Mid-term exam	**c1-4**	**1**	**2**
8.	The one-compartment open model with absorption and elimination: calculating pharmacokinetic parameters from plasma data(Extravascular PK).	**c1,c2,c3,c4, d1,d2,d3**	**2**	**2**
9.	The one-compartment open model with multiple dosing kinetics: multiple dosing IV	**c1,c2,c3,c4, d1,d2,d3**	**1**	**2**
10.	The one-compartment open model with multiple dosing kinetics: multiple dosing oral (Extravascular PK).	**c1,c2,c3,c4,c5, d1,d2,d3**	**1**	**2**

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11.	The two-compartment open model with intravenous administration.	**c1,c2,c3,c4,c5, d1,d2,d3**	**1**	**2**
12.	Designing dosing regimens and Sources of variation in intrinsic clearance	**c1,c2,c3,c4,c5, d1,d2,d3**	**1**	**2**
13.	Calculating pharmacokinetic parameters from Michaelis–Menton kinetics and Non-linear PK	**c5, d1,d2,d3**	**1**	**2**
	model.			
14.	Estimating clinical pharmacokinetic parameters, dosage regimen according to age, and diseases state.	**c5, d1,d2,d3**	**1**	**2**
15.	final-term exam	**c1-5**	**1**	**2**
Number of Weeks /and Units P r Semester			**16**	**32**

VI. a-Teaching strategies of the course:

Lecture method, Group Discussion, Problem solving sessions**,** tutorials, brainstorming and Practical sessions.

b- Assessment Methods:

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

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark
1	Homework Assignments	**a1-5, b1-3, d1-3**	Sporadic through the semester	**10**
2	Reports	**c1-5, d1-3**		

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

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No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes (CILOs symbols)
8.	**Attendance, Participation and quizzes**	**All Weeks**	10	7%	**a1-5,b1-3,** d1-3
9.	**Oral Tests and Homeworkassignments**	Sporadic through the semester	10	7%	**a1-5, b1-3,** d1-3
10.	**Attendance, Practical Reports**	**All Weeks**	15	10%	**c1-5**
11.	**Practical mid-semester exam**	7th	15	10%	**c1-4**
12.	**Theoretical mid-semester exam**	7th	30	20%	**a1-4, b1-3**
13.	**Final Exam (theoretical)**	**16th**	50	33%	**a1-5, b1-3**
14.	**Final Exam (practical)**	**16th**	20	13%	**c1-5**
	Total		**150**	**100%**	

IX. Students' Support:

Office Hours/week	Other Procedures (if any)
2 hours per week	

X. Learning Resource (MLA style or APA style)S:

5- Required Textbook(s) (maximum two)

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	1-A book prepared by the staff members 2-Shargel, L and Yu, ABC., 2016, *Applied Biopharmaceutics & pharmacokinetics*, 7th edition, McGraw-Hill Education, New York. 3-Bauer, LA, 2008, *Applied clinical pharmacokinetics*, 2nd edition, McGraw-Hill Companies, Inc, New York.
6- Recommended Readings and Reference Materials	
	1-Rowland M, Tozer T, 1995, Clinical Pharmacokinetics—Concepts and Applications, 3rd ed, Lea & Febiger, Philadelphia. 2-Levine RR, 1990, Drug Actions and Reactions, 4th ed., Little, Brown, Boston. 3- Gibaldi, M. (1991) Biopharmaceutics and Clinical Pharmacokinetics, 4th edn. Lea & Febiger, Philadelphia.
7- Electronic Materials and Web Sites *etc*.	
	www.pubmed.com http://www.sciencedirect.com/
8- Other Learning Material:	
	J Pharmacokinet Biopharm J Pharm Sci Published articles related to the discussed topics United States Pharmacopeia and National Formulary (latest edition) United States Pharmacopeial Convention Inc., Rockville, MD. British Pharmacopoeia (latest edition), HMSO. London. Martindale, W. (latest edition) The Extra Pharmacopoeia., Royal Pharmaceutical Society of Great Britain, London.

XI. Facilities Required:

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

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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.

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II.	Course Policies:
1	**Class Attendance:** ▪ 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	**Tardiness:** ▪ Non-reasonable frequent tardiness will be allowed and is considered as absence from the lectures/
3	**Exam Attendance/Punctuality:** ▪ 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:** ▪ Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator. ▪ Projects: Not applicable.
5	**Cheating:** ▪ Punishment of cheating will be according to the general policy of the university in this respect.
6	**Plagiarism:** ▪ 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:**

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	▪ General policies of the Students' Affairs of the University and the Quality Assurance Unit.