

University of 21 September for Applied and Medical Sciences

Faculty of Clinical Pharmacy

Program of Master in Clinical Pharmacy

Course Specification of Therapeutic Drug Monitoring (TDM)

Course No (CPh104)

2021/2022

Prepared By

1

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

Dr.

I. Course Identification and General Information:						
1	Course Title:	Therapeutic Drug Monitoring (TDM)				
2	Course Code & Number:	CPh104				
3	Credit hours:	C.H				TOTAL
		Th.	Seminar	Pr	Tr.	
		2	-	2	-	3
4	Study level/ semester at which this course is offered:	Level 1 / semester 1				
5	Pre –requisite (if any):	NA				
6	Co –requisite (if any):	None				
7	Program (s) in which the course is offered:	Master Degree in Clinical Pharmacy				
8	Language of teaching the course:	English				
9	Study System	semester based System				
10	Mode of delivery:	Regular				
11	Location of teaching the course:	Faculty of Clinical Pharmacy				
12	Prepared By:	Dr. Ali Alyahawi				
13	Date of Approval					

II. Course Description:	
<p>The course aims to provide the principles of pharmacokinetics and the applications of pharmacokinetics in therapeutic drug monitoring (TDM). It is mainly concerned with the application of concepts and techniques of pharmacokinetics to the rational design of individualized drug dosage regimens in the total clinical context, taking into account such special problems as hepatic and renal functional impairment, and the effects of disease.</p>	

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2

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

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III. Course Intended learning outcomes (CILOs) of the course		Referenced PILOs
a.1	Define the basic pharmacokinetic parameters of a drug	A1, A2
a.2	Understand the various aspects of a drug's pharmacokinetic properties and factors affecting them.	A1
a.3	Understand the basis of therapeutic drug monitoring.	A1, A2
b.1	Predict drug concentration after drug administration and interpret clinical findings	B1
b.2	Construct a plan of therapeutic drug monitoring for narrow therapeutic window drugs	B2
c.1	Identify clinical manifestations of potential toxicities associated with patient's medication and recommend initial dosage regimen, or adjust dosage and recommend monitoring strategy to ensure safe and effective drug therapy.	C1
c.2	Apply pharmacokinetic concepts in order to determine an individualized dosage regimen for a specific patient.	C2
d.1	Search correctly in different information sources to solve pharmacokinetics problems.	D2
d.2	Communicate effectively with patients and other healthcare professionals.	D1

(a) Alignment Course Intended Learning Outcomes of Knowledge and Understanding to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
a1- Define the basic pharmacokinetic parameters of a drug	Lectures Assignment In-class case discussion Office hour Seminar	Exam Quiz Assignment
a2- Understand the various aspects of a drug's pharmacokinetic properties and factors affecting them.	Lectures Assignment In-class case discussion	Exam Quiz Assignment

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3

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

Dr.

	Office hour Seminar	
a3- Understand the basis of therapeutic drug monitoring.	Lectures Assignment In-class case discussion Office hour Seminar	Exam Quiz Assignment

(b) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
b1- Predict drug concentration after drug administration and interpret clinical findings	Lectures Assignment In-class case discussion Office hour Seminar	Exam Quiz Assignment
b2- Construct a plan of therapeutic drug monitoring for narrow therapeutic window drugs.	Lectures Assignment In-class case discussion Office hour Seminar	Exam Quiz Assignment

(c) Alignment Course Intended Learning Outcomes of Professional and Practical Skills to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
C1- Identify clinical manifestations of potential toxicities associated with patient's medication and recommend initial dosage regimen, or adjust dosage and recommend monitoring strategy to ensure safe and effective drug therapy.	Lectures Assignment In-class case discussion Office hour Seminar	Exam Quiz Assignment
C2- Apply pharmacokinetic concepts in order to determine an individualized dosage regimen for a specific patient.	Lectures Assignment In-class case discussion Office hour Seminar	Exam Quiz Assignment

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4

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

Dr.

(D) Alignment Course Intended Learning Outcomes of Transferable Skills to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
d1- Search correctly in different information sources to solve pharmacokinetics problems.	Self-learning Assignment Seminar	Exam Quiz Assignment
d2- Communicate effectively with patients and other healthcare professionals.	In-class case discussion Seminar	Presentation

IV. Course Content:					
A – Theoretical Aspect:					
Order	Units/Topics List	Learning Outcomes	Sub Topics List	Number of Weeks	Contact hours
1	Introduction to Clinical Pharmacokinetics	a1, a2, a3, b1,b2,c1,c2,d 1	- Concepts, Equations and Calculations	2	4
2	Clinical Pharmacokinetics in Special Populations	a1, a2, a3, b1,b2,c1,c2,d 1,d2	- Heart Failure - Obesity - Drug Interactions	2	4
3	TDM in Patients with Hepatic Disease	a1, a2, a3, b1,b2,c1,c2,d 1,d2	- Hepatic drug metabolism - Determination of Child-Pugh Scores - Estimation of Drug Dosing and Pharmacokinetic Parameters for Liver Metabolized Drugs - Implications of Hepatic Disease on Serum Drug Concentration Monitoring and Drug Effects	1	2
4	TDM for Patients with Chronic Kidney Disease	a1, a2, a3, b1,b2,c1,c2,d 1,d2	- Measurement and Estimation of Creatinine Clearance - Estimation of Drug Dosing	1	2

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5

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

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			and Pharmacokinetic Parameters Using Creatinine Clearance		
5	TDM in Dialytic Patients	a1, a2, a3, b1,b2,c1,c2,d1,d2	<ul style="list-style-type: none"> - Drug Characteristics that Effect Dialysis Removal - HEMODIALYSIS - Computation of Initial Doses and Modification of Doses Using Drug Serum Concentrations - Methods to Measure Hemodialysis Clearance - HEMOFILTRATION - PERITONEAL DIALYSIS and Methods to Measure Peritoneal Dialysis Clearance 	1	2
6	Midterm Exam	a1, a2, a3, b1,b2,c1,c2		1	2
7	TDM of Aminoglycosides	a1, a2, a3, b1,b2,c1,c2,d1,d2	<ul style="list-style-type: none"> - Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Effects of Disease States and Conditions on Aminoglycoside Pharmacokinetics and Dosing - Dosing methods 	1	2
8	TDM of Vancomycin	a1, a2, a3, b1,b2,c1,c2,d1,d2	<ul style="list-style-type: none"> - Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Effects of Disease States and Conditions on Vancomycin Pharmacokinetics and Dosing - Dosing methods 	1	2
9	TDM of Digoxin	a1, a2, a3, b1,b2,c1,c2,d1,d2	<ul style="list-style-type: none"> - Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Effects of Disease States and Conditions on Digoxin 	1	2

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6

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

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			Pharmacokinetics and Dosing - Dosing methods		
10	TDM of Phenytoin	a1, a2, a3, b1,b2,c1,c2,d 1,d2	- Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Impact of Altered Plasma Protein Binding on Phenytoin Pharmacokinetics - Effects of Disease States and Conditions on Phenytoin Pharmacokinetics and Dosing - Dosing methods	1	2
11	TDM of Carbamazepine	a1, a2, a3, b1,b2,c1,c2,d 1,d2	- Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Effects of Disease States and Conditions on Carbamazepine Pharmacokinetics and Dosing - Dosing methods	1	2
12	TDM of Theophylline	a1, a2, a3, b1,b2,c1,c2,d 1,d2	- Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Effects of Disease States and Conditions on theophylline Pharmacokinetics and Dosing - Dosing methods	1	2
13	Cases Discussions	a1, a2, a3, b1,b2,c1,c2,d 1,d2	- Selected topics of course	1	2
14	Final Exam	a1, a2, a3, b1,b2,c1,c2, d1		1	2

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7

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

Dr.

Number of Weeks /and Units Per Semester	16	32
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B - Practical Aspect: (if any)				
Order	Tasks/ Experiments	Number of Weeks	contact hours	Learning Outcomes
1	N/A			
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
Number of Weeks /and Units Per Semester				

V. Teaching strategies of the course:
Lectures Assignment In-class case discussion Self-learning Office hour Seminar
VI. Teaching strategies of the course:
Exam Assignment Quiz

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 Dr. Ali Alyahawi

Reviewed By
 Dr. Ali Alkaf

Dean of Faculty
 Dr.

I. Assignments:

No	Assignments	Aligned CILOs(symbols)	Week Due	Mark
1	Assignment 1	b1,b2,c1,c2	3th	5
2	Assignment 2	b1,b2,c1,c2	12th	5
Total				10

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

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes
1	Assignments	Week 3-12	10	10%	a1, a2, a3, b1,b2,c1,c2,d1,d2
2	Quiz 1	Week 6	5	5 %	a1, a2, a3, b1,b2,c1,c2
3	Midterm Exam	Week 8	20	20%	a1, a2, a3, b1,b2,c1,c2
4	Quiz 2	Week 12	5	5 %	a1, a2, a3, b1,b2,c1,c2
5	Final Exam	Week 16	60	60%	a1, a2, a3, b1,b2,c1,c2
Total			100	100%	

III. Learning Resources:

- *Written in the following order: (Author - Year of publication – Title – Edition – Place of publication – Publisher).*

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

- Applied clinical pharmacokinetics, By Larry Bauer. 3rd Edition – 2014 (ISBN-13: 9780071794589)
- Applied pharmacokinetics & pharmacodynamics: principles of therapeutic drug monitoring, By Michael E. Burton. Edition: 4 – 2006 (ISBN-13: 978-0071603935)

2- Essential References.

- Clinical pharmacokinetics: concepts and applications**, By Malcolm Rowland, Thomas N. Tozer. Edition: 4 – 2010
- Handbook of drug monitoring methods: Therapeutics and Drugs of Abuse**, By Amitava Dasgupta. Edition: 1 – 2008
- Concepts in Clinical Pharmacokinetics**, By William Spruill and William Wade. Edition:6 – 201

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9

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

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Dr.

	<p>4. Applied Biopharmaceutics & Pharmacokinetics, 7th Edition, By Leon Shargel and Andrew YuSee – 2016 (ISBN-13: 9780071829649)</p> <p>5. Introduction to pharmacokinetics and pharmacodynamics: the quantitative basis of drug therapy, By Thomas N. Tozer, Malcolm Rowland. Edition 1: 2006</p>
3- Electronic Materials and Web Sites etc.	
	1. Relevant original and review articles from scientific journals

I. Course Policies: (Based on the Uniform Students' Bylaw (2007))	
1	<p>Class Attendance: Class Attendance is mandatory. A student is considered absent and shall be banned from taking the final exam if his/her absence exceeds 25% of total classes.</p>
2	<p>Tardiness: A student will be considered late if he/she is not in class after 10 minutes of the start time of class.</p>
3	<p>Exam Attendance/Punctuality: No student shall be allowed to the exam hall after 30 minutes of the start time, and shall not leave the hall before half of the exam time has passed.</p>
4	<p>Assignments & Projects: Assignments and projects must be submitted on time. Students who delay their assignments or projects shall lose the mark allocated for the same.</p>
5	<p>Cheating: Cheating is an act of fraud that results in the cancelation of the student's exam or assignment. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply.</p>
6	<p>Forgery and Impersonation: Forgery/Impersonation is an act of fraud that results in the cancelation of the student's exam, assignment or project. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply.</p>
7	<p>Other policies: The University official regulations in force will be strictly observed and students shall comply with all rules and regulations of the examination set by the Department, Faculty and University Administration.</p>

University of 21 September for Applied and Medical Sciences

Faculty of Clinical Pharmacy

Program of Master Degree in Clinical Pharmacy

Course Plan (Syllabus) of Therapeutic Drug Monitoring (TDM)

Course No (CPh104)

2021/2022

Prepared By

11

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

Dr.

II. - Information about Faculty Member Responsible for the Course:

Name of Faculty Member	Dr. Ali Alyahawi	Office Hours					
Location & Telephone No.	775957401	SAT	SUN	MON	TUE	WED	THU
E-mail	alyahawipharm@yahoo.com						

III. Course Identification and General Information:

1	Course Title:	Therapeutic Drug Monitoring (TDM)				
2	Course Code & Number:	CPh104				
3	Credit hours:	C.H				TOTAL
		Th.	Seminar	Pr	Tr.	
		2	--	2	--	3
4	Study level/ semester at which this course is offered:	- level 1/ semester 1				
5	Pre –requisite (if any):	None				
6	Co –requisite (if any):	-				
7	Program (s) in which the course is offered:	Master of Clinical Pharmacy				
8	Language of teaching the course:	English				
9	Study System	semester based System				
10	Mode of delivery:	Full Time				
11	Location of teaching the course:	Dr. Ali Alyahawi				

IV. Course Description:

The course aims to provide the principles of pharmacokinetics and the applications of pharmacokinetics in therapeutic drug monitoring (TDM). It is mainly concerned with the application of concepts and techniques of pharmacokinetics to the rational design of individualized drug dosage regimens in the total clinical context, taking into account such special problems as hepatic and renal functional impairment, and the effects of disease.

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12

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

Dr.

V. Course Intended learning outcomes (CILOs)	
Upon completion of this Course, student will be able to:	
a.1	Define the basic pharmacokinetic parameters of a drug
a.2	Understand the various aspects of a drug's pharmacokinetic properties and factors affecting them.
a.3	Understand the basis of therapeutic drug monitoring.
b.1	Predict drug concentration after drug administration and interpret clinical findings
b.2	Construct a plan of therapeutic drug monitoring for narrow therapeutic window drugs
c.1	Identify clinical manifestations of potential toxicities associated with patient's medication and recommend initial dosage regimen, or adjust dosage and recommend monitoring strategy to ensure safe and effective drug therapy.
c.2	Apply pharmacokinetic concepts in order to determine an individualized dosage regimen for a specific patient.
d.1	Search correctly in different information sources to solve pharmacokinetics problems.
d.2	Communicate effectively with patients and other healthcare professionals.

VI. Course Content:				
A – Theoretical Aspect:				
Order	Units/Topics List	Sub Topics List	Week Due	Contact Hours
1	Introduction to Clinical Pharmacokinetics: Concepts, Equations and Calculations	<ul style="list-style-type: none"> - Clinical Pharmacokinetic and Pharmacodynamics concepts - Clinical Pharmacokinetic Equations and Calculations 	2	4
2	TDM in Patients with Hepatic Disease	<ul style="list-style-type: none"> - Hepatic drug metabolism - Determination of Child-Pugh Scores - Estimation of Drug Dosing and Pharmacokinetic Parameters for Liver Metabolized Drugs - Implications of Hepatic Disease on Serum Drug Concentration Monitoring and Drug Effects 	1	2
3	TDM for Patients with Chronic Kidney Disease	<ul style="list-style-type: none"> - Measurement and Estimation of Creatinine Clearance - Estimation of Drug Dosing and Pharmacokinetic Parameters Using 	1	2

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13

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

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		Creatinine Clearance		
4	TDM in Dialytic Patients	<ul style="list-style-type: none"> - Drug Characteristics that Effect Dialysis Removal - HEMODIALYSIS - Computation of Initial Doses and Modification of Doses Using Drug Serum Concentrations - Methods to Measure Hemodialysis Clearance - HEMOFILTRATION - PERITONEAL DIALYSIS and Methods to Measure Peritoneal Dialysis Clearance 	1	2
5	Clinical Pharmacokinetics in Special Populations	<ul style="list-style-type: none"> - Heart Failure - Obesity - Drug Interactions 	2	4
6	Midterm Exam		1	2
7	TDM of Aminoglycosides	<ul style="list-style-type: none"> - Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Effects of Disease States and Conditions on Aminoglycoside Pharmacokinetics and Dosing - Dosing methods 	1	2
8	TDM of Vancomycin	<ul style="list-style-type: none"> - Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Effects of Disease States and Conditions on Vancomycin Pharmacokinetics and Dosing - Dosing methods 	1	2
9	TDM of Digoxin	<ul style="list-style-type: none"> - Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Effects of Disease States and Conditions on Digoxin Pharmacokinetics and Dosing - Dosing methods 	1	2
10	TDM of Phenytoin	<ul style="list-style-type: none"> - Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Impact of Altered Plasma Protein Binding on Phenytoin Pharmacokinetics - Effects of Disease States and Conditions on Phenytoin Pharmacokinetics and Dosing - Dosing methods 	1	2
11	TDM of Carbamazepine	<ul style="list-style-type: none"> - Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Effects of Disease States and Conditions on Carbamazepine Pharmacokinetics and Dosing 	1	2

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Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

Dr.

		- Dosing methods		
12	TDM of Theophylline	- Therapeutic and Toxic Concentrations - Clinical Monitoring Parameters - Effects of Disease States and Conditions on theophylline Pharmacokinetics and Dosing - Dosing methods	1	2
13	Cases Discussions	- Selected topics of course	1	2
14	Final Exam		1	2
Number of Weeks /and Units Per Semester			16	32

B - Practical Aspect: (if any)			
Order	Tasks/ Experiments	Week Due	Contact Hours
1	N/A		
2			
3			
4			
5			
6			
7			
8			
Number of Weeks /and Units Per Semester		14	28

VII. Teaching strategies of the course:
Lectures Assignment In-class case discussion Self-learning Office hour Seminar
VIII. Assessment strategies of the course:
Exam Assignment Quiz

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15

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

Dr.

IX. Assignments:

No	Assignments	Week Due	Mark
1	Assignment 1	Through the semester	5
2	Assignment 2	Through the semester	5
Total			10

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

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment
1	Assignments	Through the semester	10	10%
2	Quiz 1	Week 6	5	5 %
3	Midterm Exam	Week 8	20	20%
4	Quiz 2	Week 12	5	5 %
5	Final Exam	Week 16	60	60%
Total		100	100	100%

IV. Learning Resources:

- *Written in the following order: (Author - Year of publication – Title – Edition – Place of publication – Publisher).*

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

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Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

Dr.

3- Electronic Materials and Web Sites etc.

2. Relevant original and review articles from scientific journals

XI. Course Policies: (Based on the Uniform Students' Bylaw (2007))

1	Class Attendance: Class Attendance is mandatory. A student is considered absent and shall be banned from taking the final exam if his/her absence exceeds 25% of total classes.
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Prepared By

17

Dr. Ali Alyahawi

Reviewed By

Dr. Ali Alkaf

Dean of Faculty

Dr.