Produzieren unter GMP-Reinraumbedingungen

EU Guidelines to
Good Manufacturing Practise
Medicinal Products for Human and Veterinary Use

Annex 1
Manufacturing of Sterile Medicinal Products

1. Clean room and clean air device classification

	Maximum permitted number of particles per m³ equal to or greater than the tabulated size			
	At rest		In operation	
Grade	0.5 µm	5.0 µm	0.5 µm	5.0 µm
A	3.520	Not specified (a)	3.520	Not specified (a)
B	3.520	Not specified (a)	352.000	2.900
C	352.000	2.900	3.520.000	29.000
D	3.520.000	29.000	Not Predetermined (b)	Not Predetermined (b)

(a) Classification including 5µm particles considered where indicated by the CCS or historical trends.
(b) For Grade D, in operation limits are not permidetermined. The manufacturer should establish in operations limits based on a risk assessment and routine data where applicable.

2. Recommended limits for microbiological monitoring of clean areas during operation:

	Recommended limits for microbial contamination (c)			
Grade	air sample cfu/m³	settle plates (diameter 90 mm) cfu/4 hours (d)	contact plates (diameter 55 mm) cfu/plate	glove print 5 fingers cfu/glove
A	< 1	< 1	< 1	< 1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

(c) These are average values.
(d) Individual settle plates may be exposed for less than 4 hours.

Stand September 2023

GREEN CLEANROOM®
Rein in die Zukunft

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