

Produzieren unter Reinraumbedingungen

Vergleich verschiedener Reinraumklassen Comparison of different cleanroom classes

ISO 14644-1:2016		9	8	7	6	5	4	3	2	1
Maximale Partikelzahl pro m ³ größer gleich Maximum permitted number of particles per m ³ greater than	5,0 µm	293'000	29'300	2'930	293	-	-	-	-	-
	1,0 µm	8'320'000	832'000	83'200	8'320	832	83	-	-	-
	0,5 µm	35'200'000	3'520'000	352'000	35'200	3'520	352	35	-	-
	0,3 µm	-	-	-	102'000	10'200	1'020	102	10	-
	0,2 µm	-	-	-	237'000	23'700	2'370	237	24	-
	0,1 µm	-	-	-	1'000'000	100'000	10'000	1'000	100	10
Maximale Partikelzahl pro ft ³ größer gleich Maximum permitted number of particles per cuft greater than	5,0 µm	-	700	70	7	-	-	-	-	-
	1,0 µm	-	23'000	2'300	230	-	-	-	-	-
	0,5 µm	-	100'000	10'000	1'000	100	10	1	-	-
	0,3 µm	-	-	-	-	300	30	3	-	-
	0,2 µm	-	-	-	-	750	75	8	-	-
	0,1 µm	-	-	-	-	-	350	35	-	-
Lüftungsart		turbulente Mischlüftung	turbulente Mischlüftung	turbulente Mischlüftung	annähernd turbulenzarme Verdrängungs- lüftung	turbulenzarme Verdrängungs- lüftung	turbulenzarme Verdrängungs- lüftung	turbulenzarme Verdrängungs- lüftung	turbulenzarme Verdrängungs- lüftung	turbulenzarme Verdrängungs- lüftung
Type of airflow		non laminar flow	non laminar flow	non laminar flow	almost laminar flow	laminar flow	laminar flow	laminar flow	laminar flow	laminar flow
Luftwechsel ISO Air change	h-1	5 - 10	10 - 20	30 - 70	70 - 160	330 - 530	530 - 600	530 - 600	> 700	> 800

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SCHILLING
ENGINEERING
Industrial Handling
Cleanroom Systems

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 m ³ 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 predetermined. 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/m ³	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.

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