

# Cleanroom Standards

BS EN ISO 14644-1:1999.

Table 1 : Selected airborne particulate cleanliness classes for cleanrooms and clean zones

ISO Classification Number (N)	Maximum concentration limits (particles / m <sup>3</sup> of air) for particles equal to and larger than the considered sizes below						FED STD 209E  Nearest equivalent Class	BS5295 1989  Nearest equivalent Class
	0.1µm	0.2µm	0.3µm	0.5µm	1µm	5µm		
ISO Class 1	10	2						
ISO Class 2	100	24	10	4				
ISO Class 3	1000	237	102	35	8		1	C
ISO Class 4	10000	2370	1020	352	83		10	D
ISO Class 5	100 000	23 700	10 200	3520	832	29	100	E (F)
ISO Class 6	1 000 000	237 000	102 000	35 200	8320	293	1000	H (G)
ISO Class 7				352 000	83 200	2930	10 000	J
ISO Class 8				3 520 000	832 000	29 300	100 000	K
ISO Class 9				35 200 000	8 320 000	293 000		

## EC GMP ANNEX 1 MANUFACTURE OF STERILE MEDICINAL PRODUCTS

Airborne particulate classification

GRADE	at rest		in operation	
	Maximum permitted number of particles / m <sup>3</sup> equal to or above			
	0.5µm	5µm	0.5µm	5µm
A	3500	0	3500	0
B	3500	0	350 000	2000
C	350 000	2000	3 500 000	20 000
D	3 500 000	20 000	not defined	not defined

The particulate conditions given in the table for the at rest state should be achieved in the unnamed state after a short clean up period of 15-20 minutes (guidance value), after completion of operation

## Recommended limits for microbiological monitoring of clean areas during operation

GRADE	Recommended limits for microbial containment			
	Air sample cfu/m <sup>3</sup>	Settle Plates (diam.90mm) cfu/4 hours	contact plates (diam.55mm) 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	-