

Standards, Regulations and Recommendations

EN 1822:2009 Classification

class 10,000. M 5.5. ISO 7; class D to class 100,000. M 6.5 ISO 8.

Filter group	Filter class	MPPS integral values		MPPS local values			
		Minimum efficiency (%)	Maximum penetration (%)	Minimum P.C.	Minimum efficiency (%)	Maximum penetration (%)	Minimum P.C.
EPA (E)	E10	85	15	6.7	-	-	-
	E11	95	5	20	-	-	-
	E12	99.5	0.5	200	-	-	-
HEPA (H)	H13	99.95	0.05	2,000	99.75	0.25	400
	H14	99.995	0.005	20,000	99.975	0.025	4,000
ULPA (U)	U15	99.9995	0.0005	200,000	99.9975	0.0025	40,000
	U16	99.99995	0.00005	2,000,000	99.99975	0.00025	400,000
	U17	99.999995	0.000005	20,000,000	99.99999	0.0001	1,000,000

EPA : Efficiency Particulate Air (filter)
 HEPA : High Efficiency Particulate Air (filter)
 ULPA : Ultra Low Penetration Air (filter)
 P.C. : Purification Coefficient

Classification as per Eurovent 4/4 recommendation, NaCl method

EUROVENT 4/4	Initial efficiency Ei (%)	Penetration Pi (%)
Filter class	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 ³ of a size greater than or equal to				Max. nbr: of μorganisms per m ³ (active)
	0.5 μm	5 μm	0.5 μm	5 μm	
	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

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 on CD 14644-1 (1996)	Maximum permissible concentrations (particles/m ³ 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 part / m³