MAXIMUM ACTION LIMITS FOR MICROBIAL CONTAMINATION

GMP Grade	Air Sample CFU/m³	Settle plates (Ø 90mm) CFU/4 hours	Contact plates (Ø 55mm) CFU/plate	Glove print 5 fingers, both hands CFU/glove
A	No growth			
B	10	5	5	5
C	100	50	25	–
D	200	100	50	–

SCHEDULE OF TESTING TO DEMONSTRATE COMPLIANCE FOR ALL ISO CLASSES

Test parameter	Max. time interval	Classification	Test method
Particle count test	6 months	≤ ISO Class 5	ISO 14644-1
Particle count test	12 months	> ISO Class 5	ISO 14644-1
Airflow volume or velocity	12 months	All Classes	ISO 14644-3
Air pressure difference	12 months	All Classes	ISO 14644-3
Airflow visualization	24 months	All Classes	ISO 14644-3
Recovery test	24 months	All Classes	ISO 14644-3

SCHEDULE OF TESTING TO DEMONSTRATE COMPLIANCE FOR ALL GRADES ACCORDING TO GMP ANNEX 1

GMP Grade	A	B	C	D
Suggested time interval for requalification of cleanroom*	6 months	6 months	12 months	12 months

* The frequency must be justified based on risk within the CCS (contamination control strategy)

DIFFERENT CLEANROOM CLASSES ACCORDING TO ISO 14644 AND FED STD 209E

ISO Class	FED STD 209E equivalent	Maximum particles /m^3 (at rest and in operation)					
		≥ 0.1 µm	≥ 0.2 µm	≥ 0.3 µm	≥ 0.5 µm	≥ 1 µm	≥ 5 µm
ISO 1		10					
ISO 2		100	24	10			
ISO 3	Class 1	1.000	237	102	35		
ISO 4	Class 10	10.000	2.370	1.020	352	83	
ISO 5	Class 100	100.000	23.700	10.200	3.520	832	
ISO 6	Class 1.000	1.000.000	237.000	102.000	35.200	8.320	293
ISO 7	Class 10.000				352.000	83.200	2.930
ISO 8	Class 100.000				3.520.000	832.000	29.300
ISO 9	Room air				35.200.000	8.320.000	293.000

MAXIMUM PERMITTED TOTAL PARTICLE CONCENTRATION FOR CLASSIFICATION ACCORDING TO GMP ANNEX 1

GMP Annex 1	Maximum particles/m^3			
	At rest		In operation	
	≥ 0.5 µm	≥ 5 µm	≥ 0.5 µm	≥ 5 µm
GMP Grade A	3.520	Not specified (a)	3.520	Not specified (a)
GMP Grade B	3.520	Not specified (a)	352.000	2.930
GMP Grade C	352.000	2.930	3.520.000	29.300
GMP Grade D	3.520.000	29.300	Not pre-determined (b)	Not pre-determined (b)

NOTE GMP ANNEX 1

(a) Classification including 5 µm particles may be considered where indicated by the contamination control strategy (CCS) or historical trends.
(b) For grade D, in operation limits are not predetermined. The manufacturer should establish in operation limits based on a risk assessment and routine data where applicable.