

Table 13-3B Class 10,000 Monitoring

Country document	U.S. standard	USP < 1116 >	EU (at rest)	EU (Dynamic)	ISO 14644-1
Classification	M5.5 (10,000)	M5.5	C	C	7
Frequency of monitoring	Not stated	Each operating shift	Not stated	Not stated	Not stated
Total particle count	353,000/m ³ or 1000/ft ³ ≥ 0.5 μm	10,000/ft ³ ≥ 0.5 μm	350,000/m ³ ≥ 0.5 μm	3,500,000/m ³ ≥ 0.5 μm	352,000/m ³ ≥ 0.5 μm
Airborne viable units	Not stated	0.5 CFU/ ft ³	2000/m ³ ≥ 5 μm	20,000/m ³ ≥ 5 μm <100 CFU/ m ³ Settle plate (90 mm) 50 CFU/4 hrs	930/m ³ ≥ 5 μm
Surface viable units (except floors)	Not stated	5 CFU/plate	Not stated	25 CFU/plate	Not stated
Surface viable units—floors	Not stated	10 CFU/plate	Not stated	Not stated	Not stated
Personnel gown	Not stated	20 CFU/plate	Not stated	Not stated	Not stated
Personnel gloves	Not stated	10 CFU/pl	Not stated	Not stated	Not stated
Frequency of ΔP monitoring	Not stated	Each shift twice/week	Not stated	Not stated	Not stated

Grade C—Terminally sterilized products—preparation of solutions and filling of these products.

Aseptically prepared products—preparation of solutions to be sterile filtered.

Adjacent to Class 100.

Source: From Ref. 11.

Table 13-3C Class 100,000 Monitoring

Country document	U.S. standard	USP < 1116 >	EU (at rest)	EU (dynamic)	ISO 14644-1
Classification	M6.5 (100)	M6.5	D	D	8
Frequency of monitoring	Not stated	Twice a week	Not stated	Not stated	Not stated
Total particle count	3,533,000/m ³ or 100,000/ft ³ ≥ 0.5 μm	100,000/ft ³ ≥ 0.5 μm	3,500,000/m ³ ≥ 0.5 μm	Not stated	3,520,000/m ³ ≥ 0.5 μm
Airborne viable units	Not stated	2.5 CFU/ft ³	20,000/m ³ ≥ 5 μm	200 CFU/m ³ Settle plate (90 mm) 100 CFU/4 hr	29,300/m ³ ≥ 5 μm
Surface viable units (except floors)	Not stated	Not stated	Not stated	50 CFU/plate	Not stated
Surface viable units—floors	Not stated	Not stated	Not stated	Not stated	Not stated
Frequency of ΔP monitoring	Not stated	Weekly	Not stated	Continuous	Not stated

Grade D—Terminally sterilized products—preparation of solutions and components for subsequent filling.

Aseptically prepared products—handling of components after washing.

Source: From Ref. 11.

VIABLE PARTICLES

Viable particles usually are fewer in number than nonviable ones and are detectable as CFUs after a suitable incubation period at, for example, 30°C to 35°C for up to 48 hours. Thus, test results will not be known for 48 hours after the samples are taken, although eventually rapid-acting microbiological test methods will obviate the need for incubation time beyond an hour or two.