

# Republic of Yemen

Ministry of Higher Education & Scientific Research

21 September University for Medicals and Applied Sciences



## Faculty of Clinical Pharmacy

### Clinical Pharmacy & Doctor of Pharmacy (Pharm D)

#### Course Specification of Clinical Pharmacokinetics

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Course No. (02.01.223)

2022

## I. Course Identification and General Information:

|    |                                                        |                                                  |              |          |            |
|----|--------------------------------------------------------|--------------------------------------------------|--------------|----------|------------|
| 1  | Course Title:                                          | Clinical Pharmacokinetics                        |              |          |            |
| 2  | Course Code & Number:                                  | 02.01.223                                        |              |          |            |
| 3  | Credit Hours:                                          | Credit Hours                                     | Theory Hours |          | Lab. Hours |
|    |                                                        |                                                  | Lecture      | Exercise |            |
|    |                                                        | 3                                                | 2            | --       | 2          |
| 4  | Study Level/ Semester at which this Course is offered: | 4 <sup>th</sup> Level / 2 <sup>nd</sup> Semester |              |          |            |
| 5  | Pre –Requisite (if any):                               | Biopharmaceutics & Pharmacokinetics              |              |          |            |
| 6  | Co –Requisite (if any):                                | None                                             |              |          |            |
| 7  | Program (s) in which the Course is Offered:            | Bachelor of Clinical Pharmacy & Pharm. D.        |              |          |            |
| 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:                       | Faculty of Clinical Pharmacy                     |              |          |            |
| 12 | Prepared by:                                           | Dr. Ali Alyahawi                                 |              |          |            |
| 13 | Date of Approval:                                      | 2022                                             |              |          |            |

## I. Course Description:

The course aims to understanding the fundamental concepts of pharmacokinetics in humans and skills in applications of pharmacokinetics in therapeutic drug monitoring (TDM). It is mainly concerned with the application of concepts and techniques of pharmacokinetics and pharmacodynamics 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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| Prepared by:     | Reviewed by:         | Head of the Department: | Vice Dean for Quality affairs | Dean of College: |
| Dr. Ali Alyahawi | Dr. Abdulelah Thabet | Dr. -----               | Dr. Abdulelah Thabet          | Dr. Ali Alyahawi |

| II. Course Intended learning outcomes (CILOs) of the course                                                      |                                                                                                                                                                                                                                   | Referenced PILOs (Learning out of program) |
|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>A. Knowledge and Understanding:</b> Upon successful completion of the course, students will be able to:       |                                                                                                                                                                                                                                   |                                            |
| a.1                                                                                                              | Define the basic pharmacokinetic parameters of a drug                                                                                                                                                                             | A2                                         |
| a.2                                                                                                              | Understand the various aspects of a drug's pharmacokinetic properties and factors affecting them.                                                                                                                                 | A2                                         |
| a.3                                                                                                              | Understand the basis of therapeutic drug monitoring.                                                                                                                                                                              | A3                                         |
| <b>B. Intellectual Skills:</b> Upon successful completion of the course, students will be able to:               |                                                                                                                                                                                                                                   |                                            |
| b.1                                                                                                              | Predict drug concentration after drug administration and interpret clinical findings                                                                                                                                              | B2                                         |
| b.2                                                                                                              | Construct a plan of therapeutic drug monitoring for narrow therapeutic window drugs                                                                                                                                               | B4                                         |
| <b>C. Professional and Practical Skills:</b> Upon successful completion of the course, students will be able to: |                                                                                                                                                                                                                                   |                                            |
| 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. | C4                                         |
| c.2                                                                                                              | Apply pharmacokinetic concepts in order to determine an individualized dosage regimen for a specific patient.                                                                                                                     | C5                                         |
| <b>D. Transferable Skills:</b> Upon successful completion of the course, students will be able to:               |                                                                                                                                                                                                                                   |                                            |
| d.1                                                                                                              | Search correctly in different information sources to solve pharmacokinetics problems.                                                                                                                                             | D3                                         |
| 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                                        | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |
| a2                                                                                                                               | - Understand the various aspects of a drug's pharmacokinetic properties and factors affecting | <ul style="list-style-type: none"> <li>Lectures</li> </ul>                                                                                             | <ul style="list-style-type: none"> <li>Exam</li> </ul>                                   |

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|    |                                                       |                                                                                                                                                        |                                                                                          |
|----|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
|    | them.                                                 | <ul style="list-style-type: none"> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul>                   | <ul style="list-style-type: none"> <li>Quiz</li> <li>Assignment</li> </ul>               |
| a3 | -Understand the basis of therapeutic drug monitoring. | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |

| <b>(b) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and Assessment Strategies:</b> |                                                                                        |                                                                                                                                                        |                                                                                          |
|---------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
|                                                                                                                                 | <u>Course Intended Learning Outcomes</u>                                               | <u>Teaching strategies</u>                                                                                                                             | <u>Assessment Strategies</u>                                                             |
| b1                                                                                                                              | - Predict drug concentration after drug administration and interpret clinical findings | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |
| b2                                                                                                                              | - Construct a plan of therapeutic drug monitoring for narrow therapeutic window drugs. | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |

| <b>(c) Alignment Course Intended Learning Outcomes of Professional and Practical Skills to Teaching Strategies and Assessment Strategies:</b> |                                                                                                                                                                                                                                     |                                                                                                                                                        |                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
|                                                                                                                                               | <u>Course Intended Learning Outcomes</u>                                                                                                                                                                                            | <u>Teaching strategies</u>                                                                                                                             | <u>Assessment Strategies</u>                                                             |
| 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. | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |
| C2                                                                                                                                            | - Apply pharmacokinetic concepts in order to determine an individualized dosage regimen for a specific patient.                                                                                                                     | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |

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| (D) Alignment Course Intended Learning Outcomes of Transferable Skills to Teaching Strategies and Assessment Strategies: |                                                                                                      |                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Course Intended Learning Outcomes                                                                                        | Teaching strategies                                                                                  | Assessment Strategies                                                                    |
| <b>d1-</b> Search correctly in different information sources to solve pharmacokinetics problems.                         | <ul style="list-style-type: none"> <li>Self-learning</li> <li>Assignment</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |
| <b>d2-</b> Communicate effectively with patients and other healthcare professionals.                                     | <ul style="list-style-type: none"> <li>In-class case discussion</li> <li>Seminar</li> </ul>          | <ul style="list-style-type: none"> <li>Presentation</li> </ul>                           |

| Course Content:         |                                                                                 |                                                                                                                                                                                                                                                                                                                      |                 |               |                                |
|-------------------------|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------------|--------------------------------|
| A – Theoretical Aspect: |                                                                                 |                                                                                                                                                                                                                                                                                                                      |                 |               |                                |
| Order                   | Units/Topics List                                                               | Sub Topics List                                                                                                                                                                                                                                                                                                      | Number of Weeks | Contact hours | Learning Outcomes              |
| 1                       | Introduction to Clinical Pharmacokinetics: Concepts, Equations and Calculations | <ul style="list-style-type: none"> <li>Clinical Pharmacokinetic and Pharmacodynamics concepts</li> <li>Clinical Pharmacokinetic Equations and Calculations</li> </ul>                                                                                                                                                | 2               | 4             | a1, a2, a3, b1,b2,c1,c2, d1    |
| 2                       | TDM in Patients with Hepatic Disease                                            | <ul style="list-style-type: none"> <li>Hepatic drug metabolism</li> <li>Determination of Child-Pugh Scores</li> <li>Estimation of Drug Dosing and Pharmacokinetic Parameters for Liver Metabolized Drugs</li> <li>Implications of Hepatic Disease on Serum Drug Concentration Monitoring and Drug Effects</li> </ul> | 1               | 2             | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 3                       | TDM for Patients with Chronic Kidney Disease                                    | <ul style="list-style-type: none"> <li>Measurement and Estimation of Creatinine Clearance</li> <li>Estimation of Drug Dosing and Pharmacokinetic Parameters Using Creatinine Clearance</li> </ul>                                                                                                                    | 1               | 2             | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 4                       | TDM in Dialytic Patients                                                        | <ul style="list-style-type: none"> <li>Drug Characteristics that Effect Dialysis Removal</li> <li>HEMODIALYSIS</li> <li>Computation of Initial Doses and Modification of Doses Using Drug Serum Concentrations</li> <li>Methods to Measure</li> </ul>                                                                |                 |               | a1, a2, a3, b1,b2,c1,c2, d1,d2 |

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|    |                                                  |                                                                                                                                                                                                                                                                                                                                             |   |   |                                |
|----|--------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|---|--------------------------------|
|    |                                                  | <ul style="list-style-type: none"> <li>- Hemodialysis Clearance</li> <li>- HEMOFILTRATION</li> <li>- PERITONEAL DIALYSIS</li> <li>- and Methods to Measure Peritoneal Dialysis Clearance</li> </ul>                                                                                                                                         | 1 | 2 |                                |
| 5  | Clinical Pharmacokinetics in Special Populations | <ul style="list-style-type: none"> <li>- Heart Failure</li> <li>- Obesity</li> <li>- Drug Interactions</li> </ul>                                                                                                                                                                                                                           | 2 | 4 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 6  | Midterm Exam                                     |                                                                                                                                                                                                                                                                                                                                             | 1 | 2 | a1, a2, a3, b1,b2,c1,c2        |
| 7  | TDM of Aminoglycosides                           | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Effects of Disease States and Conditions on Aminoglycoside Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul>                                                                              | 1 | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 8  | TDM of Vancomycin                                | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Effects of Disease States and Conditions on Vancomycin Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul>                                                                                  | 1 | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 9  | TDM of Digoxin                                   | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Effects of Disease States and Conditions on Digoxin Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul>                                                                                     | 1 | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 10 | TDM of Phenytoin                                 | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Impact of Altered Plasma Protein Binding on Phenytoin Pharmacokinetics</li> <li>- Effects of Disease States and Conditions on Phenytoin Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul> | 1 | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 11 | TDM of Carbamazepine                             | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic</li> </ul>                                                                                                                                                                                                                                                                   | 1 | 2 | a1, a2, a3,                    |

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|                                         |                     |                                                                                                                                                                                                                                                              |    |   |                                |
|-----------------------------------------|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|---|--------------------------------|
|                                         |                     | <ul style="list-style-type: none"> <li>- Concentrations Monitoring</li> <li>- Clinical Parameters</li> <li>- Effects of Disease States and Conditions on Carbamazepine Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul>                      |    |   | b1,b2,c1,c2, d1,d2             |
| 12                                      | TDM of Theophylline | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Effects of Disease States and Conditions on theophylline Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul> | 1  | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 13                                      | Cases Discussions   | <ul style="list-style-type: none"> <li>- Selected topics of course</li> </ul>                                                                                                                                                                                | 1  | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 14                                      | Final Exam          |                                                                                                                                                                                                                                                              | 1  | 2 | a1, a2, a3, b1,b2,c1,c2        |
| Number of Weeks /and Units Per Semester |                     |                                                                                                                                                                                                                                                              | 16 | 3 |                                |

**B. Practical Aspect (Lab/Clinical) (if any):**

| No. | Tasks/ Experiments                                                                              | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|-----|-------------------------------------------------------------------------------------------------|-----------------|---------------|---------------------------|
| 1   | Zero order and first order Pharmacokinetic                                                      | 1               | 2             | a1, a2, b1,b2,c1,c2       |
| 2   | Determination of elimination rate constant, half life                                           | 1               | 2             | b1,b2,c1,c2               |
| 3   | Determination of fraction of drug unbound, Calculation of absolute and relative bioavailability | 1               | 2             | b1,b2,c1,c2               |
| 4   | Calculation of creatinine clearance                                                             | 1               | 2             | b1,b2,c1,c2               |
| 5   | Calculation of renal and hepatic clearance                                                      | 1               | 2             | b1,b2,c1,c2               |
| 6   | Midterm Exam                                                                                    | 1               | 2             | b1,b2,c1,c2               |

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| No.                                              | Tasks/ Experiments                                                   | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|--------------------------------------------------|----------------------------------------------------------------------|-----------------|---------------|---------------------------|
| 7                                                | Calculation of different pharmacokinetic parameters for Digoxin      | 1               | 2             | c1,c2                     |
| 8                                                | Determination of pharmacokinetic parameters for Theophylline         | 1               | 2             | c1,c2                     |
| 9                                                | Non-linear Pharmacokinetic                                           | 1               | 2             | c1,c2                     |
| 10                                               | Calculation of different of pharmacokinetic parameters for Phenytoin | 1               | 2             | c1,c2                     |
| 11                                               | Determination of pharmacokinetic parameters for Aminoglycosides      | 1               | 2             | c1,c2                     |
| 12                                               | Final Exam                                                           | 1               | 2             | b1,b2,c1,c2               |
| Number of Weeks /and Units Per Semester 12 weeks |                                                                      | 12              | 24            |                           |

### III. Teaching strategies of the course:

Lectures  
Assignment  
In-class case discussion  
Self-learning  
Office hour  
Seminar

### IV. Teaching strategies of the course:

Exam  
Assignment  
Quiz

### I. Assignments:

| No | Assignments | Aligned CILOs(symbols) | Week Due | Mark |
|----|-------------|------------------------|----------|------|
|----|-------------|------------------------|----------|------|

|                  |                      |                         |                               |                  |
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|       |              |                               |      |    |
|-------|--------------|-------------------------------|------|----|
| 1     | Assignment 1 | a1, a2, a3, b1,b2,c1,c2,d1,d2 | 3th  | 5  |
| 2     | Assignment 2 | a1, a2, a3, b1,b2,c1,c2,d1,d2 | 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    | 10   | 10 %                           | 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   | 10   | 10 %                           | a1, a2, a3, b1,b2,c1,c2          |
| 5     | Final Exam        | Week 16   | 50   | 50%                            | 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 ).

1. Larry Bauer,2014, **Applied clinical pharmacokinetics**,3rd Edition
2. Michael E. Burton, 2006, **Applied pharmacokinetics & pharmacodynamics: principles of therapeutic drug monitoring**, 4TH Edition:

### 2- Essential References.

1. **Clinical pharmacokinetics: concepts and applications**, By Malcolm Rowland, Thomas N. Tozer. Edition: 4 – 2010
2. **Handbook of drug monitoring methods: Therapeutics and Drugs of Abuse**, By Amitava Dasgupta. Edition: 1 – 2008
3. **Concepts in Clinical Pharmacokinetics**, By William Spruill and William Wade. Edition:6 – 201
4. **Applied Biopharmaceutics & Pharmacokinetics**, 7th Edition, By Leon Shargel and Andrew YuSee – 2016 (ISBN-13: 9780071829649)
5. **Introduction to pharmacokinetics and pharmacodynamics: the quantitative basis of drug therapy**, By Thomas N. Tozer, Malcolm Rowland. Edition 1: 2006

### 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

### Class Attendance:

Class Attendance is mandatory. A student is considered absent and shall be banned from taking

|                  |                      |                         |                               |                  |
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|   |                                                                                                                                                                                                                                                                                |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | the final exam if his/her absence exceeds 25% of total classes.                                                                                                                                                                                                                |
| 2 | <b>Tardiness:</b><br>A student will be considered late if he/she is not in class after 10 minutes of the start time of class.                                                                                                                                                  |
| 3 | <b>Exam Attendance/Punctuality:</b><br>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.                                                                                  |
| 4 | <b>Assignments &amp; Projects:</b><br>Assignments and projects must be submitted on time. Students who delay their assignments or projects shall lose the mark allocated for the same.                                                                                         |
| 5 | <b>Cheating:</b><br>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.                                        |
| 6 | <b>Forgery and Impersonation:</b><br>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. |
| 7 | <b>Other policies:</b><br>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.                                     |

## Republic of Yemen

Ministry of Higher Education & Scientific Research

**21 September University of Medicals & Applied Sciences**

|                  |                      |                         |                               |                  |
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## Second Part of Course Specification

### Faculty of Clinical Pharmacy

#### Program of Clinical Pharmacy & Doctor of Pharmacy (Pharm. D.)

#### Course Plan (Syllabus) of **Clinical Pharmacokinetics**

Course No. (02.01.223)

2022/2023

|                  |                      |                         |                               |                  |
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| Prepared by:     | Reviewed by:         | Head of the Department: | Vice Dean for Quality affairs | Dean of College: |
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## Course Plan (Syllabus) of Clinical Pharmacokinetics

Course No. (02.01.223)

### 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                   | <a href="mailto:alyahawipharm@yahoo.com">alyahawipharm@yahoo.com</a> |              |     |     |     |     |     |

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## I. Course Identification and General Information:

|    |                                                        |                                                  |              |          |            |
|----|--------------------------------------------------------|--------------------------------------------------|--------------|----------|------------|
| 1  | Course Title:                                          | Clinical Pharmacokinetics                        |              |          |            |
| 2  | Course Code & Number:                                  | 02.01.223                                        |              |          |            |
| 3  | Credit Hours:                                          | Credit Hours                                     | Theory Hours |          | Lab. Hours |
|    |                                                        |                                                  | Lecture      | Exercise |            |
|    |                                                        | 3                                                | 2            | --       | 2          |
| 4  | Study Level/ Semester at which this Course is offered: | 4 <sup>th</sup> Level / 2 <sup>nd</sup> Semester |              |          |            |
| 5  | Pre –Requisite (if any):                               | Biopharmaceutics & Pharmacokinetics              |              |          |            |
| 6  | Co –Requisite (if any):                                | None                                             |              |          |            |
| 7  | Program (s) in which the Course is Offered:            | Bachelor of Clinical Pharmacy & Pharm. D.        |              |          |            |
| 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:                       | Faculty of Clinical Pharmacy                     |              |          |            |
| 12 | Prepared by:                                           | Dr. Ali Alyahawi                                 |              |          |            |
| 13 | Date of Approval:                                      | 2022                                             |              |          |            |

## V. Course Description:

The course aims to understanding the fundamental concepts of pharmacokinetics in humans and skills in applications of pharmacokinetics in therapeutic drug monitoring (TDM). It is mainly concerned with the application of concepts and techniques of pharmacokinetics and pharmacodynamics 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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| Course Intended learning outcomes (CILOs) of the course                                                          |                                                                                                                                                                                                                                   |
|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>A. Knowledge and Understanding:</b> Upon successful completion of the course, students 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>B. Intellectual Skills:</b> Upon successful completion of the course, students will be able to:               |                                                                                                                                                                                                                                   |
| 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                                                                                                                                               |
| <b>C. Professional and Practical Skills:</b> Upon successful completion of the course, students will be able to: |                                                                                                                                                                                                                                   |
| 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.                                                                                                                     |
| <b>D. Transferable Skills:</b> Upon successful completion of the course, students will be able to:               |                                                                                                                                                                                                                                   |
| d.1                                                                                                              | Search correctly in different information sources to solve pharmacokinetics problems.                                                                                                                                             |
| d.2                                                                                                              | Communicate effectively with patients and other healthcare professionals.                                                                                                                                                         |

| (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 | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |

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|    |                                                                                                     |                                                                                                                                                        |                                                                                          |
|----|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
|    |                                                                                                     | <ul style="list-style-type: none"> <li>Office hour</li> <li>Seminar</li> </ul>                                                                         |                                                                                          |
| a2 | - Understand the various aspects of a drug's pharmacokinetic properties and factors affecting them. | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |
| a3 | -Understand the basis of therapeutic drug monitoring.                                               | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |

**(b) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and Assessment Strategies:**

|    | <u>Course Intended Learning Outcomes</u>                                               | <u>Teaching strategies</u>                                                                                                                             | <u>Assessment Strategies</u>                                                             |
|----|----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| b1 | - Predict drug concentration after drug administration and interpret clinical findings | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |
| b2 | - Construct a plan of therapeutic drug monitoring for narrow therapeutic window drugs. | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |

**(c) Alignment Course Intended Learning Outcomes of Professional and Practical Skills to Teaching Strategies and Assessment Strategies:**

|    | <u>Course Intended Learning Outcomes</u>                                                                                                                                                                                            | <u>Teaching strategies</u>                                                                                                                             | <u>Assessment Strategies</u>                                                             |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| 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. | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |
| C2 | - Apply pharmacokinetic concepts in order to determine an individualized dosage regimen for a specific patient.                                                                                                                     | <ul style="list-style-type: none"> <li>Lectures</li> <li>Assignment</li> </ul>                                                                         | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> </ul>                     |

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|  |  | <ul style="list-style-type: none"> <li>In-class case discussion</li> <li>Office hour</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Assignment</li> </ul> |
|--|--|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|

| (D) Alignment Course Intended Learning Outcomes of Transferable Skills to Teaching Strategies and Assessment Strategies: |                                                                                                      |                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Course Intended Learning Outcomes                                                                                        | Teaching strategies                                                                                  | Assessment Strategies                                                                    |
| <b>d1-</b> Search correctly in different information sources to solve pharmacokinetics problems.                         | <ul style="list-style-type: none"> <li>Self-learning</li> <li>Assignment</li> <li>Seminar</li> </ul> | <ul style="list-style-type: none"> <li>Exam</li> <li>Quiz</li> <li>Assignment</li> </ul> |
| <b>d2-</b> Communicate effectively with patients and other healthcare professionals.                                     | <ul style="list-style-type: none"> <li>In-class case discussion</li> <li>Seminar</li> </ul>          | <ul style="list-style-type: none"> <li>Presentation</li> </ul>                           |

| Course Content:         |                                                                                 |                                                                                                                                                                                                                                                                                                                      |                 |               |                                |
|-------------------------|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------------|--------------------------------|
| A – Theoretical Aspect: |                                                                                 |                                                                                                                                                                                                                                                                                                                      |                 |               |                                |
| Order                   | Units/Topics List                                                               | Sub Topics List                                                                                                                                                                                                                                                                                                      | Number of Weeks | Contact hours | Learning Outcomes              |
| 1                       | Introduction to Clinical Pharmacokinetics: Concepts, Equations and Calculations | <ul style="list-style-type: none"> <li>Clinical Pharmacokinetic and Pharmacodynamics concepts</li> <li>Clinical Pharmacokinetic Equations and Calculations</li> </ul>                                                                                                                                                | 2               | 4             | a1, a2, a3, b1,b2,c1,c2, d1    |
| 2                       | TDM in Patients with Hepatic Disease                                            | <ul style="list-style-type: none"> <li>Hepatic drug metabolism</li> <li>Determination of Child-Pugh Scores</li> <li>Estimation of Drug Dosing and Pharmacokinetic Parameters for Liver Metabolized Drugs</li> <li>Implications of Hepatic Disease on Serum Drug Concentration Monitoring and Drug Effects</li> </ul> | 1               | 2             | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 3                       | TDM for Patients with Chronic Kidney Disease                                    | <ul style="list-style-type: none"> <li>Measurement and Estimation of Creatinine Clearance</li> <li>Estimation of Drug Dosing and Pharmacokinetic Parameters Using Creatinine Clearance</li> </ul>                                                                                                                    | 1               | 2             | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 4                       | TDM in Dialytic Patients                                                        | <ul style="list-style-type: none"> <li>Drug Characteristics that Effect Dialysis Removal</li> <li>HEMODIALYSIS</li> </ul>                                                                                                                                                                                            |                 |               | a1, a2, a3, b1,b2,c1,c2, d1,d2 |

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|    |                                                  |                                                                                                                                                                                                                                                                                                               |   |   |                                |
|----|--------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|---|--------------------------------|
|    |                                                  | <ul style="list-style-type: none"> <li>- Computation of Initial Doses and Modification of Doses Using Drug Serum Concentrations</li> <li>- Methods to Measure Hemodialysis Clearance</li> <li>- HEMOFILTRATION</li> <li>- PERITONEAL DIALYSIS and Methods to Measure Peritoneal Dialysis Clearance</li> </ul> | 1 | 2 |                                |
| 5  | Clinical Pharmacokinetics in Special Populations | <ul style="list-style-type: none"> <li>- Heart Failure</li> <li>- Obesity</li> <li>- Drug Interactions</li> </ul>                                                                                                                                                                                             | 2 | 4 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 6  | Midterm Exam                                     |                                                                                                                                                                                                                                                                                                               | 1 | 2 | a1, a2, a3, b1,b2,c1,c2        |
| 7  | TDM of Aminoglycosides                           | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Effects of Disease States and Conditions on Aminoglycoside Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul>                                                | 1 | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 8  | TDM of Vancomycin                                | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Effects of Disease States and Conditions on Vancomycin Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul>                                                    | 1 | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 9  | TDM of Digoxin                                   | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Effects of Disease States and Conditions on Digoxin Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul>                                                       | 1 | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 10 | TDM of Phenytoin                                 | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Impact of Altered Plasma Protein Binding on Phenytoin Pharmacokinetics</li> </ul>                                                                                          | 1 | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |

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|-----------------------------------------|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|---|--------------------------------|
|                                         |                      | <ul style="list-style-type: none"> <li>- Effects of Disease States and Conditions on Phenytoin Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul>                                                                                               |    |   |                                |
| 11                                      | TDM of Carbamazepine | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Effects of Disease States and Conditions on Carbamazepine Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul> | 1  | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 12                                      | TDM of Theophylline  | <ul style="list-style-type: none"> <li>- Therapeutic and Toxic Concentrations</li> <li>- Clinical Monitoring Parameters</li> <li>- Effects of Disease States and Conditions on theophylline Pharmacokinetics and Dosing</li> <li>- Dosing methods</li> </ul>  | 1  | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 13                                      | Cases Discussions    | <ul style="list-style-type: none"> <li>- Selected topics of course</li> </ul>                                                                                                                                                                                 | 1  | 2 | a1, a2, a3, b1,b2,c1,c2, d1,d2 |
| 14                                      | Final Exam           |                                                                                                                                                                                                                                                               | 1  | 2 | a1, a2, a3, b1,b2,c1,c2        |
| Number of Weeks /and Units Per Semester |                      |                                                                                                                                                                                                                                                               | 16 | 3 |                                |

#### B. Practical Aspect (Lab/Clinical) (if any):

| No. | Tasks/ Experiments                                                                              | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|-----|-------------------------------------------------------------------------------------------------|-----------------|---------------|---------------------------|
| 1   | Zero order and first order Pharmacokinetic                                                      | 1               | 2             | a1, a2, b1,b2,c1,c2       |
| 2   | Determination of elimination rate constant, half life                                           | 1               | 2             | b1,b2,c1,c2               |
| 3   | Determination of fraction of drug unbound, Calculation of absolute and relative bioavailability | 1               | 2             | b1,b2,c1,c2               |
| 4   | Calculation of creatinine clearance                                                             | 1               | 2             | b1,b2,c1,c2               |

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| No.                                              | Tasks/ Experiments                                                   | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|--------------------------------------------------|----------------------------------------------------------------------|-----------------|---------------|---------------------------|
| 5                                                | Calculation of renal and hepatic clearance                           | 1               | 2             | b1,b2,c1,c2               |
| 6                                                | Midterm Exam                                                         | 1               | 2             | b1,b2,c1,c2               |
| 7                                                | Calculation of different pharmacokinetic parameters for Digoxin      | 1               | 2             | c1,c2                     |
| 8                                                | Determination of pharmacokinetic parameters for Theophylline         | 1               | 2             | c1,c2                     |
| 9                                                | Non-linear Pharmacokinetic                                           | 1               | 2             | c1,c2                     |
| 10                                               | Calculation of different of pharmacokinetic parameters for Phenytoin | 1               | 2             | c1,c2                     |
| 11                                               | Determination of pharmacokinetic parameters for Aminoglycosides      | 1               | 2             | c1,c2                     |
| 12                                               | Final Exam                                                           | 1               | 2             | b1,b2,c1,c2               |
| Number of Weeks /and Units Per Semester 12 weeks |                                                                      | 12              | 24            |                           |

## VI. Teaching strategies of the course:

Lectures  
Assignment  
In-class case discussion  
Self-learning  
Office hour  
Seminar

## VII. Teaching strategies of the course:

Exam  
Assignment  
Quiz

|                  |                      |                         |                               |                  |
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#### IV. Assignments:

| No | Assignments  | Aligned CILOs(symbols)        | Week Due | Mark |
|----|--------------|-------------------------------|----------|------|
| 1  | Assignment 1 | a1, a2, a3, b1,b2,c1,c2,d1,d2 | 3th      | 5    |
| 2  | Assignment 2 | a1, a2, a3, b1,b2,c1,c2,d1,d2 | 12th     | 5    |
|    | Total        |                               |          | 10   |

#### V. 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    | 10   | 10 %                           | 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   | 10   | 10 %                           | a1, a2, a3, b1,b2,c1,c2          |
| 5   | Final Exam        | Week 16   | 50   | 50%                            | a1, a2, a3, b1,b2,c1,c2          |
|     | Total             |           | 100  | 100%                           |                                  |

#### VI. Learning Resources:

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

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

- Larry Bauer, 2014, **Applied clinical pharmacokinetics**, 3rd Edition
- Michael E. Burton, 2006, **Applied pharmacokinetics & pharmacodynamics: principles of therapeutic drug monitoring**, 4TH Edition:

##### 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
- Applied Biopharmaceutics & Pharmacokinetics**, 7th Edition, By Leon Shargel and Andrew YuSee – 2016 (ISBN-13: 9780071829649)
- Introduction to pharmacokinetics and pharmacodynamics: the quantitative basis of drug therapy**, By Thomas N. Tozer, Malcolm Rowland. Edition 1: 2006

##### 3- Electronic Materials and Web Sites etc.

- Relevant original and review articles from scientific journals

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

|   |                                                                                                                                                                                                                                                                                |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | <b>Class Attendance:</b><br>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.                                                                                      |
| 2 | <b>Tardiness:</b><br>A student will be considered late if he/she is not in class after 10 minutes of the start time of class.                                                                                                                                                  |
| 3 | <b>Exam Attendance/Punctuality:</b><br>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.                                                                                  |
| 4 | <b>Assignments &amp; Projects:</b><br>Assignments and projects must be submitted on time. Students who delay their assignments or projects shall lose the mark allocated for the same.                                                                                         |
| 5 | <b>Cheating:</b><br>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.                                        |
| 6 | <b>Forgery and Impersonation:</b><br>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. |
| 7 | <b>Other policies:</b><br>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.                                     |

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