

I. COURSE DESCRIPTION:

This course will focus on the Standards of Practice for the preparation of sterile products. The principles of sterile technique and the skills required to prepare sterile compounds will be practiced within the lab setting. Accuracy and quality assurance will be emphasized in this course.

This course is designed to enable students to attain competencies specified in the National Association of Pharmacy Regulatory Authorities (NAPRA) Professional Competencies for Canadian Pharmacy Technicians at Entry to Practice September 2007. (Full document available at www.napra.ca)

This course is designed to enable students to attain the educational outcomes specified in the Canadian Pharmacy Technician Educators Association (CPTEA) Educational Outcomes for Pharmacy Technician Programs in Canada.(March 2007). (Full document available at www.cptea.ca)

This course is designed to enable students to meet and maintain the standards of practice expected within the pharmacy technician's role. The standards are specified in the National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards of Practice for Canadian Pharmacy Technicians. November 2011. (Full document available at www.napra.ca)

II. LEARNING OUTCOMES AND ELEMENTS OF THE PERFORMANCE:

This course meets NAPRA competency categories:

1.1,1.2,1.3, 2.1, 3.1, 3.2, 3.3, 4.1, 5.1, 5.2, 7.1, 7.2, 7.3, 8.1,8.2, 8.3, 9.1, 9.2, 9.3

Upon successful completion of this course, the student will demonstrate the ability to:

1. dispense pharmaceutical products accurately, efficiently and in compliance with legislation and all established policies and procedures.

Potential Elements of the Performance:

- Understand commonly used medical and pharmacy terminology, directions, abbreviations, acronyms and symbols related to sterile preparation
- Identify the components required on a compounded sterile preparation label
- Understand the regulations and procedures that must be adhered to when preparing various products for parenteral administration
- Explain storage conditions commonly required for compounded sterile products
- Summarize legislative and other guidelines that govern the use of narcotics and controlled drugs in sterile compounding
- Select and use credible reference and online materials effectively, including Canadian Society of Hospital Pharmacists (CSHP) and USP Chapter 797 standards

2. describe the equipment, apparel, and supplies required to prepare sterile products.

Potential Elements of the Performance:

- Identify the different types of hoods used for sterile compounding
- Identify a variety of supplies used for sterile compounds
- Identify critical sites of commonly used sterile equipment and supplies
- Describe the various components of commonly used sterile equipment
- Describe the components and operations of the horizontal and vertical laminar airflow hood

3. describe the policies and procedures in place for the manufacture of sterile products.

Potential Elements of the Performance:

- Describe anteroom and clean room setup and characteristics
- Understand and demonstrate the procedures for aseptic hand washing, gloving and garbing
- Recognize and respond appropriately to situations that compromise asepsis during garbing, gloving and hand washing
- Explain and demonstrate the proper technique in cleaning laminar airflow hoods
- Explain procedures required for proper setup of materials and supplies while maintaining a sterile environment
- Understand the need for continued training and testing of personnel's knowledge and technique
- Describe the proper procedure for cleaning a cytotoxic drug contamination/spill
- Demonstrate the correct procedure for safe handling and disposal of sharps/chemotherapeutic drugs
- Describe the quality control procedure for batch testing and drug stability

4. evaluate a coworker's preparation of pharmaceutical product through an independent double check.

Potential Elements of the Performance:

- Be able to detect errors when verifying calculations
- Accurately interpret terminology and admixing directions used in written procedures and master formulas
- Be able to independently review a coworkers work which involves being able to accurately interpret the prescription, determine the procedure required, calculate all ingredients required, as well as, rates, diluents, stability dates required, to ensure the correct patient receives the correct product at the correct time.
- Understand what a high alert drug is and name the drugs and/or its classes considered to be high alert medications

5. perform calculations accurately pertaining to IV admixtures and demonstrate problem solving skills.

Potential Elements of the Performance:

- Understand the principles of pharmacy dosage calculations
- Solve mathematical problems related to pharmaceutical calculations including dilutions, percentages,, ratio and proportion, dimensional analysis , IV flow rates, alligation, and daily volumes
- Determine the best method of problem solving pharmaceutical calculations based on the sterile compounding procedure required

6. explain the rationale and importance of maintaining aseptic technique and sterility during the preparation of IV products, as well as, demonstrate how to maintain a sterile environment and prevent product contamination.

Potential Elements of the Performance:

- Define aseptic technique and key principles essential for ensuring a sterile product
- Recognize potential contaminants in the sterile environment
- Understand the rationale for using a hood during sterile product compounding
- Demonstrate the technique for handling a needle and syringe, for withdrawing from an ampoule or vial, for reconstituting a powdered drug, for transferring a drug or IV solution from one container to another, using a vented or non-vented tubing set and reconstitution while working in various hoods
- Explain the concepts of compatibility and sterility

7. prepare products accurately in a sterile environment, with focus on proper technique, accurate measurement of ingredients and following all policies and procedures.

Potential Elements of the Performance:

- Demonstrate correct technique in the preparation of large volume parenteral, small volume parenteral, and ampule-based products in various types of hoods
- Discuss selection of correctly sized packaging and labelling procedures for a syringe, minibag and large volume parenterals
- Demonstrate correct technique in the preparation of powdered drug reconstitution while following all manufacturing guidelines

8. demonstrate preparation techniques specifically designed for chemotherapy and total parenteral nutrition (TPN) as well as narcotic preparations, such as PCA pumps and epidural products, and pediatric products.

III. TOPICS:

1. Introduction to Aseptic Technique
2. Equipment and Supplies
3. The Environment
4. Aseptic Techniques, Principles and Procedures
5. Applied mathematics
6. Basic Sterile preparations
7. Total Parenteral Nutrition Solutions
8. Narcotic preparations
9. Pediatric Preparations
10. Cancer Chemotherapy
11. Applied Mathematics
12. Quality Assurance

IV. REQUIRED RESOURCES/TEXTS/MATERIALS:

1. *Sterile Compounding and Aseptic Technique: Concepts, Training and Assessment for Pharmacy Technicians* by author Lisa McCartney, Paradigm Publishing. ISBN 978-0-76384-083-9 Text and DVD
2. Sault College Learning Management System (D2L)

V. EVALUATION PROCESS/GRADING SYSTEM:

| | |
|---------------------------------|-------------|
| Labs (15 x 3 %) | 45% |
| Assignments (2 X 2.5%) | 5% |
| Tests (2 x 10%) | 20% |
| Practical Assessments (2 X 15%) | 30% |
| Total | 100% |
| Sterile Preparation Math Test | pass/fail |

1. To pass this course, students must achieve an overall course grade of at least 60% (calculated as indicated above) **and** pass the Sterile Preparation Math Test. ALL components of this course must be completed to be successful.
2. **Sterile Preparation Math Test:** Students must achieve a minimum mark of 80% to pass.
3. All policies and procedures as outlined in the current Student Success Guide related to submitting assignments, scholarly work/academic honesty, tests and examinations will be followed.
4. **No supplements** will be provided for labs or tests.

5. Students missing labs or tests because of illness or other serious reason must contact the professor before the lab or test to inform him/her (by phone or email). Those students who have notified the professor of their absence, according to policy, will be eligible to arrange an opportunity to complete the lab or test at another time. Students must contact the professor on their first day back at school following a missed lab or test. Those students who do not follow the above procedures will receive a zero for that lab or test. The professor reserves the right to request documentation to support the absence.

The following semester grades will be assigned to students:

| <u>Grade</u> | <u>Definition</u> | <u>Grade Point Equivalent</u> |
|--------------|--|-------------------------------|
| A+ | 90 – 100% | 4.00 |
| A | 80 – 89% | 3.00 |
| B | 70 - 79% | 3.00 |
| C | 60 - 69% | 2.00 |
| D (Fail) | 50 – 59% | 1.00 |
| F (Fail) | 49% and below | 0.00 |
| CR (Credit) | Credit for diploma requirements has been awarded. | |
| S | Satisfactory achievement in field /clinical placement or non-graded subject area. | |
| U | Unsatisfactory achievement in field/clinical placement or non-graded subject area. | |
| X | A temporary grade limited to situations with extenuating circumstances giving a student additional time to complete the requirements for a course. | |
| NR | Grade not reported to Registrar's office. | |
| W | Student has withdrawn from the course without academic penalty. | |

Mid Term grades are provided in theory classes and clinical/field placement experiences. Students are notified that the midterm grade is an interim grade and is subject to change.

Note: For such reasons as program certification or program articulation, certain courses require minimums of greater than 50% and/or have mandatory components to achieve a passing grade.

A minimum of a "C" grade is required to be successful in **most** PTN coded courses.

It is also important to note, that the minimum overall GPA required in order to graduate from a Sault College program remains 2.0.

VI. SPECIAL NOTES:Attendance:

Sault College is committed to student success. There is a direct correlation between academic performance and class attendance; therefore, for the benefit of all its constituents, all students are encouraged to attend all of their scheduled learning and evaluation sessions. This implies arriving on time and remaining for the duration of the scheduled session.

VII. COURSE OUTLINE ADDENDUM:

The provisions contained in the addendum located on the portal form part of this course outline.