Safe Injection Preparation

Immediate Use Sterile Compounding

What is sterile compounding?

Sterile compounding is the combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a commercially prepared drug product. Common examples could include adding an antibiotic* to IV fluids or mixing three or less medications to create a custom injection.

Ideally, compounded medications would be prepared in a controlled environment within a pharmacy. There are times when this is not feasible, such as an emergent situation or within health care settings that do not have readily available access to a compounding pharmacy. This practice is considered **immediate use sterile compounding**, and it is imperative that rigorous infection prevention and medication safety practices are followed to ensure optimal safety for the patient. Facilities must ensure all processes follow federal, state, and local laws along with any regulatory requirements.

*Does not include reconstituting or diluting antibiotics per the instructions for use (IFU).

Immediate use sterile compounding considerations

Are you able to use manufacturer-prepared medications?

Manufacturer-prepared medications should be used as much as possible as they provide specific doses that are ready to administer to patients or residents.

No

Can you outsource to a third-party pharmacy?

If able, outsource to a pharmacy that specializes in compounded medications or utilize a pharmacy to prepare all sterile compounded medications.

No

Prepare medications onsite.

Prepare immediate use sterile compounded medications onsite following strict infection prevention and medication preparation protocols. Recommendations for safe practice are included on pages 2 and 3.

Immediate use sterile compounding: recommendations for safe practice

Your facility may consider preparing immediate use sterile compounded medications onsite if manufacturer-prepared medications are unavailable or sterile compounding cannot be outsourced to a third-party pharmacy.

Follow the recommendations for safe preparation, administration, and training and competency related to immediate use sterile compounding below.

Preparation

❑ Dedicate a **medication preparation site** that:

- Is in a space separated from traffic and distractions (such as a medication room).
- Is away from potential contamination (such as sinks or point-of-care testing).
- Has all needed supplies readily available.

❑ Confirm **medication components****, ensuring:

- There are no more than three different components involved in preparing the sterile compound.
- Single dose components are not used for more than one patient.
- Hazardous drug components are not included.

**Refer to United States Pharmacopeia (USP) General Chapter <797>: Frequently Asked Questions (PDF) question 22 for more information.

❑ Use **aseptic technique** including:

- Practicing proper hand hygiene.
- Cleaning the preparation surface.
- Disinfecting the rubber septum on the medication vial prior to access.

❑ Label appropriately with **patient identification information**, including:

- Names and amounts of all medications being compounded.
- Patient name or identifier.
- Name or initials of the person who prepared it.
- The exact 4-hour beyond use date and time.
- Administration must occur no later than 4 hours after preparation.

❑ Avoid **bulk preparation** (the preparation of multiple individual doses at the same time), if possible. If bulk preparation is unavoidable ensure:

- Each dose is labeled individually after it is made.
- Prepared medications are stored in a protected area.
- Medications are stored for no longer than 4 hours once prepared.

Administration

- ❑ **Administer as close as possible** to the time the medication was prepared.
- ❑ Transport prepared medication in a manner that **protects it from contamination**.
- ❑ **Perform hand hygiene and utilize aseptic technique** to administer medication.

Training and competency

- ❑ **Develop written protocols**, following evidence-based best practices.
- ❑ Ensure staff responsible for immediate use sterile compounding have **documented training and competency** according to their facility's policy. For facilities whose policies do not define a frequency for training and competency, the recommended cadence is upon hire, annually, and with any change in role or process.
- ❑ **Audit the immediate use sterile compounding practices** periodically and provide feedback on adherence to health care personnel and leadership.

Guidance and additional information

- American Society of Health-System Pharmacists (ASHP) Guidelines on Compounding Sterile Preparations journal article
- CDC (Centers for Disease Control and Prevention) Preventing Unsafe Injection Practices webpage
- CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings
- Department of Health Services (DHS) Healthcare-Associated Infections (HAI) Prevention Program Health Care Resources webpage
- DHS HAI Infection Prevention in Ambulatory Care webpage
- Institute for Safe Medication Practices Guidelines for Sterile Compounding and the Safe Use of Sterile Compounding Technology (PDF)
- USP General Chapter <797>: Pharmaceutical Compounding – Sterile Preparations webpage
- USP <797> Frequently Asked Questions (PDF)

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