Chapter 21

Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs

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Introduction

Although compounded sterile preparations (CSPs) are within the confines of a cleanroom, storage and other handling conditions can be largely controlled. Because CSPs must be transported for use in various patient care settings, handling of these preparations outside the pharmacy or compounding facility must also be considered (see *Note* below). Efforts must focus on the acceptability of the sterile preparation for patient use—including sterility, purity, and stability of ingredients—and also on the reduction of waste and preparation costs. Factors to consider in these efforts include the transfer of the sterile preparation from the sterile compounding area, storage conditions during transport and in the patient care setting, and methods for return, recycling, and disposal.[1-9] USP Chapter <1079> Good Storage and Distribution Practices for Drug Products addresses various good storage and distribution practices used so that medications reach their intended destination (patient or practitioner) with their quality intact.[10] USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations states that compounding personnel are responsible for ensuring that CSPs are stored properly until the beyond-use dating is reached or until administration to the patient begins.[7] All personnel (including couriers and other nonpharmacy staff) who package, handle, transport, and store CSPs outside the pharmacy must be appropriately trained so that this expectation is met.

Delivery Methods

Hospital Campuses

CSPs can be delivered by healthcare personnel or by automated means. Many hospitals also use the centralized pharmacy to provide CSPs for on-campus ambulatory services and long-term care sites. Procedures and systems to ensure proper training of delivery person-

Note: For this chapter, the terms *pharmacy* and *compounding facility* are used synonymously.

nel, product security, and timeliness of delivery remain the responsibility of the compounding facility personnel.

With the extensive use of polyvinyl chloride, ethyl vinyl acetate and other durable flexible plastic containers for CSPs, rapid turnaround time can be readily offered by using pneumatic tube systems for delivery. However, some medications and CSPs are not suitable for this method of transport. In the absence of uniform standards related to delivering medications by pneumatic tube systems—and considering the variety of features and capabilities of different brands of these systems—organizations have developed their own guidelines for acceptable use of pneumatic tube systems. Special "Do Not Tube" labels can be affixed to the medication labels to ensure that these medications are handled properly when they are issued and when they are returned to the pharmacy. **Table 21-1** summarizes some representative guidelines for this method of transportation of CSPs. Syringes also may require special handling to prevent the plunger from depressing and causing leakage into the tube container or system. Padding specifically designed for use in pneumatic tube cartridges can minimize this potential problem.

Home Care and Off-Premises Settings

Additional steps to safeguard the integrity of CSPs are required when providing these services for home care patients and off-premises care settings, including long-term care facilities, physicians' offices, and remote site ambulatory clinics. Both the distance from the compounding pharmacy and the drug's stability affect how CSPs are transported for delivery.[4,13]

Temperature control during off-premises delivery of CSPs is very important. The pharmacy must provide appropriate packaging for the preparation

Table 21-1.
Suggested Guidelines for CSP and Delivery Using Pneumatic Tube Systems[11,12]

1. Do not attempt to exceed the weight or size limitations of the tube cartridge (as established by the tube system vendor). This can cause the tube system to fail or result in breakage, damage, or leaking of the contents.
2. If a sterile preparation container is breakable (such as a glass IV bottle, ampule, vial, or some fragile/brittle plastic bags), or if it could be inadvertently opened or activated by the tube transit process (such as a syringe), ensure that it is adequately secured and padded in the tube cartridge.
3. Many tube systems have a security feature that facilitates transporting CSPs of controlled substances with a security release code. In these circumstances, appropriate measures can be taken to minimize the risk of diversion. In the absence of this capability, controlled substances should not be sent via pneumatic tubes.
4. When the cost of an ingredient in a sterile preparation is very high, it is difficult to procure, and the compounding process is extensive or difficult, it is important to avoid the risk of losing the preparation through an unsecured transport process.
5. Do not transport hazardous, potentially infectious, explosive (e.g., freshly prepared CO_2-generating compounds) or flammable materials (e.g., medical ethanol for injection) via this method. This includes sterile preparations such as chemotherapy, cytotoxic medications (e.g., ganciclovir), caustic agents, radiopharmaceuticals, blood, or blood products.[9]
6. Always avoid the risk of altering the active ingredient or diluent system of CSPs when using a pneumatic tube system. This system can (1) denature or inactivate the ingredients (e.g., immune globulins, colony-stimulating factors, monoclonal antibodies, interferons) and crack emulsions (e.g., lipids, total nutrient admixtures); and (2) generate foam that will affect the measurement of the dosage (as happens with many protein compounds). If any ingredient in a CSP includes a "Do Not Shake" or similar warning, then the preparation should be transported using another method.

CO_2 = carbon dioxide; CSPs = compounded sterile preparations; IV = intravenous.