

Manual 054

6 Appendices

Appendix A - Comparison table particles, EU GMP Annex 1, FDA Guidance for Industry “Sterile Drug Products Produced by Aseptic Processing” and ISO 14644-1.

EU GMP Annex 1					FDA		ISO 14644-1	
Grade	At rest		In operation		Description	In operation	In operation	
	Maximum permitted number of particles/m ³ equal to or above		Maximum permitted number of particles/m ³ equal to or above			Maximum permitted number of particles/m ³ equal to or above	Maximum permitted number of particles/m ³ equal to or above	
	0,5 µm	5 µm	0,5 µm	5 µm		0,5 µm	ISO Class	0,5 µm
A	3.500	1	3.500	1	Critical	3.520	5	3.520
B	3.500	1	350.000	2.000	Supporting Clean Area	352.000	7	352.000
C	350.000	2.000	3.500.000	20.000	Supporting Clean Area	3.520.000	8	3.520.000
D	3.500.000	20.000	-	-	-	-	9	35.200.000

* - = not defined