

USP <797> Sampling Analysis and Supplies

The USP <797> chapter covers standards for compounded sterile preparations (CSPs) and requirements to minimize microbial contamination in these environments. The chapter sets regulations for the types of testing, action levels and frequency for monitoring areas most prone to contamination during compounding. Your compliance plan should include the testing method listed below along with documentation and regular reschedule.

Viable Air Sampling



Monthly Surface Sampling



Gloved Fingertip Sampling



Media Fill Kit Sampling



| Matrix | Analysis | Supplies |
|-----------------------|---|---|
| Air | Bacterial Counts to genus level as per new revision Fungal Counts to genus level as per new revision | TSA petri plates or contact plates SabDex petri plates or contact plates |
| Surface | Bacterial Counts to genus level as per new revision Fungal Counts to genus level as per new revision | TSA contact plates, 15x65mm SabDex contact plates, 15x55mm |
| Glove Fingertip (GFT) | Bacterial culture with counts Fungal culture with counts | TSA petri plates, 15x100mm |
| Media Fill | Sterility competency for media fill GFT and surface sampling must be performed immediately following the media fill test | <i>Kits include:</i> Empty sterile Bags Empty sterile vials Sterile Tryptic Soy Broth Bag Sterile Tryptic Soy Broth Vials Syringe(s) |

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