

Table 13-3A Class 100 Monitoring

Country document	U.S. standard	USP < 1116>	EU (at rest)	EU (dynamic)	EU (dynamic)	ISO 14644-1
Classification	M3.5 (100)	M3.5	A and B	A	B	5
Frequency of monitoring	Not stated	Each operating shift	Not stated	Frequent, using a variety of methods	Frequent, using a variety of methods	Not stated
Total particle count	3500/m ³ or 100/ft ³ ≥ 0.5 μm	100/ft ³ ≥ 0.5 μm	3500/m ³ ≥ 0.5 μm	3500/m ³ ≥ 0.5 μm	350,000/m ³ ≥ 0.5 μm	3520/m ³ ≥ 0.5 μm
Airborne viable units	Not stated	0.1 CFU/ft ³	0/m ³ ≥ 5 μm Not stated	0/m ³ ≥ 5 μm <1 CFU/m ³ Settle plate (90 mm) <1 CFU/4 hr	2000/m ³ ≥ 5 μm <10 CFU/m ³ Settle plate (90 mm) 5 CFU/4 hr	29/m ³ ≥ 5 μm Not stated
Surface viable units (except floors)	Not stated	3 CFU/plate	Not stated	<1 CFU/plate	5 CFU/plate	Not stated
Surface viable units—floors	Not stated	3 CFU/plate	Not stated	<1 CFU/plate	5 CFU/plate	Not stated
Personnel gown	Not stated	3 CFU/plate	Not stated	Not stated	Not stated	Not stated
Personnel gloves	Not stated	3 CFU/pl	Not stated	Glove-5 fingers <1 CFU/glove	Glove-5 fingers 5 CFU/glove	Not stated
Air velocity unidirectional	Not stated	Not stated	0.45 m/sec ± 20%	0.45 m/sec ± 20%	Not appropriate	Not stated
Frequency of ΔP monitoring	Not stated	Each shift	Not stated	Continuous	Continuous	Not stated

Grade A—Terminally sterilized products—filling of these products.

Grade B—Aseptically prepared products—aseptic preparation and filling; handling of sterile starting materials and components; transfer of partially closed containers in open trays.

Source: From Ref. 11.

scattered from particles as they pass through the cell of the optical system (e.g., of suppliers: *Climet*, *HIAC Royco*, *Met One*, *Particle Measuring Systems*).

Principle of Light Scattering

When a beam of light strikes a solid object, three events occur: some of the light is absorbed, some of the light is transmitted, and the rest of the light is scattered. Scattered light is a composite of diffracted, refracted, and reflected light. Particle counters that operate on the basis of light scattering are designed to measure the intensity of light scattered at fixed angles to the direction of the light beam (see chap. 29 for more details).

As liquid flows into a light-sensing zone, particles in the fluid scatter light in all directions. The scattered light is directed onto a system of elliptical mirrors which then focus the light onto a photodetector. The light trap is designed to absorb most of the main light beam photons.

Met One and Climet particle counters represent examples of counters operating under this principle. Met One particle counters are laser-based particle counters that have become very popular instruments in the pharmaceutical industry both for airborne and liquid-borne particles. These instruments not only count particles but also provide a size distribution based on the magnitude of the light scattered from the particle. While a volume of air measured by an electronic particle counter will detect all particles instantly, these instruments cannot differentiate between viable (e.g., bacterial and fungal) and nonviable ones. However, because of the need to control the level of microorganisms in the environment in which sterile products are processed, it is also necessary to detect viable particles.