

Surface Sampling

Every pharmacy must develop an environmental sampling plan to check for microbial contamination in the compounding area. The plan will include sampling for airborne viable particles and conducting surface sampling. The sampling plan will detail where samples are taken, how samples are taken, when samples are taken and under what conditions. This article details the requirements of surface sampling; an earlier article addressed viable air sampling.

Surface sampling is useful in evaluating the facility's cleaning and disinfecting procedures and compounders' work practices. On a periodic basis the facility shall sample areas with the greatest risk of contamination in all ISO classified areas. These areas include the work surface inside the hood, counters and work areas in the buffer and ante areas and any pass-through. Growth media must be adequate to support microbial growth and also be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80). Surfaces may be sampled with either a contact plate or via the swab method. The media plate shall be properly incubated, for example, TSA with lecithin and polysorbate would be incubated at 30 to 35 degrees for 48 to 72 hours. The number of cfu per contact plate is counted after incubation.

All cfu shall be analyzed down to the genus because highly pathogenic microorganisms require immediate remedy. Any growth of the following microorganisms: gram-negative rods, coagulase positive staphylococcus, mold and yeast requires action. The action limits for other microorganisms are below:

ISO Classification	CFU per Contact Plate
ISO Class 5	>3
ISO Class 7	>5
ISO Class 8	>100

Facilities must track and trend the data collected in the environmental sampling plan to evaluate the overall control of the compounding environment. If a sampled area consistently shows growth the facility shall also take action and consult with competent microbiology personnel.

When responding to microbial growth the facility should re-evaluate procedures and shall investigate into the source of the contamination. Procedures such as personnel work practices, cleaning procedures, and operational procedures should be evaluated. Possible sources of contamination include HVAC systems, HEPA filters, and personnel. After identifying and correcting potential sources of contamination and correcting procedural concerns the facility shall clean the area and resample.