Course Specification

*For Guidance on the completion of this template, please refer to of Handbook 2 Internal Quality Assurance Arrangements*

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| Institution: King Saud Riyadh University |
| College of Pharmacy /Department of Pharmaceutics |

A. Course Identification and General Information

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| 1. Course title and code: Sterile & parenteral preparations (PHT 427) |
| 2. Credit hours: 2 (1+1) |
| 3. Program(s) in which the course is offered.  (If general elective available in many programs indicate this rather than list programs)  Doctor of Pharmacy |
| 4. Name of faculty member responsible for the course : |
| 5. Level/year at which this course is offered Level 8 |
| 6. Pre-requisites for this course (if any): PHT 311, PHT 416 |
| 7. Co-requisites for this course (if any): N/A |
| 8. Location if not on main campus |
| 9. course language: English |

B Objectives

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| 1. Summary of the main learning outcomes for students enrolled in the course.   By the end of the course, the student should be able to:   * + Define sterile pharmaceutical dosage forms.   + Identify the basic ingredients that are used for formulation of sterile dosage forms   + Discuss the method of sterilization for pharmaceutical products.   + Describe preservative systems for pharmaceutical dosage forms.   + Prepare label and package for sterile products.   + Describe fluid and electrolyte therapy, IV admixture and incompatibilities,   + Explain procedures required for the proper setup of materials and supplies while maintaining a sterile environment.   + Discuss the equipment and facilities related to sterile preparations.   + Review the procedures related to sterile compounding.   + Calculate the correct dose for the patient and the flow rate of parenteral products.   + Review the control procedures related to sterile preparations. |
| 1. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web based reference material, changes in content as a result of new research in the field)    1. Introducing more sources of information including newly released soft wares.    2. Updating of references used.    3. Introduce new courses due to the development of the filed. |

1. Course Description (Note: General description in the form to be used for the Bulletin or Handbook should be attached)

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| Topics to be Covered | | |
| Topic | No of Weeks | Contact hours |
| 1- Overview of Sterile Preparation Formulation Introduction and characteristics of sterile dosage forms | 1 | 1 |
| 2- Sterile preparation formulation Components, containers and closure | 1 | 1 |

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| 3- Parenteral formulations: Vehicles; additive | 1 | 1 |
| 4- Physiological Norms Pyrogenicity  Tonicity  Particulate matter Stability  Storage | 1 | 1 |
| 5- Sterile Preparation Facilities and Equipment Syringes and needles  Ampules or vials  Laminar airflow hoods Biological Safety Cabinets  IV bags | 2 | 2 |
| 6- Procedure for Compounding Solutions IV admixture incompatibility | 2 | 2 |
| 7- Methods of sterilization | 2 | 2 |
| 8- Ophthalmic preparations | 2 | 2 |
| Exams | 2 | 2 |

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| 2 Course components (total contact hours per semester): hours | | | |
| Lecture: 14 |  | Practical/Fieldwork  /Internship: N/A 14 x 3 = 42 hours | Other: N/A |

3. Additional private study/learning hours expected for students per week. (This should be an average: for the semester not a specific requirement in each week)

one hour per week

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| 1. Development of Learning Outcomes in Domains of Learning   For each of the domains of learning shown below indicate:   * + A brief summary of the knowledge or skill the course is intended to develop;   + A description of the teaching strategies to be used in the course to develop that knowledge or skill;   + The methods of student assessment to be used in the course to evaluate learning outcomes in the domain concerned. |
| (i) Description of the knowledge to be acquired  The course gives a comparative evaluation of the therapeutic indications, physicochemical, pharmaceutical, biopharmaceutical and pharmacokinetic aspects of commonly prescribed drugs.  Technical knowledge for preparation of sterile pharmaceuticals |
| (ii) Teaching strategies to be used to develop that knowledge via: 1- lecturers.  2- Laboratory experiments |
| (iii) Methods of assessment of knowledge acquired   1. Written quiz, midterm, final exams and problem solving.   2- Evaluation of home assignments.  3- Practical exam |
| b. Cognitive Skills |
| (i) Cognitive skills to be developed  Technical knowledge for premonition of sterile pharmaceutical medics   1. Critical thinking 2. Analyzing information in sterile compounding. 3. Alertness during compounding and dispensing the sterile preparations 4- Precision during the directions giving to the patients. |
| 1. Teaching strategies to be used to develop these cognitive skills    1. Arranging the lectures in a form of questions and answers.    2. Starting with wrong statements and asking for corrections from the students. |

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| 3- Using some audiovisual aids and power point presentations. |
| 1. Methods of assessment of students’ cognitive skills 1- Discussion to be presented in groups of students.    1. Evaluation of the students' submitted presentations.    2. Assignments requesting feedbacks on issues related and unrelated to the topics. |
| c. Interpersonal Skills and Responsibility |
| (i) Description of the interpersonal skills and capacity to carry responsibility to be developed  1- Giving group assignments to enhance their abilities to work in groups. 2-Giving indications to patients in professional way.  3- The student should be engaged in higher responsibilities |
| 1. Teaching strategies to be used to develop these skills and abilities 1- Students will be trained on simulating situations.    1. Video tapes will be used to show students the professional ways of communication with patient and community.    2. Oral exams will be made. 4- Group discussion.   5- Group projects will be carried out. |
| 1. Methods of assessment of students’ interpersonal skills and capacity to carry responsibility    1. Monitoring of students’ attitudes in lectures and labs.    2. Participation of students in the community activities. 3- Assessment of home assignments and reports. 2. Evaluation of the group projects. 3. Monitoring the action/reaction of students when entitled to higher responsibilities. |
| d. Communication, Information Technology and Numerical Skills |
| 1. Description of the skills to be developed in this domain.    1. Search utilizing internet to cope with course demand.    2. Follow the update knowledge concerning the course demand. |

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| 1. Presentation using power point. 2. Report form visit to the IV unit in Hospital |
| 1. Teaching strategies to be used to develop these skills    1. Training on different software and special programs related to the course e.g. labelling of the dosage forms    2. Students will be asked to present a research project utilizing the I.T. showing the latest information about certain topics. |
| (iii) Methods of assessment of students numerical and communication skills  1- Evaluation of the extent of comprehension of students in problem solvation. 2- Assessment of home assignments.   1. The positive role of the student in group projects. 2. The effective participation of the student in the activities of his society. |
| e. Psychomotor Skills (if applicable) |
| N/A |

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| 5. Schedule of Assessment Tasks for Students During the Semester | | | |
| Assessment | Assessment task (e.g. essay, test, group  project, examination etc.) | Week due | Proportion  of Final Assessment |
| 3 | Midterm 1 | 15 | 15 |
| 4 | Quiz 2 | 7 | 30 |
| 5 | Presentations seminars |  | 10 |
| 6 | assignments | 10 | 5 |
| 7 | Practical exam | 13 (+Visit  to IV Unit) | 15 |
| 8 | Final exam | 40 | 40 |
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1. Student Support
   1. Arrangements for availability of faculty for individual student consultations and academic advice. (include amount of time faculty are available each week)

Lecture time, office hours and Tutorial hours.

E Learning Resources

:الكتب الريسية المطلوبه :

* + 1. Sterile product facility design and project management by Jeffrey N. odum , 2nd edition ( 2004 )
    2. Principles of sterile prouduct preparation by E .buchnan , Barbara T . mckinnon douglas . scheckloff and phillip J. Schneider ( 2002)
    3. The theory and practice on industrial phamce by Lachman, H.librerman & .

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| 4-Electronic Materials, Web Sites etc.  [www.emedicine.com](http://www.emedicine.com/) [www.sciencedirect.com](http://www.sciencedirect.com/) [www.blackwell.com](http://www.blackwell.com/) [www.ovid.com](http://www.ovid.com/)  [www.pubmed.com](http://www.pubmed.com/) |
| 5- Other learning material such as computer-based programs/CD, professional standards/regulations  CD of British Pharmacopeia (B.P), United States Pharmacopeia (USP), British Pharmaceutical Codex (B.P.C).  Martindale (extra pharmacopeia). Clinical Pharmacology software. |

F. Facilities Required

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| Indicate requirements for the course including size of classrooms and laboratories (ie  number of seats in classrooms and laboratories, extent of computer access etc.) |
| 1. Accommodation (Lecture rooms, laboratories, etc.) Number of seats in each classroom would be up to 100 seats. Number of seats in each laboratory would be up to 30 seats. |
| 2. Computing resources |

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| There are central computer labs in the College building |
| 3. Other resources (specify --e.g. If specific laboratory equipment is required, list requirements or attach list) |

G. Course Evaluation and Improvement Processes

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| 1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching  Questionnaire is given to students to be filled about course content and teaching procedures.  Evaluation of standards of the students in the quizzes, midterm, final exams, and home assignments, reports, and presentation. |
| 2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department Verbal discussion should be done by the staff member in presence of students about course content and teaching procedures in order to express the extent of comprehension and understanding.  Listening to students, complaints. |
| 3. Processes for Improvement of Teaching   1. Continuous updating of the course materials and adding new sources of information. 2. Increase the tutorial hours. 3. Training of staff members on new methodology for teaching. |
| 4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent faculty member of a sample of student work, periodic exchange and remarking of a sample of assignments with a faculty member r in another institution)  Check marking of a sample of student work by the demonstrators and lecturers working in the same course.  Staff member trinig |
| 5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.  Establishing an academic committee in each department to control:  Periodical reviewing of the course content, midterms , final exams, students’ complaints , time factor, discipline, attendance of students and tutors. |