# Course Specification of Biopharmaceutics

| I. Course Identification and General Information: | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | Course Title: | Biopharmaceutics | | | | | |
| 2 | Course Number & Code: | Ph2711 | | | | | |
| 3 | Credit hours: 3 hrs | C.H | | | | Total | |
| | | Theoretical | Practical | Training | Seminar | | |
| | | 2 | 2 | | | 3 | |
| 4 | Study level/ semester at which this course is offered: | Fourth year/ First semester | | | | | |
| 5 | Pre –requisite (if any): | Pharmaceutics I-IV | | | | | |
| 6 | Co –requisite (if any): | | | | | | |
| 7 | Program (s) in which the course is offered: | Bachelor of Pharmacy | | | | | |
| 8 | Language of teaching the course: | English | | | | | |
| 9 | The department in which the course is offered: | Pharmaceutics and Industrial Pharmacy | | | | | |
| 10 | Location of teaching the course: | Faculty of Pharmacy-Sana'a University | | | | | |
| 11 | Prepared by: | Prof Dr / Mahmoud Mahyoob Alburyhi | | | | | |
| 12 | Date of approval: | | | | | | |

## II. Course description:

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This course aims to provide the students with a comprehensive theoretical foundation of biopharmaceutics in new drug design**.** Examines the interrelationship of the physical / chemical properties of the drug, the dosage form (drug product) in which the drug is given, and the route of administration on the rate and extent of systemic drug absorption. To develop and select the dosage form that will provide a consistent bioavailability at desirable rate especially for narrow therapeutic index drugs.

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

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

1. Describe the ADME and the mechanisms of gastrointestinal absorption of drugs.
2. Discuss the factors affecting gastrointestinal absorption of drugs.
3. Identify the role of dosage form on drug bioavailability.
4. Identify the factors affecting drug absorption, distribution and elimination.
5. Identify bioavailability and bioequivalance.
6. Utilization the effect of absorption, distribution, metabolism, and excretion (ADME) of drugs in the body for dosage optimization and evaluating drug dosage regimen.
7. Demonstrate the biopharmaceutical considerations in drug product design.
8. Recognize the relationship between product design and the drug absorption, distribution and elimination.
9. Predict the effect of excipients and food on drug absorption, distribution and elimination.
10. Analyze the results of the in-vitro and in-vivo studies.
11. Assess physicochemical characteristics of drug substances as a factor affecting drug absorption.
12. Analyze bioavailability and bioequivalence studies.
13. Examine the biopharmaceutical consideration in dosage form design.
14. Communicating the dosage adjustment with physicians, suggesting therapeutic monitoring plans for physicians and use different information sources to solve medication problems.
15. Retrieve information from a variety of sources, including libraries, databases and internet.
16. Work effectively in a team and demonstrate time management skills.

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

## (A) Knowledge and Understanding:

| Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: **Knowledge and Understanding.** | | | |
|---|---|---|---|
| **Program Intended Learning Outcomes (Sub-PILOs) in: Knowledge and Understanding** | | **Course Intended Learning Outcomes (CILOs) in: Knowledge and Understanding** | |
| **After completing this program, students will be able to:** | | **After completing this course, students will be able to:** | |
| **A1-** | Recognize the principles of physical, chemical, clinical, social, behavioral, health and pharmaceutical sciences. | **a1-** | Describe the ADME and the mechanisms of gastrointestinal absorption of drugs. |
| **A3-** | Describe the general cellular, biochemical and physiological aspects of human body and recognize the pharmacokinetics, pharmacodynamics, disease pathophysiology, and pharmacogenetic of therapeutic agents to provide pharmaceutical care and facilitate management of patient's medication, rationalize drug use and overall health needs. | **a2-** | Discuss the factors affecting gastrointestinal absorption of drugs. |
| **A4** | Recognize the pharmaceutical dosage form design and the quality control of pharmaceutical formulations according to GMP and pharmacopeial requirements to support the pharmaceutical industries and research | **a3-** | Identify the role of dosage form on drug bioavailability. |
| **A5** | Demonstrate the basic knowledge of pharmacoecnomics, pharmacovigilence, policy, legislation, marketing, administration and distribution of pharmaceutical and cosmetic products as well as ethics of health care | **a4-** | Identify the factors affecting drug absorption, distribution and elimination. |
| | | **a5-** | Identify bioavailability and bioequivalance. |
| | | | |
| | | | |
| **Teaching And Assessment Methods For Achieving Learning Outcomes:** | | | |
| **Alignment of Learning Outcomes of Knowledge and Understanding to Teaching and Assessment Methods:** | | | |

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| Course Intended Learning Outcomes (CILOs) in Knowledge and Understanding | | Teaching strategies/methods to be used | Methods of assessment |
|---|---|---|---|
| **completing this course, students will be able to:** | | Lectures, and group discussion | Attendance, Written, oral exams and small projects |
| **a1-** | Describe the ADME and the mechanisms of gastrointestinal absorption of drugs. | | |
| **a2-** | Discuss the factors affecting gastrointestinal absorption of drugs. | | |
| **a3-** | Identify the role of dosage form on drug bioavailability. | | |
| **a4-** | Identify the factors affecting drug absorption, distribution and elimination. | | |
| **a5-** | Identify bioavailability and bioequivalance. | | |

## (B) Intellectual Skills:

**Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: Intellectual skills**

| Program Intended Learning Outcomes (Sub-PILOs) in Intellectual skills | | Course Intended Learning Outcomes (CILOs) of Intellectual Skills | |
|---|---|---|---|
| **After completing this program, students will be able to:** | | **After completing this course, students will be able to:** | |
| **B1** | Consolidate the chemical, biochemical and physiological principles to construct the pharmacophores of the structure and their effect on the stability, pharmacokinetic and pharmacodynamic profiles of the drug. | **b1-** | Utilization the effect of absorption, distribution, Metabolism, and excretion (ADME) of drugs in the body for dosage optimization and evaluating drug dosage regimen. |
| **B3** | Design different types of safe and effective pharmaceutical dosage forms and develop novel methods of qualitative and quantitative analytical and biological analysis for pharmaceutical and biopharmaceutical products that support pharmaceutical research. | **b2-** | Demonstrate the biopharmaceutical considerations in drug product design. |

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|---|---|---|---|
| **B5** | Interpret the prescriptions, patient and clinical data, Analysis all the encountered pharmaceutical problems and plan the strategies for their solution, to develop the health care. | **b3-** | Developing dosing regimens for the individualization of therapy for the patient. |

## Teaching And Assessment Methods For Achieving Learning Outcomes:

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

| Course Intended Learning Outcomes (CILOs) in Intellectual Skills. | | Teaching strategies/methods to be used | Methods of assessment |
|---|---|---|---|
| **After completing this course, students will be able to:** | | Lectures, solving problem brainstorming and group discussion | Project, homework, Written, oral exams and small projects |
| **b1-** | Utilization the effect of absorption, distribution, Metabolism, and excretion (ADME) of drugs in the body for dosage optimization and evaluating drug dosage regimen. | | |
| **b2-** | Demonstrate the biopharmaceutical considerations in drug product design. | | |
| **b3-** | Recognize the relationship between product design and the drug absorption, distribution and elimination. | | |
| **b4-** | Predict the effect of excipients and food on drug absorption, distribution and elimination. | | |

## (C) Professional and Practical Skills:

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

| Program Intended Learning Outcomes (Sub-PILOs) in Professional and Practical Skills | Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills |
|---|---|
| **After completing this program, students will be able to:** | **After completing this course, students will be able to:** |

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|---|---|---|---|
| **C1** | Operate different pharmaceutical equipments and instruments and use emerging technologies in design, synthesis, pre-formulation, formulation, packaging, storage and analysis of pharmaceutical products according to GLP, GSP and cGMP guidelines. | **c1-** | Analyze the results of the in-vitro and invivo studies. |
| **C3** | Extract, isolate, purify, identify and formulate the natural products and assure their rational use. | **c2-** | Assess physicochemical characteristics of drug substances as a factor affecting drug absorption. |
| | | **c3-** | Analyze bioavailability and bioequivalence studies. |
| **C4** | Provide patient-oriented pharmaceutical care by collaboration with other health care professionals to optimize therapeutic outcomes. | **c4-** | Examine the biopharmaceutical consideration in dosage form design. |
| **C5** | Conduct research studies and utilize the results in different pharmaceutical fields. | | |

## Teaching And Assessment Methods For Achieving Learning Outcomes:

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

| Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills | | Teaching strategies/methods to be used | Methods of assessment |
|---|---|---|---|
| **After completing this course, students will be able to:** | | Lectures , practical, discussion and brain storm | Written, practical, oral exams, report, project and observation. |
| **c1-** | Analyze the results of the in-vitro and in-vivo studies. | | |
| **c2-** | Assess physicochemical characteristics of drug substances as a factor affecting drug absorption. | | |
| **c3-** | Analyze bioavailability and bioequivalence studies. | | |
| **c4-** | Examine the biopharmaceutical consideration in dosage form design. | | |

## (D) General / Transferable Skills:

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

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

## Teaching And Assessment Methods For Achieving Learning Outcomes:

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

| Course Intended Learning Outcomes (CILOs) in General and Transferable Skills | | Teaching strategies/methods to be used | Methods of assessment |
|---|---|---|---|
| **After completing this course, students will be able to:** | | Lectures , practical, discussion and brain storm | Written, practical, oral exams, report, project and observation. |
| **d1-** | Communicating the dosage adjustment with physicians, suggesting therapeutic monitoring | | |
| | plans for physicians and use different information sources to solve medication problems. | | |
| **d2-** | Retrieve information from a variety of sources, including libraries, databases and internet. | | |
| **d3** | Work effectively in a team and demonstrate time management skills. | | |

## V. Course Content:

### 1 – Course Topics/Items:

| a – Theoretical Aspect | | | | | |
|---|---|---|---|---|---|
| **Order** | **Topic List / Units** | **CILOs (symbols)** | **Sub-topic List** | **Number of weeks** | **Contact hours** |
| 1 | Introduction to biopharmaceutics , pharmacokinetic, pharmacodynamic and clinical pharmacokinetics | **a1,a2,a3, b1,b2,b3,b4, d1** | Definitions, Define pharmacokinetics and describe how pharmacokinetics is related to pharmacodynamics and drug toxicity, parameters and Mechanisms | **1** | **2** |
| 2 | Drug absorption, Mechanisms of drug absorption | **a1,a2, b1,b2,b3, b4,d1,d2,d3** | Definition, Mechanisms of drug absorption process, factors affecting absorption | **1** | **2** |
| 3 | Physiologic factors related to drug absorption | **a3,a4, b2,b3,b4, d1,d2,d3** | Types of factors pH, gastric and GIT factors | **1** | **2** |
| 4 | Physiochemical factors related to drug absorption | **a4, b2,b3,b4, d1,d2,d3** | Nature of drug, drug solubility, dissolution and drug stability | **1** | **2** |
| 5 | Biopharmaceutical aspects of the active pharmaceutical ingredient and pharmaceutical equivalence | **a4, b2, d1,d2,d3** | Formulation factors, method of manufacture, excipients, drug dosage and dosage regimen | **1** | **2** |

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|---|---|---|---|---|---|
| 6 | Drug distribution<br>Physiologic drug distribution and protein binding | **a4, b1,b2,b3,b4, d1,d2,d3** | Definition, parameters, volume of distribution, Mechanisms , factors and Clinical Application | **1** | **2** |
| 7 | Mid-term exam | **a1-4, b1-4** | | **1** | **2** |
| 8 | Drug metabolism | **a3,a4,a5, b1,b2,b3,b4 d1,d2,d3** | Definition and parameters, | **1** | **2** |
| 9 | Pharmacogenetics and drug metabolism | **a5, b3,b4, d1,d2,d3** | Mechanisms, classification and factors | **1** | **2** |
| 10 | Drug excretion | **a5, b1,b2,b3,b4, d1,d2,d3** | Definition and parameters, | **1** | **2** |
| 11 | Drug elimination, clearance, and renal clearance | **a4, b3,b4, d1,d2,d3** | Mechanisms, classification and factors | **1** | **2** |
| 12 | Drug elimination and hepatic clearance | **a4, b3,b4, d1,d2,d3** | Mechanisms, types and factors | **1** | **2** |
| 13 | Bioavailability | **a2,a3,,a5, b1,b2,b3, b4,d1,d2,d3** | Definition, classification, Relative bioavailability, Absolute bioavailability parameters and evaluations | **1** | **2** |
| 14 | Bioavailability and bioequivalence | **a2,a3, b1,b2,b3,b4, d1,d2,d3** | Model parameters , drug absorption and bioavailability of dosage forms. | **1** | **2** |
| 15 | Biopharmaceutic considerations in drug product design and in vitro drug product performance | **a3, b1,b2,b3, d1,d2,d3** | Pharmaceutical alternative, Pharmaceutical equivalent | **1** | **2** |

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|---|---|---|---|---|---|
| 1. | final-term exam | **a1-5, b1-4** | | **1** | **2** |
| **Number of Weeks /and Units Per Semester** | | | | **16** | **32** |

## b- Practical Aspect:

| Order | Practical Tasks | CILOs (symbols) | Number of weeks | Contact hours |
|---|---|---|---|---|
| 1 | Biopharmaceutic considerations in drug product design | **c1, d1,d2,d3** | **1** | **2** |
| 2 | Practice how stomach emptying, GI residence time, and gastric window affect drug absorption | **c1,c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 3 | Determine the drugs for which gastric pH can affect bioavailability | **c1,c2,c3, d1,d2,d3** | **1** | **2** |
| 4 | Determine the particle size, crystal form, solubility, dissolution, and ionization affect in vivo dissolution and absorption. | **c1,c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 5 | Dissolution test methods and relation to in vivo performance. | **c1,c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 6 | Determine the simulating drug distribution in the body | **c1,c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 7 | Mid-term exam | **c1-4** | **1** | **2** |
| 8 | Determine the formulation factors and manufacturing method affecting PE and TE. | **c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 9 | Practice use plasma or urine data to calculate fraction of drug excreted and metabolized. | **c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 10 | Practice use plasma or urine data to calculate fraction of drug excreted and metabolized. | **c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 11 | Practice application of the physiologically factors include understanding the effect of renal impairment | **c1,c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 12 | Practice drug elimination and hepatic clearance Application of the physiologically factors include understanding the effect of hepatic | **c4, d2 d1,d2,d3** | **1** | **2** |
| | clearance | | | |

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| 13 | Determine the methods of drug excretion from the body | **c4, d1,d2,d3** | **1** | **2** |
| 14 | Determine the select API from multiple sources while meeting PE (pharmaceutical equivalence) and TE (therapeutic equivalence) requirement as defined in CFR. How pharmaceutical equivalence affects therapeutic equivalence and Pharmaceutical alternatives. | **c1-4, d1,d2,d3** | **1** | **2** |
| 15 | Bioavailability and bioequivalence test methods, and analysis. | **c2-4, d1,d2,d3** | **1** | **2** |
| 1. | Final-term exam | **c1-4** | **1** | **2** |
| **Number of Weeks /and Units Per Semester** | | | **16** | **32** |

**VI- a-Teaching strategies of the course:**

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

**b- Assessment Methods:**

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

## VII. Assignments:

| No. | Assignments | Aligned CILOs (symbols) | Week Due | Mark |
|---|---|---|---|---|
| 1 | Homework Assignments | **a1-5, b1-4, d1-3** | Sporadic through the semester | **10** |
| 2 | Reports | **c1-4, d1-3** | | |

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

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| No. | Assessment Method | Week Due | Mark | Proportion of Final Assessment | Aligned Course Learning Outcomes (CILOs symbols) |
|---|---|---|---|---|---|
| 1. | **Attendance, Participation and quizzes** | **All Weeks** | 10 | 7% | **a1-5,b1-4, d1-3** |
| 2. | **Oral Tests and Homeworkassignments** | Sporadic through the semester | 10 | 7% | **a1-5, b1-4, d1-3** |
| 3. | **Attendance, Practical Reports** | **All Weeks** | 15 | 10% | **c1-4** |
| 4. | **Practical mid-semester exam** | 7th | 15 | 10% | **c1-4** |
| 5. | **Theoretical mid-semester exam** | 7th | 30 | 20% | **a1-4, b1-4** |
| 6. | **Final Exam (theoretical)** | **16th** | 50 | 33% | **a1-5, b1-4** |
| **7.** | **Final Exam (practical)** | **16th** | 20 | 13% | **c1-4** |
| | **Total** | | **150** | **100%** | |

## IX. Students' Support:

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

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

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

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

## XI. Facilities Required:

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

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

## XII. Course Improvement Processes:

### 1- Strategies for obtaining student feedback on effectiveness of teaching

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

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

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

### 3- Processes for improvement of teaching.

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

### 4- Processes for verifying standards of students' achievement

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

### 5- Procedures for periodically reviewing of course effectiveness and planning for improvement

- Student rating and feedback
- Peer rating and feedback
- Regular meeting of the Curriculum Committee of the faculty.

### 6- Course development plans

- Conducting regular workshops for the staff for improving their course specification skills.
- Regular revision of course specification and syllabus items.

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| 6- Course Policies: | |
|---|---|
| 1 | **Class Attendance:**<br>▪ Attendance of all lectures and practical sessions is required. Unexcused absence exceeding 25% of the lectures or practical sessions will disqualify the student from entering the final exam. |
| 2 | **Tardiness:**<br>▪ Non-reasonable frequent tardiness will be allowed and is considered as absence from the lectures/ |
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| 4 | **Assignments & Projects:**<br>▪ Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator. ▪ Projects: Not applicable. |
| 5 | **Cheating:**<br>▪ Punishment of cheating will be according to the general policy of the university in this respect. |
| 6 | **Plagiarism:**<br>▪ Plagiarism in written essays, reports, etc. is not accepted, and students who plagiarize the works of others will be punished according to the general policy of the university. |
| 7 | **Other policies:**<br>▪ General policies of the Students' Affairs of the University and the Quality Assurance Unit. |

## I. - Information about Faculty Member Responsible for the Course:

| Name of Faculty Member | Prof Dr/ Mahmoud Mahyoob Alburyhi | Office Hours | | | | | |
|---|---|---|---|---|---|---|---|
| Location & Telephone No. | 777970600 | SAT | SUN | MON | TUE | WED | THU |
| E-mail | buryhi@yahoo.com | | | 2hrs | 2hrs | | |

## II. Course Identification and General Information:

| | | | | | | |
|---|---|---|---|---|---|---|
| 1- | Course Title: | Biopharmaceutics | | | | |
| 2- | Course Number & Code: | Ph2711 | | | | |
| 3- | Credit hours: 3hrs | C.H | | | | Total |
| | | Th. | Seminar | Pr. | F. Tr. | |
| | | 2 | - | 2 | | 3 |
| 4- | Study level/year at which this course is offered: | Fourth year/First semester | | | | |
| 5- | Pre –requisite (if any): | Pharmaceutics I-IV | | | | |
| 6- | Co –requisite (if any): | | | | | |
| 7- | Program (s) in which the course is offered | Bachelor of Pharmacy | | | | |
| 8- | Language of teaching the course: | English | | | | |
| 9- | System of Study: | Semesters | | | | |
| 10- | Mode of delivery: | Regular | | | | |
| 11- | Location of teaching the course: | Faculty of Pharmacy-Sana'a University | | | | |

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## III. Course description:

This course aims to provide the students with a comprehensive theoretical foundation of biopharmaceutics in new drug design**.** Examines the interrelationship of the physical / chemical properties of the drug, the dosage form (drug product) in which the drug is given, and the route of administration on the rate and extent of systemic drug absorption. To develop and select the dosage form that will provide a consistent bioavailability at desirable rate especially for narrow therapeutic index drugs.

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

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

1. Describe the ADME and the mechanisms of gastrointestinal absorption of drugs.
2. Discuss the factors affecting gastrointestinal absorption of drugs.
3. Identify the role of dosage form on drug bioavailability.
4. Identify the factors affecting drug absorption, distribution and elimination.
5. Identify bioavailability and bioequivalance.
6. Utilization the effect of absorption, distribution, metabolism, and excretion (ADME) of drugs in the body for dosage optimization and evaluating drug dosage regimen.
7. Demonstrate the biopharmaceutical considerations in drug product design.
8. Recognize the relationship between product design and the drug absorption, distribution and elimination.
9. Predict the effect of excipients and food on drug absorption, distribution and elimination.
10. Analyze the results of the in-vitro and in-vivo studies.
11. Assess physicochemical characteristics of drug substances as a factor affecting drug absorption.
12. Analyze bioavailability and bioequivalence studies.
13. Examine the biopharmaceutical consideration in dosage form design.
14. Communicating the dosage adjustment with physicians, suggesting therapeutic monitoring plans for physicians and use different information sources to solve medication problems.
15. Retrieve information from a variety of sources, including libraries, databases and internet.
16. Work effectively in a team and demonstrate time management skills.

## V. Course Content:

### 1 – Course Topics/Items:

**a – Theoretical Aspect**

| Order | Topic List / Units | CILOs (symbols) | Sub-topic List | Number of weeks | Contact hours |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| 1 | Introduction to biopharmaceutics , pharmacokinetic, pharmacodynamic and clinical pharmacokinetics | **a1,a2,a3, b1,b2,b3,b4, d1** | Definitions, Define pharmacokinetics and describe how pharmacokinetics is related to pharmacodynamics and drug toxicity, parameters and Mechanisms | **1** | **2** |
| 2 | Drug absorption, Mechanisms of drug absorption | **a1,a2, b1,b2,b3, b4,d1,d2,d3** | Definition, Mechanisms of drug absorption process, factors affecting absorption | **1** | **2** |
| 3 | Physiologic factors related to drug absorption | **a3,a4, b2,b3,b4, d1,d2,d3** | Types of factors pH, gastric and GIT factors | **1** | **2** |
| 4 | Physiochemical factors related to drug absorption | **a4, b2,b3,b4, d1,d2,d3** | Nature of drug, drug solubility, dissolution and drug stability | **1** | **2** |
| 5 | Biopharmaceutical aspects of the active pharmaceutical ingredient and pharmaceutical equivalence | **a4, b2, d1,d2,d3** | Formulation factors, method of manufacture, excipients, drug dosage and dosage regimen | **1** | **2** |
| 6 | Drug distribution Physiologic drug distribution and protein binding | **a4, b1,b2,b3,b4, d1,d2,d3** | Definition, parameters, volume of distribution, | **1** | **2** |
| | | | Mechanisms , factors and Clinical Application | | |
| 7 | Mid-term exam | **a1-4, b1-4** | | **1** | **2** |

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| | | | | | |
|---|---|---|---|---|---|
| 8 | Drug metabolism | **a3,a4,a5, b1,b2,b3,b4 d1,d2,d3** | Definition and parameters, | **1** | **2** |
| 9 | Pharmacogenetics and drug metabolism | **a5, b3,b4, d1,d2,d3** | Mechanisms, classification and factors | **1** | **2** |
| 10 | Drug excretion | **a5, b1,b2,b3,b4, d1,d2,d3** | Definition and parameters, | **1** | **2** |
| 11 | Drug elimination, clearance, and renal clearance | **a4, b3,b4, d1,d2,d3** | Mechanisms, classification and factors | **1** | **2** |
| 12 | Drug elimination and hepatic clearance | **a4, b3,b4, d1,d2,d3** | Mechanisms, types and factors | **1** | **2** |
| 13 | Bioavailability | **a2,a3,,a5, b1,b2,b3, b4,d1,d2,d3** | Definition, classification, Relative bioavailability, Absolute bioavailability parameters and evaluations | **1** | **2** |
| 14 | Bioavailability and bioequivalence | **a2,a3, b1,b2,b3,b4, d1,d2,d3** | Model parameters , drug absorption and bioavailability of dosage forms. | **1** | **2** |
| 15 | Biopharmaceutic considerations in drug product design and in vitro drug product performance | **a3, b1,b2,b3, d1,d2,d3** | Pharmaceutical alternative, Pharmaceutical equivalent | **1** | **2** |
| 2. | final-term exam | **a1-5, b1-4** | | **1** | **2** |
| **Number of Weeks /and Units Per Semester** | | | | **16** | **32** |

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## b- Practical Aspect:

| Order | Practical Tasks | CILOs (symbols) | Number of weeks | Contact hours |
|---|---|---|---|---|
| 1 | Biopharmaceutic considerations in drug product design | **c1, d1,d2,d3** | **1** | **2** |
| 2 | Practice how stomach emptying, GI residence time, and gastric window affect drug absorption | **c1,c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 3 | Determine the drugs for which gastric pH can affect bioavailability | **c1,c2,c3, d1,d2,d3** | **1** | **2** |
| 4 | Determine the particle size, crystal form, solubility, dissolution, and ionization affect in vivo dissolution and absorption. | **c1,c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 5 | Dissolution test methods and relation to in vivo performance. | **c1,c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 6 | Determine the simulating drug distribution in the body | **c1,c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 7 | Mid-term exam | **c1-4** | **1** | **2** |
| 8 | Determine the formulation factors and manufacturing method affecting PE and TE. | **c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 9 | Practice use plasma or urine data to calculate fraction of drug excreted and metabolized. | **c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 10 | Practice use plasma or urine data to calculate fraction of drug excreted and metabolized. | **c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 11 | Practice application of the physiologically factors include understanding the effect of renal impairment | **c1,c2,c3,c4, d1,d2,d3** | **1** | **2** |
| 12 | Practice drug elimination and hepatic clearance Application of the physiologically factors include understanding the effect of hepatic clearance | **c4, d2 d1,d2,d3** | **1** | **2** |
| 13 | Determine the methods of drug excretion from the body | **c4, d1,d2,d3** | **1** | **2** |
| | | | **1** | **2** |

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| | | | | |
|---|---|---|---|---|
| 14 | Determine the select API from multiple sources while meeting PE (pharmaceutical equivalence) and TE (therapeutic equivalence) requirement as defined in CFR. How pharmaceutical | **c1-4, d1,d2,d3** | | |
| | equivalence affects therapeutic equivalence and Pharmaceutical alternatives. | | | |
| 15 | Bioavailability and bioequivalence test methods, and analysis. | **c2-4, d1,d2,d3** | **1** | **2** |
| 2. | Final-term exam | **c1-4** | **1** | **2** |
| **Number of Weeks /and Units Per Semester** | | | **16** | **32** |

**VI- a-Teaching strategies of the course:**

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

**b- Assessment Methods:**

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

## VII. Assignments:

| No. | Assignments | Aligned CILOs (symbols) | Week Due | Mark |
|---|---|---|---|---|
| 1 | Homework Assignments | **a1-5, b1-4, d1-3** | Sporadic through the semester | **10** |
| 2 | Reports | **c1-4, d1-3** | | |

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

| No. | Assessment Method | Week Due | Mark | Proportion of Final Assessment | Aligned Course Learning Outcomes (CILOs symbols) |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| 8. | **Attendance, Participation and quizzes** | **All Weeks** | 10 | 7% | **a1-5,b1-4, d1-3** |
| 9. | **Oral Tests and Homeworkassignments** | Sporadic through the semester | 10 | 7% | **a1-5, b1-4, d1-3** |
| 10. | **Attendance, Practical Reports** | **All Weeks** | 15 | 10% | **c1-4** |
| 11. | **Practical mid-semester exam** | 7th | 15 | 10% | **c1-4** |
| 12. | **Theoretical mid-semester exam** | 7th | 30 | 20% | **a1-4, b1-4** |
| 13. | **Final Exam (theoretical)** | **16th** | 50 | 33% | **a1-5, b1-4** |
| **14.** | **Final Exam (practical)** | **16th** | 20 | 13% | **c1-4** |
| | **Total** | | **150** | **100%** | |

## IX. Students' Support:

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

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

**5- Required Textbook(s) ( maximum two )**

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

## XI. Facilities Required:

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

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

## XII. Course Improvement Processes:

**7- Strategies for obtaining student feedback on effectiveness of teaching**

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

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

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

**9- Processes for improvement of teaching.**

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

**10- Processes for verifying standards of students' achievement**

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

**11- Procedures for periodically reviewing of course effectiveness and planning for improvement**

- Student rating and feedback
- Peer rating and feedback
- Regular meeting of the Curriculum Committee of the faculty.

**6- Course development plans**

- Conducting regular workshops for the staff for improving their course specification skills.
- Regular revision of course specification and syllabus items.

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