

Monitoring Guidance	U.S. FDA (Aseptic Processing Guidance)	USP <1116>	EU Annex 1, PIC/S and WHO Annex 4	Japan (Aseptic Processing Guidance)	JP XVI
Frequency (Airborne total particulate and viable count. Surface viable count. Personnel sampling as noted)	Class 100: Each production shift. Gloves daily or each lot. Other classes not specified.	ISO 5: Each production shift. ISO 7: Each operating shift. ISO 8: Twice per week.	A: In operation, continuous particulate monitoring required for critical operations. Frequent viable sampling. B: In operation, frequent particle monitoring is required. C, D: Monitoring on risk basis. Surfaces and personnel should be monitored after critical operations.	A, B: Each operating shift for airborne micro, surfaces and personnel; continuous particulate monitoring. C, D: Airborne micro twice per week; airborne particulate once per month; personnel not required.	A: Each operating shift. B: Each operating shift. C, D (potential product/container contact): Twice per week C, D (no potential product/container contact): Once per week
Airborne viable action levels (Active air sampling)	Class 100: 1 CFU/m ³ Class 10,000: 10 CFU/m ³ Class 100,000: 100 CFU/m ³	Recommends use of incident rate (% of samples with micro contamination) rather than count levels, as follows ⁽²⁾ : ISO 5: <1% ISO 7: <5% ISO 6: <3% ISO 8: <10% Applies to all active air, passive air, and surface samples.	A: <1 CFU/m ³ C: 100 CFU/m ³ B: 10 CFU/m ³ D: 200 CFU/m ³	A: <1 CFU/m ³ C: 100 CFU/m ³ B: 10 CFU/m ³ D: 200 CFU/m ³	A: <1 CFU/m ³ C: 100 CFU/m ³ B: 10 CFU/m ³ D: 200 CFU/m ³ 0.5 m ³ sample required for A, B 0.2 m ³ sample required for C, D
Airborne viable action levels (Passive air sampling)	Class 100: 1 CFU Class 10,000: 5 CFU Class 100,000: 50 CFU 90 mm diameter settle plate/4 hr Use of settling plates is optional.	Same sample incident rate as active air. 90 mm diameter settle plate/4 hr	A: <1 CFU/m ³ C: 50 CFU/m ³ B: 5 CFU/m ³ D: 100 CFU/m ³ 90 mm diameter settle plate/4 hr	A: <1 CFU/m ³ C: 50 CFU/m ³ B: 5 CFU/m ³ D: 100 CFU/m ³ 90 mm diameter settle plate/4 hr.	Not specified
Surface Viables Action Levels ⁽³⁾	Not specified	Same sample incident rate as active air. Use contact plate or swab.	A: <1 C: 25 B: 5 D: 50 55 mm diameter contact plate	A: <1 C: 25 B: 5 D: 50 24–30 cm ² contact or swab area	A: <1 C: 25 B: 5 D: 50 24–30 cm ² (5.4–6.2 cm diameter contact or 25 cm ² swab area)
Personnel viables action levels (gown)	Not specified. Gown sampling must be established based on job responsibility.	Same sample incident rate as active air. ⁽⁴⁾	Not specified	Not specified	Not specified
Personnel viables action levels (gloves)	Not specified	Same sample incident rate as active air.	Glove print, 5 fingers A: <1 CFU/glove B: <5 CFU/glove	Glove print, 5 fingers A: <1 CFU/5 fingers B: <5 CFU/5 fingers	Glove print, 5 fingers A: <1 CFU/5 fingers B: <5 CFU/5 fingers