

Environmental Monitoring - Sterile Compounding

Viable Air Sampling— A sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites should include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the compounding areas at greatest risk of contamination. The plan should include sample location (map), method of collection (active), frequency of sampling (at least semiannually), volume of air sampled (min 1000 liters), and time of day as related to activity in the compounding area and action levels.

Sampling data should be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. Any cfu count that exceeds its respective action level shall prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.

Surface Sampling - Surface sampling shall be performed in all ISO classified areas on a periodic basis* and can be accomplished using contact plates and/or swabs and shall be done at the conclusion of compounding. with a non-shedding wipe soaked in sterile 70% IPA. Results shall be reported as cfu per unit of surface area. The size of the plate to be used for each sampled location usually ranges from 24 to 30 cm². Contact plates are filled with general solid agar growth medium and neutralizing agents above the rim of the plate, and they are used for sampling regular or flat surfaces. Swabs may be used for sampling irregular surfaces, especially for equipment. Locations to be sampled should be defined in a sample plan or on a form. Immediately after sampling a surface with the contact plate, the sampled area shall be thoroughly wiped

Incubation periods: TSA should be incubated at 35° ± 2 ° for 2–3 days. MEA or other suitable fungal media (SDA) should be incubated at 28° ± 2 ° for 5–7 days.

Recommended Action Levels for Microbial Contamination

ISO Class	Active Airborne (cfu*/m ³)	Glove Fingertip (cfu/contact plate)	Inanimate Surfaces (cfu/contact plate)
5	> 1	> 3	> 3
7	> 10	not required	> 5
8	> 100	not required	> 100

* cfu = colony forming units

Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level). Highly pathogenic microorganisms can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

**recommended weekly, alternating TSA and MEA or SDA - per LDT Health Solutions
 Source: USP Chapters <797>, <1116> 2015*