|  |  |
| --- | --- |
| **Course Title:** | **Sterile Dosage Forms** |
| **Course Code:** | **PHCU536** |
| **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 10 / 5th year | | | | |
| **4. Pre-requisites for this course** (if any)**:** Industrial Pharmacy (PHCU535) | | | | | | | | | | | | | | | | |
| **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 student with physiochemical characteristics as well as formulation design of parenteral and ophthalmic dosage form. The topic cover in this subject includes: introduction to sterile product; *Parenteral dosage forms* – preparation, advantages and disadvantages, route of administration for parenteral, official types of injections, formulation components, production facility and evaluation of parenteral preparations; *Ophthalmic dosage forms* - definition, physiology and anatomy of eye, type of ophthalmic preparations, formulation components and packaging of ophthalmic preparations. |
|  |
| 2. Course Main Objective |
| 1. To study the physiochemical characteristics of sterile dosage forms - parenteral and ophthalmic drug delivery.  2. To study the formulation design perspectives of sterile dosage forms - parenteral and ophthalmic drug delivery. |

## 3. Course Learning Outcomes

| **CLOs** | | **Aligned****PLOs** |
| --- | --- | --- |
| 1 | **Knowledge:** |  |
| 1.1 | Concept of sterile dosage forms with detail of parenteral and ophthalmic products | K3 |
| 1.2 | Principles of formulations/dosage forms design for parenteral and ophthalmic drug delivery | K3 |
|  |  |  |
| **2** | **Skills :** |  |
| 2.1 | Evaluate the quality of sterile dosage forms for parenteral and ophthalmic drug delivery | S1 |
| 2.2 | Strategies to improve the biopharmaceutic of parenteral and ophthalmic drug delivery | S2 |
| 2.3 | Interpret the pharmaceutical calculation related to isotinicity, specific gravity and dose | S3 |
| **3** | **Competence:** |  |
| 3.1 | Work independently and professionally | C1 |
|  |  |  |

# C. Course Content

|  |  |  |
| --- | --- | --- |
| **No** | **List of Topics [Theory]** | **Contact Hours** |
| 1 | Introduction to sterile preparations, *Parenteral dosage forms*: preparation, advantages and disadvantages | 2 |
| 2 | Routes of administration of parenteral and Different types of parenteral preparation | 2 |
| 3 | Formulation components of parenteral product | 2 |
| 4 | Production facilities for parenteral product | 4 |
| 5 | Evaluation of parenteral preparations | 2 |
| 6 | *Ophthalmic preparations*: definition, physiology and anatomy of the eye | 2 |
| 7 | Classification of ocular preparation: solutions, suspensions, semisolids dosage forms, solids dosage forms, intraocular dosage forms | 2 |
| 8 | Inactive ingredients in topical ophthalmic drops: vehicles, tonicity adjusting agents, pH adjusting agents and buffers, stabilizers and antioxidants, surfactants and viscosity modifiers. | 2 |
| 9 | *Semisolid ophthalmic dosage forms:* ointments, gels; *Solid dosage forms:* ocular inserts; Packaging of ophthalmic preparations. | 4 |
| 10 | Intraocular dosage forms | 2 |
| 11 | Miscellaneous: ocular iontophoresis, vesicular dosage forms, contact lenses and care solutions | 4 |
| 12 | Revision | 2 |
| **Total** | | 30 |

|  |  |  |
| --- | --- | --- |
| **No** | **List of Topics [Practical]** | **Contact Hours** |
| 1 | Preparation of i.v. infusions | 2 |
| 2 | Ophthalmic preparations: eye drops, eye lotions and eye ointments | 4 |
| 3 | Sterilization techniques | 2 |
| 4 | Introduction to Isotonicity | 2 |
| 5 | Isotonicity adjustment by sodium chloride equivalent method | 4 |
| 6 | Isotonicity adjustment by freezing point depression method | 2 |
| 7 | Isotonicity adjustment by white-Vincent method and U.S.P method | 4 |
| 8 | Math's and dosage calculation for parenteral products | 4 |
| 9 | Problems related to dosage calculation | 2 |
| 10 | Calculation of i.v. admixtures and i.v. infusion flow rate | 2 |
| 11 | 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 sterile dosage forms with detail of parenteral and ophthalmic products | Lectures | 1.Theoretical exam  2. Assignments |
| 1.2 | Principles of formulations/dosage forms design for parenteral and ophthalmic drug delivery | Lectures | 1.Theoretical exam  2. Assignments |
|  |  |  |  |
| **2.0** | **Skills** | | |
| 2.1 | Evaluate the quality of sterile dosage forms for parenteral and ophthalmic drug delivery | Lectures,  Problems Solving | Theoretical exam |
| 2.2 | Strategies to improve the biopharmaceutic of parenteral and ophthalmic drug delivery | Practical work | 1.Work place-based assessment (WPBA)  2. Practical Exam |
| 2.3 | Interpret the pharmaceutical calculation related to isotinicity, specific gravity and dose | Practical work | Practical Exam |
| **3.0** | **Competence** | | |
| 3.1 | Work independently and professionally | Practical work | 1. Work place-based assessment (WPBA)  2. 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. Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems, 8th Edition, edited by Allen L.V., Popovich N. G. and Ansel H. C.  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 by Loyd 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. Autoclave  2. Hot air oven  3. Water bath  4. Membrane filtration  5. Vortex mixer  6. Hot plate with magnetic stirrer |

# 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 |  |