Sterile Compounding and Aseptic Technique

Contaminated sterile preparations have led to increased morbidity and mortality including loss of vision, hospitalization, and death. Unfortunately, the contamination is often identified by the poor outcome after the patient receives it. No pharmacist, technician or nurse intends to contaminate a sterile compound. However, it is our job to ensure best practices for sterile compounding are carried out daily to prevent this occurrence.

YOU have the responsibility to ensure the highest quality of the sterile drugs you may mix for your patients.

In January 2004, United States Pharmacopeia (USP) Chapter <797>, Pharmaceutical Compounding-Sterile Preparations, became the first official publication to describe required conditions and practice standards for **compounded sterile products**, or **CSPs**. Now, Chapter <797> is enforced by many state boards and may be used to some extent for accreditation criteria by organizations such as Joint Commission.[3]

USP Chapter <797> can be enforced in any setting preparing sterile compounds, such as hospitals, clinics, pharmacies, physician offices, and long-term care facilities. Other professional organizations providing guidance for sterile compounding, such as the American Society of Health-System Pharmacists (ASHP) *Guidelines on Compounding Sterile Preparations*, have aligned their recommendations with USP Chapter <797>. Recommendations include instructions for pharmacy design, washing, garbing, cleaning, quality assurance, and personnel training and evaluation.

A Review of Sterile Compounding for Nursing

Sterile compounding may occur in a variety of settings in your facility. Preferably, sterile compounds are made in the hood (ISO Class 5 environment) located within a clean room (ISO Class 7 environment) in the Pharmacy, but sometimes they are prepared elsewhere. Even with the best aseptic technique, sterility of the preparation may be limited if performed outside of the preferred environment. In addition, if the compounding requires multiple manipulations or uses non-sterile products, the risks become a little higher.

When can a nurse compound a sterile product? (Immediate-Use CSPs)

- When the Pharmacy is closed
- Emergent timing rules out Pharmacy preparing the product (example: Code or Stat situation)
- Not more than 3 products are used (including the IV solution)
- Administration begins not later than one hour after start of preparation
- CSP will be discarded if administration has not begun within one hour
- Maximum expiration dating is 12 hours

Immediate-Use CSPs

Immediate-use preparations are for emergency use or immediate patient administration (i.e., cardiac or respiratory arrest situations, emergency room or operating room treatments, or any emergent time that rules out Pharmacy preparing the product that would put the patient at risk of harm because of delays in treatment).
Administration of immediate-use preps must commence within one hour or less from the start of preparation. (Otherwise, they should be discarded.)

> *Example of immediate-use preps*: a Cardizem drip prepared by the nurse in the Emergency Department, the reconstitution of a Solu-Medrol vial or Geodon vial for immediate patient administration, a Zofran IV dose drawn up in a syringe.

All procedures for proper aseptic technique must still be performed, such as hand hygiene, etc. Evidence demonstrates higher contamination rates when sterile preps are prepared outside of the pharmacy in a less controlled environment. Pharmacy should lead efforts to educate colleagues on appropriate aseptic practices. In addition, it's important to work with your colleagues to minimize immediate-use preps when possible.

Labeling - it's important to make sure immediate-use preps are properly labeled with patient identification (two identifiers), drug name and amount, name or initials of who prepared the drug, and exact expiration date and time.

Beyond Use Dating – for compounded sterile preparations, the beyond-use date is the date or time beyond which a preparation should NOT be used. This dating takes into account the compound's stability and its sterility.

Any sterile product compounded by Nursing by further dilution into an IV solution container has a MAXIMUM beyond use date of 12 hours.

Beyond-Use Dates of Vials – Single Dose Vials vs. Multi-dose Vials

Another important beyond-use date is that given to vials used for sterile compounding. A multi-dose vial, by definition, contains a preservative. This is the main difference between a multi-dose vial and a single-dose vial. The maximum beyond-use date for multi-dose vials is 28 days after entering with a needle, or puncturing the stopper, unless otherwise specified by the manufacturer. If any type of contamination of a multi-dose vial is suspected, discard the vial immediately.

By TRMC policy, multi-dose vials must be dated with the beyond-use date of 28 days from initial entry into the vial.

Multi-dose vials must be drawn from in non-patient areas (medication room); if brought into a patient's room, it must only be used for that patient.

For single-use containers (e.g., bags, bottles, vials, etc.), the maximum beyond-use date is one hour after the first entry into the vial.

Once ampules have been opened, they should not be stored for any period of time, regardless of the air quality.

Practicing Aseptic Technique

What is aseptic technique? How do you ensure you are following aseptic technique when performing sterile compounding?

Aseptic technique describes the process of working with sterile products so that they remain sterile.
Think of this as a separate component of sterile compounding. Part of sterile compounding is correct equipment and environment, but the other part is using the correct technique.

Here are the highlights of GREAT Aseptic Technique:

- Use the 'designated area' in your unit or clinic for sterile compounding or 'mixing IVs'
- Prepare the IV mixing area surface – clean it appropriately with an approved cleaning agent (ex. Sani-Cloth Plus wipes)
- Gather all necessary supplies – correct size syringes, needles, medications and diluents – READ the labels
- Perform all calculations prior to mixing – READ the provider's order, validate patient identity and patient allergies
- Proper handwashing for 30 seconds per CDC guidelines
- Put on sterile, powder-free gloves
- Use alcohol swab to cleanse every port and vial stopper. Wipe rubber stopper firmly in one direction to disinfect and remove particles. Rubber stoppers are NOT sterile under the plastic caps!
- Reconstitution of powdered vials – choose the proper diluent, aim diluent fluid at side of vial, do not remove until dissolved
- Avoid pressurization of vials – enter equal amount of air as volume withdrawing to avoid liquid spewing out of vial
- Ampules – tap the top to make sure fluid is in the bottom, disinfect the neck of the ampule with alcohol swab and break away from you. Use a filter needle to withdraw the medication out of the ampule to prevent any glass particles from being drawn up in the syringe. Then replace the filter needle with a new needle; do not use the same filter needle for withdrawing and injecting.
- Be sure to open syringe and needle packages as indicated on the package – do NOT break or push them threw the paper package
- Avoid touching the needle and syringe tips and the plunger of the syringe – these are sterile areas.
- Use the flat end of the syringe to pull back the plunger
- Inspect your final mixture for incompatibilities, cores or particulate matter
- Label the final product appropriately with all required label components: patient name, patient identifier, drug(s), amounts, prep date and time, expiration date and time, your initial

TEST Questions

Question #1

What is the purpose of USP Chapter <797>?

- a. Provide guidance for appropriately performing calculations for compounding
- b. Instruct on using tools for measuring and weighing drugs used in compounding
- c. Provide standards for safe handling of hazardous drugs
- d. Outline best practices and quality standards in compounding sterile preparations

Question #2

When can a nurse compound a sterile product?

- a. Whenever they feel like it
- b. A ‘banana bag’ is ordered in ED with 3 drugs added to an IV solution
- c. An insulin infusion bag is mixed which won’t be started for 4 hours
- d. Pharmacy is closed and the patient needs a Phenylephrine drip

Question #3

USP <797> practice standards are not applicable to IV, IM or subQ products in the clinic setting?

- a. True
- b. False

Question #4

Immediate Use CSP preparations do NOT include:

- a. Cardizem drip mixed in the ICU during an emergent situation.
- b. A premixed Levaquin IV piggyback.
- c. Solu-Medrol 125mg mix-o-vial reconstituted.
- d. Reconstituting a vial of Cefazolin and transferring it into a sterile syringe in OR.

Question #5

The Beyond Use Date of a CSP is the date beyond which a preparation should NOT be used.

- a. True
- b. False

Question #6

Which is the correct statement to define guidelines for the use of multi-dose vials.

- a. Multi-dose vials can be brought into multiple patient rooms for drawing up doses.
- b. The maximum beyond-use date is one hour after the first entry into the vial.
- c. The beyond use date is 28 days from initial entry into the vial.
- d. A Water for Irrigation liter bottle is a multi-dose container.

Question #7

How should you handle syringes and needles to maintain aseptic technique?

- a. Open syringes and needles by breaking open through the side of the package.
- b. Wrap your hand around the plunger to pull back on the syringe.
- c. Connect syringes and needles immediately after opening the packages.
- d. Use a 20ml syringe to measure a 5ml volume of drug.

Question #8

How should you handle vials and ampules to prevent contamination of sterile compounds?

- a. Disinfect vials and/or ampules with alcohol swab before opening or breaking open.
- b. Wipe a vial's rubber stopper back and forth firmly with disinfectant.
- c. Swirl ampules upside down to ensure fluid is in the top of the ampule before breaking.
- d. Use the same filter needle for both the withdrawing and injecting of ampule fluid.