

# Standards, Regulations and Recommendations

Classification as per Eurovent 4/4 recommendation, NaCl method

EUROVENT 4/4 Filter class	Initial efficiency Ei (%)	Penetration Pi (%)
Limits of filter classes		
EU 10	95 ≤ Ei < 99.9	5 ≥ Pi > 0.1
EU 11	99.9 ≤ Ei < 99.97	0.1 ≥ Pi > 0.03
EU 12	99.97 ≤ Ei < 99.99	0.03 ≥ Pi > 0.01
EU 13	99.99 ≤ Ei < 99.999	0.01 ≥ Pi > 0.001
EU 14	99.999 ≤ Ei	0.001 ≥ Pi

## Clean rooms

Classification of different air qualities required for manufacture of sterile products

	Maximum number of particles per m <sup>3</sup> of a size greater than or equal to				
	0.5 μm	5 μm	0.5 μm	5 μm	Max. nbr. of μorganisms per m <sup>3</sup> (active)
	inactive (b)		active		
A	3.500	0	3.500	0	< 1
B	3.500	0	350.000	2.000	10
C	350.000	2.000	3.500.000	20.000	100
D	3.500.000	20.000	not defined (c)	not defined (c)	200

## Pharmaceutical industry

Pharmaceutical industry

Guide to Good Manufacturing Practice (2002)

(b) Corresponds approximately to the US Federal Standard 209 E and ISO as follows: classes A and B to class 100. M 3.5. ISO 5; class C to class 10,000. M 5.5. ISO 7; class D to class 100,000. M 6.5 ISO 8.

Comparison of international classification standards

Nbr of part 0.5 μm/ m³ (approx.)	US Fed. Std 209 E 1992	EN ISO 14644 -1 1996	France AFNOR NF X 44.101 1981	European Union Pharma Industry Guide GMP 1989	Nbr of part 0.1 μm/ m³ (approx.)	
-	-	-	ISO 1	-	10	
1	-	-	-	-	35	
4	-	-	ISO 2	-	100	
10	M 1	-	-	-	350	
35	M 1.5	1	ISO 3	-	1,000	
100	M 2	-	-	-	3,500	
353	M 2.5	10	ISO 4	-	10,000	
1,000	M 3	-	-	-	35,000	
3,530	M 3.5	100	ISO 5	4,000	A and B	100,000
10,000	M 4	-	-	-	-	350,000
35,300	M 4.5	1,000	ISO 6	-	-	1,000,000
100,000	M 5	-	-	-	-	-
353,000	M 5.5	10,000	ISO 7	400,000	C	-
1,000,000	M 6	-	-	-	-	-
3,530,000	M 6.5	100,000	ISO 8	4,000,000	D	-
10,000,000	M 7	-	-	-	-	-
35,000,000	-	-	ISO 9	-	-	-

Permissible particle levels in different classes of clean rooms and clean zones

ISO classification CD 14644-1 (1996)	Maximum permissible concentrations (particles/m <sup>3</sup> of air) of particles of a size greater than or equal to the size shown below					
	0.1 μm	0.2 μm	0.3 μm	0.5 μm	1 μm	5 μm
ISO 1	10	2	-	-	-	-
ISO 2	100	24	10	4	x	-
ISO 3	1,000	237	102	35	8	-
ISO 4	10,000	2,370	1,020	352	83	-
ISO 5	100,000	23,700	10,200	3,520	832	29
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7	-	-	-	352,000	83,200	2,930
ISO 8	-	-	-	3,520,000	832,000	29,300
ISO 9	-	-	-	35,200,000	8,320,000	293,000

$$C = 10N(0.1/D)2.08 \text{ part / m}^3$$

## US Fed Std 209 E (1992)

		Class Limits				
Class Name		0.1 μm	0.2 μm	0.3 μm	0.5 μm	5 μm
		Volume Units	Volume Units	Volume Units	Volume Units	Volume Units
S1 English		m <sup>3</sup>	m <sup>3</sup>	m <sup>3</sup>	m <sup>3</sup>	m <sup>3</sup>
M 1	-	350	75.7	30.9	10.0	-
M 1.5	1	1,240	265	106	35.3	-
M 2	-	3,500	757	309	100	-
M 2.5	10	12,400	2,650	1,060	353	-
M 3	-	35,000	7,570	3,090	1,000	-
M 3.5	100	-	26,500	10,600	3,530	-
M 4	-	-	75,700	30,900	10,000	-
M 4.5	1000	-	-	-	35,300	247
M 5	-	-	-	-	100,000	618
M 5.5	10,000	-	-	-	353,000	2,470
M 6	-	-	-	-	1,000,000	6,180
M 6.5	100,000	-	-	-	3,530,000	24,700
M 7	-	-	-	-	10,000,000	61,800

$$\text{particles / m}^3 = 10M(0.5/d)2.2$$

$$\text{particles / ft}^3 = Nc(0.5/d)2.2$$