|  |  |
| --- | --- |
| **Course Title:** | **Pharmaceutics-III** |
| **Course Code:** | **PHCU534** |
| **Program:** | **Pharmaceutical Sciences** |
| **Department:** | **Pharmaceutics** |
| **College:** | **Pharmacy** |
| **Institution:** | **Najran University** |

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# A. Course Identification

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Credit hours:** 3 hours (2+1) | | | | | | | |  | | | | | | | | |
| **2. Course type** | | | | | | | | | | | | | | | | |
| **a.** | University | |  | College | | | **√** | | Department | | | |  | Others |  |  |
| **b.** | | Required | | | **√** | Elective | | | |  |  | | | | | |
| **3. Level/year at which this course is offered:** | | | | | | | | | | | | Level 9 / 5th year | | | | |
| **4. Pre-requisites for this course** (if any)**:** Pharmaceutics-II (PHCU433) | | | | | | | | | | | | | | | | |
| **5. Co-requisites for this course** (if any)**:** None | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |

## 6. Mode of Instruction (mark all that apply)

| **No** | **Mode of Instruction** | **Contact Hours** | **Percentage** |
| --- | --- | --- | --- |
| **1** | **Traditional classroom** | 60 | 100 |
| **2** | **Blended** |  |  |
| **3** | **E-learning** |  |  |
| **4** | **Correspondence** |  |  |
| **5** | **Other** |  |  |

**7. Actual Learning Hours** (based on academic semester)

|  |  |  |
| --- | --- | --- |
| **No** | **Activity** | **Learning Hours** |
| **Contact Hours** | | |
| **1** | **Lecture** | 30 |
| **2** | **Laboratory/Studio** | 30 |
| **3** | **Tutorial** | 0 |
| **4** | **Others** (specify) | 0 |
|  | **Total** | 60 |
| **Other Learning Hours\*** | | |
| **1** | **Study** | 40 |
| **2** | **Assignments** | 10 |
| **3** | **Library** | 0 |
| **4** | **Projects/Research Essays/Theses** | 0 |
| **5** | **Others** (specify) | 0 |
|  | **Total** | 50 |

**\*** The length of time that a learner takes to complete learning activities that lead to achievement of course learning outcomes, such as study time, homework assignments, projects, preparing presentations, library times

# B. Course Objectives and Learning Outcomes

|  |
| --- |
| 1. Course Description The course is designed to familiarize the students with drug absorption, factor influencing bioavailability and drug disposition. Pharmacokinetics including absorption, distribution, metabolism, elimination and protein binding of drug. Calculation of pharmacokinetics parameters. Assessment of bioavailability. Pharmacokinetics in drug discovery and development: bioequivalence testing, drug product selection and biopharmaceutic classification system. |
|  |
| 2. Course Main Objective |
| 1. To study the biopharmaceutical principles of drug delivery 2. To understand the impact of formulation/dosage forms design on the pharmacokinetic of drug |

## 3. Course Learning Outcomes

| **CLOs** | | **Aligned****PLOs** |
| --- | --- | --- |
| 1 | **Knowledge:** |  |
| 1.1 | Concept of biopharmaceutics and novel drug delivery system | K3 |
| 1.2 | Principles of pharmaceutical dosage forms influencing biopharmaceutical performance of drug | K3 |
|  |  |  |
| **2** | **Skills :** |  |
| 2.1 | Evaluate the influence of various factors on biopharmaceutical performance of drug | S1 |
| 2.2 | Strategies to improve the biopharmaceutic of poorly soluble drug | S2 |
| 2.3 | Interpret the pharmacokinetic calculation | S3 |
| **3** | **Competence:** |  |
| 3.1 | Work independently and professionally | C1 |
| 3.2 | Use properly pharmaceutical excipients in formulation design according to the rules of good manufacturing practice | C2 |

# C. Course Content

|  |  |  |
| --- | --- | --- |
| **No** | **List of Topics [Theory]** | **Contact Hours** |
| 1 | Introduction to Biopharmaceutics | 1 |
| 2 | Absorption of drug "main factors affecting oral absorption" | 1 |
| 3 | Physiologic Factors Related to Drug Absorption | 2 |
| 4 | Anatomic and Physiologic Considerations of GIT for oral absorption of drug, gastric emptying rate and GIT motility affecting oral drug absorption, effect of food on oral drug absorption | 4 |
| 5 | Pharmaceutical factors affecting drug absorption | 2 |
| 6 | Physicochemical factors affecting drug absorption | 2 |
| 7 | Drug distribution and factors affecting the process | 4 |
| 8 | Pharmacokinetic modeling: Non-compartmental and compartmental method | 2 |
| 9 | Protein-binding of drug and factors affecting the process | 2 |
| 10 | Metabolism of drug and factors affecting the process | 2 |
| 11 | Excretion of drug and factors affecting the process | 2 |
| 12 | Concept of Bioavailability and Bioequivalence | 2 |
| 13 | Introduction to modified-drug release system, drug product selection and Biopharmaceutics classification system (BCS) | 4 |
| **Total** | | 30 |

|  |  |  |
| --- | --- | --- |
| **No** | **List of Topics [Practical]** | **Contact Hours** |
| 1 | Introduction | 2 |
| 2 | Common routes of drug administration | 2 |
| 3 | Factors affecting absorption of drug | 2 |
| 4 | Diagrammatic representation of plasma drug concentration of different routes of administration | 2 |
| 5 | Diagram Resulted after plotting the plasma drug concentration versus time and estimating the route of administration. | 4 |
| 6 | Diagrammatic discussion of Minimum effective concentration, Minimum safe concentration, Therapeutic index, Duration of action, Dose regimen, Cmax, onset of action, onset time, lag time. | 2 |
| 7 | Area Under curve, Slope, Kel | 2 |
| 8 | Determination of area under curve (AUC) by trapezoidal method | 2 |
| 9 | Bioavailability and related numerical problem | 2 |
| 10 | Determination of Bioavailability by AUC method | 4 |
| 11 | Determination of Bioavailability by area method | 2 |
| 12 | Determination of Bioavailability by cut and weight method. | 2 |
| 13 | Revision | 2 |
| **Total** | | 30 |

# D. Teaching and Assessment

## 1. Alignment of Course Learning Outcomes with Teaching Strategies and Assessment Methods

| **Code** | **Course Learning Outcomes** | **Teaching Strategies** | **Assessment Methods** | |
| --- | --- | --- | --- | --- |
| **1.0** | **Knowledge** | | |
| 1.1 | Concept of biopharmaceutics and novel drug delivery system | Lectures | Theoretical exams;  Assignments |
| 1.2 | Principles of pharmaceutical dosage forms influencing biopharmaceutical performance of drug | Lectures | Theoretical exams  Assignments |
|  |  |  |  |
| **2.0** | **Skills** | | |
| 2.1 | Evaluate the influence of various factors on biopharmaceutical performance of drug | Lectures,  Problem solving | Theoretical exams |
| 2.2 | Strategies to improve the biopharmaceutic of poorly soluble drug | Lectures,  Practical work | Work place-based assessment;  Practical exam |
| 2.3 | Interpret the pharmacokinetic calculation | Practical work | Practical exam |
| **3.0** | **Competence** | | |
| 3.1 | Work independently and professionally | Practical work | Work place-based assessment;  Practical exam |
| 3.2 | Use properly pharmaceutical excipients in formulation design according to the rules of good manufacturing practice | Practical work | Practical exam |

## 2. Assessment Tasks for Students

| **#** | **Assessment task\*** | **Week Due** | **Percentage of Total Assessment Score** |
| --- | --- | --- | --- |
| **1** | Midterm exam 1 | 6 | 15% |
| **2** | Midterm exam 2 | 10 | 15% |
| **3** | Assignments | 12 | 05% |
| **4** | Lab. Practical Quiz | 9 | 05% |
| **5** | Observation card in lab | 2-12 | 05% |
| **6** | Final Practical exam | 15 | 15% |
| **7** | Final Theory exam | 17 | 40% |
| **8** | Total |  | 100% |

**\*Assessment task** (i.e., written test, oral test, oral presentation, group project, essay, etc.)

# E. Student Academic Counseling and Support

|  |
| --- |
| **Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice :** |
| 1. Office hour (2 hours per week): Each faculty member must set fixed two hours each week to fulfill the students’ academic requirements. 2. Office hours must be announced in the office door and course blackboard. |

# F. Learning Resources and Facilities

## 1. Learning Resources

|  |  |
| --- | --- |
| **Required Textbooks** | 1. Applied Biopharmaceutics & Pharmacokinetics, Seventh edition, edited by Leon Shargel, and Andrew B.C. Yu. 2. Pharmaceutics - The Science of Dosage Form Design, Second edition, edited by M.E. Aulton. |
| **Essential References Materials** | 1. Remington: The Science and Practice of Pharmacy, 22nd Edition, edited byLoyd V. Allen Jr. 2. Power point slides/word file |
| **Electronic Materials** | https://sdl.edu.sa/SDLPortal/en/Publishers.aspx  http://dlaf.nu.edu.sa/en/e-libraries |
| **Other Learning Materials** | Excel software for calculations |

## 2. Facilities Required

| **Item** | **Resources** |
| --- | --- |
| **Accommodation**  (Classrooms, laboratories, demonstration rooms/labs, etc.) | 1. Suitable lecture room equipped with data show and internet and sufficient number of seats.  2. Suitable laboratories equipped with health and safety tools, internet and sufficient number of seats. |
| **Technology Resources**  (AV, data show, Smart Board, software, etc.) | Computers, data show, sound systems and internet |
| **Other Resources**  (Specify, e.g. if specific laboratory equipment is required, list requirements or attach a list) | 1. Dissolution apparatus  2. UV-Spectrophotometer  3. Vortex mixer  4. Hot plate with magnetic stirrer  5. Water bath  6. Tablet Friablator  7. Tablet disintegrating apparatus |

# G. Course Quality Evaluation

| **Evaluation**  **Areas/Issues** | **Evaluators** | **Evaluation Methods** |
| --- | --- | --- |
| Effectiveness of teaching strategies | Head of departments and Students | Indirect  Questionnaires (indirect) |
| Achievement of course learning outcomes (CLOs) | Student  peer reviewer | Direct  Indirect |
| Quality of learning resources | Students | Questionnaires (indirect) |

**Evaluation areas** (e.g., Effectiveness of teaching and assessment, Extent of achievement of course learning outcomes, Quality of learning resources, etc.)

**Evaluators** (Students, Faculty, Program Leaders, Peer Reviewer, Others (specify)

**Assessment Methods** (Direct, Indirect)

# H. Specification Approval Data

|  |  |
| --- | --- |
| **Council / Committee** | Pharmaceutics Department Council |
| **Reference No.** | Department meeting No.1 |
| **Date** | 10/09/2019 |