USP <797> At a Glance

USP <797> establishes standards for compounded sterile preparations (CSPs) and requirements to minimize microbial contamination. This chapter addresses the types of testing, action levels, and frequency for monitoring those areas most prone to contamination during compounding. Your environmental compliance plan must include the following types of tests along with documentation of processes, results, and actions taken.

Viable Surface Sampling:

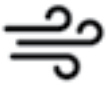
Monthly surface sampling must be conducted for Category 1 and Category 2 CSPs to ensure proper cleaning and disinfecting procedures are in place and effective. For Category 3 CSPs, surface sampling must be completed prior to assigning a Beyond Use Date (BUD) and at least weekly thereafter. Surface sampling must also be conducted after compounding each batch. If a self-enclosed robotic compounding device is used, surface sampling must be conducted at least once daily at the end of compounding operations, but before cleaning and disinfection.

Media-Fill Testing and Aseptic Techniques:

Competency testing in aseptic manipulation is designed to simulate the compounding procedures a person in a CSP will encounter. Throughout this challenge, the subject will complete the evaluation to ensure that the sterility of the CSP is not compromised by contamination risks or personnel error. For Category 1 and 2 CSPs, media-fill testing must be conducted every 6 months for compounding personnel, and every 3 months for Category 3 CSPs.

Gloved Fingertip Sampling:

Directly following the media-fill or aseptic challenge, gloved fingertip and thumb sampling must be completed on both hands. A result of ≤3 cfu is considered successful for the personnel completing the evaluation. This sampling is the last step in ensuring that your facility has proper SOPs in place and can perform CSOs with risk contamination measures in place and effective.



Viable Air Sampling:

Facilities used for compounding CSPs are designed specifically to minimize the risk of airborne contamination. ISO classifications are standards that must be tested against using viable air sampling. Under the revised guidelines, a baseline air sampling has to be performed to establish the air quality for all compounding locations. Viable air sampling must still be conducted every 6 months for Category 1 and 2 CSPs. However, Category 3 CSPs now require sampling within 30 days prior to the start of compounding and monthly thereafter.

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