# USP <797> Sampling

## Air and Surface Sampling for USP <797>

### Objective

- To perform environmental monitoring in the context of USP general chapter Pharmaceutical Compounding – Sterile Preparations. To detect and quantify viable particles (bacteria or fungi) in ISO-classified cleanrooms.
- Cleanroom ISO classifications include direct compounding area (ISO5), buffer room (ISO7) and ante room (ISO8).

### Advantages and Disadvantages

- **Advantages**
  - Concrete instructions and guidance for air and surface sampling.
  - Culturable samples allow for isolation and identification of the organisms.
- **Disadvantages**
  - Sterility during the process of sampling including garbing and disinfection of sampling equipment are crucial to the sampling process.
  - Relatively high sample volumes are required for air samples.
  - Results for culture testing require time and cannot be rushed.

### Equipment

- Impactor air sampler with ability to pull 1000 liters at high flow rate without drying out plates for air sampling.
- Sterile contact plates with appropriate media or sterile swabs for surface sampling.

### Sampling Protocols

- **Air sampling:** Prepare carefully for the sampling including garbing and disinfection of equipment. When setting up the sampling pull 1000 liters or more for ISO5 classified areas and 400 – 1000 liters or more for ISO 7 and ISO 8 classified areas. Take a least one sample for each ISO classified area for routine monitoring. For all air monitoring use media that supports broad range of bacteria as well as yeast and other fungi (e.g. Tryptic Soy Agar, TSA). For monitoring of complex compounding activities and/or if a final sterilization step is required (high risk sterile compounding) perform additional testing with media that support broad fungal growth (e.g. Malt Extract Agar, MEA).
- **Surface sampling:** Media used for surface sampling (contact plates) shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g. TSA with lecithin and polysorbate 80). Alternatively, sterile swabs may be used for surface sampling. Swab area equivalent to the size of contract plates (24 – 30 $cm^2$).
- Air sampling shall be performed at least semiannually (i.e. every 6 months), as part of the re-certification of facilities and equipment, and if the facility undergoes construction or equipment servicing or re-location. Surface sampling is performed "periodically" (typically together with air sampling).
- Gloved fingertip and media-fill testing are part of personnel training covered in the USP general chapter <797>.
- See USP chapter <797> for interpretation of results.

## Shipping

- Samples should be shipped to the laboratory for overnight delivery. Protect samples from physical damage and avoid/address potential extremes (e.g. in hot season use cooler and add cold packs).

## References


- USP Compounding Compendium (available at USP.org).
- Eurofins Built Environment USP <797> Sampling Instructions - Surface Testing