

Labeling Sterile Preparations

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INTRODUCTION

A proper compounded sterile preparation (CSP) must be labeled accurately and completely to facilitate appropriate and safe administration to the patient. Checking the accuracy and thoroughness of the CSP labeling, independently, compared to the original physician order/prescription and the ingredients used to compound the preparation is an integral part of pharmacist verification before release of the preparation. The primary and auxiliary labels on sterile preparations are communication tools about proper handling, storage, administration, and drug information for the person administering the drug. Therefore, the terminology used on the label should be descriptive but still appropriate to the knowledge of the user with the use of abbreviations minimized. All labels should be legible and affixed to the final container so that the information can be read both before and while the sterile preparation is being administered. If a container is to be hung, each label must be positioned so that it is right side up during administration. Light-resistant bags for photosensitive drugs and other overwraps should not limit the readability of the label.

Small containers may require unique methods of affixing the label. For medium-sized syringes, labels often are affixed just using the two ends of the label so that syringe markings are not covered or obstructed. This method of attaching the label is called *flagging*. Labels are often flagged for CSPs dispensed in small vials and ophthalmic bottles. Very small syringes can be sealed in a larger bag or overwrap, which is then labeled. If the syringe might be removed from the bag some time before administration, a second, smaller label on the syringe should give key information (e.g., drug name, concentration, beyond-use date [BUD], and route). Based on the sterilization method (e.g., steam), final labeling with all required labeling components may need to occur *after* sterilization.

The exact information on a label varies depending on the preparation type and the patient location/setting—not the *United States Pharmacopeia's* (USP) CSP risk level category. Effective in 2004, there are official USP required labeling elements for all CSPs regardless of where the patient is receiving the preparation.^{1,2} These same labeling elements are required in the revised USP Chapter <797> Pharmaceutical Compound-

ing—Sterile Preparations standards, which became official June 1, 2008, with a few additional requirements noted in the 2016 draft revision of USP Chapter <797> standards. General label content is similar, but slight variations exist in addition to the USP standard for patient-specific labeling in institutional and home care settings and for compounded sterile batch preparations.³⁻⁵ This chapter will review general labeling guidelines, the USP labeling requirements for sterile preparations, batch labeling elements (both required and optional patient-specific and perioperative labeling elements as specified by ASHP and The Joint Commission), and other labeling strategies that can be used to help prevent medication errors and facilitate proper disposal of returned preparations to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations.^{4,6-12}

GENERAL LABELING GUIDELINES

To ensure proper labeling, the following guidelines should be followed:

- Drug labeling is required unless the CSP meets the USP immediate-use provision (i.e., it is not administered immediately and completely by the person who prepared the medication, or the preparer does not witness the immediate and complete administration of the drug).¹
- The label must conform to all applicable federal, state, and local laws and regulations. Some states require specific labeling elements to be in a larger bold-face font than the rest of the label information. The Institute of Safe Medication Practices (ISMP) recommends that patient name, generic drug name, and the patient-specific dose be printed in bold typeface on medication labels in a minimum 12-point font size.¹³ USP Chapter <17> Prescription Container Labeling provides standards for prescription container labeling that are focused on prominent placement of critical information (drug's generic and brand name, strength, and dosing instructions) utilizing clear, simple language with only essential evidenced-based auxiliary information.^{14,15} USP Chapter <7> Labeling provides general labeling standards, which include the amount of each active ingredient per dosage unit and specified warnings for high-risk drug classes (e.g., neuromuscular blocking [paralyzing] agents).¹⁶

- Medication labels are typed or electronically printed in a standardized format to ensure accurate and complete labeling. The label is legible, easily read, and free from erasures and strikeovers. The background color for labels enables clear visualization of text and barcodes, when applicable.¹³ Adequate space between data elements is essential in medication label design.¹⁵ Unlabeled CSPs or those with incomplete labeling are either corrected or discarded immediately and safely. ISMP offers guidelines for formatting electronically generated CSP labels and recommends matching the format and units of measure of the prescriber's order.¹⁷
- The appropriate primary and auxiliary labels are firmly affixed to the container. Pharmacy preparation labels are not to be used as the final CSP product label.^{17,18}
- Metric units of measure should be used instead of the apothecary system.
- Numbers, letters, coined names, unofficial synonyms, and prohibited abbreviations as well as trademark symbols are not used to identify medications with the exception of approved letter or number codes for investigational drugs.^{11,13}
- All medications with illegible or worn labels are properly and safely destroyed.
- A uniform, systematic labeling method is used. One order or drug preparation batch is filled and labeled at a time.
- During the hours the pharmacy is open, sterile product compounding and labeling are done in a pharmacy. Within the pharmacy, only a pharmacist or authorized pharmacy technician under the direction and supervision of a pharmacist, may label and dispense medications, make labeling changes, or transfer medications to different containers.

USP LABEL REQUIREMENTS FOR COMPOUNDED STERILE PREPARATIONS

With the introduction of the new USP Chapter <797> in 2004, there exists a minimum labeling standard for CSPs that applies to all healthcare settings, not just healthcare institutions and pharmacies.² The revised USP Chapter <797> effective June 1, 2008, requires the same labeling elements as the 2004 version; however, it has more clearly defined criteria as to when an immediate-