

HVAC QUALIFICATION

Sr. No.	Test	Frequency		
		Period	Times	
			Initial	Re-Qualification (Periodic)
1.	Air Velocity/ Air Changes Per Hour/Airflow Volume	Six Months	Once	Once
2.	HEPA Filter Integrity	Six Months	Once	Once
3.	Differential Air Pressure	Six Months	For 7 days	For 3 Days
4.	Temperature and Relative Humidity	Six Months	For 7 days	For 3 Days
5.	Non-Viable Airborne Particulate Count (Static & Dynamic)	Six Months	For 7 days At Static For 7 days At Dynamic	Once (For 1 day)
6.	Viable Particulate Count	Six Months	For 7 Days	For 3 Days
7.	Recovery Test	One Year	Once	Once
8.	Air Flow Pattern	Twenty Four Months	Once	Once

Grade	Maximum Number of Permitted Particles/m ³ equal to or above				Recommended Limit for Microbial Contamination	
	At Rest (Static)		Sample (cfu/m ³)At Operation (Dynamic)		Microbial Active Air Sample (cfu/m ³)	Microbial Passive Sample (dia.90mm; cfu/4hrs)
	≥ 0.5µm	≥ 5.0µm	≥ 0.5µm	≥ 5.0µm		
A	3,520	20	3,520	20	<01	<01
B	3,520	29	3,52,000	2,900	10	05
C	3,52,000	2,900	35, 20,000	29,000	100	50
D	35,20,000	29,000	Not Defined	Not Defined	200	100

Area (Grade)	Sample Volume (Static) in Liter	Sample Volume (Dynamic) in Liter	Times for particle counter operation to get air as per sample volume Capacity of Particle Counter- 28.3 liter/min.*	
			Static	Dynamic
Grade A (ISO-5)	1000	1000	36 minute	36 minute
Grade B(ISO-5)	690	6.9	25 minute	01 minute
Grade C (ISO-7)	6.9	0.69	01 minute	01 minute
Grade D(ISO-8)	0.69	Not Defined	01 minute	Not Defined

Establishment of Single sample volume and sampling time per location

At each sampling location , sample a volume of air sufficient to detect a minimum of 20 particles if the particle concentration for the largest select particle size were at the class limit for the designated ISO class.

The single sample volume, V_s per sampling location is determine by using Formula:

$$V_s = 20 / C_{n,m} \times 1000$$

Where ,

V_s = is the minimum single sample volume per location , expressed in liters.

C_{nm} = is the class limit (number of particles per cubic meter) for the largest considered particle size specified for the relevant class.

20 = is the number of particle that could be counted if the particle concentration were at the class limit.

Grade	Maximum Number of Permitted Particles/m ³ equal to or above			
	At Rest (Static)		Sample (cfu/m ³)At Operation (Dynamic)	
	≥ 0.5µm	≥ 5.0µm	≥ 0.5µm	≥ 5.0µm
A	3,520	20	3,520	20
Formula		$V_s = 20 / C_{n,m} \times 1000$ $V_s = 20/20 \times 1000$ $V_s = 1000 \text{ Liter}$		$V_s = 20 / C_{n,m} \times 1000$ $V_s = 20/20 \times 1000$ $V_s = 1000$
Required Sample Volume in Liter	1000 Liters		1000 Liters	
Times for particle counter operation to get air as per sample volume Capacity of Particle Counter- 28.3 liter/min.	28.3 liter/min = 36 minute 100 liter/min = 10 minute		28.3 liter/min = 36 minute 100 liter/min = 10 minute	
B	3,520	29	3,52,000	2,900
Formula		$V_s = 20 / C_{n,m} \times 1000$ $V_s = 20/29 \times 1000$ $V_s = 689.65 \text{ Liter}$ $V_s = 690 \text{ Liter}$		$V_s = 20 / C_{n,m} \times 1000$ $V_s = 20/2900 \times 1000$ $V_s = 6.89 \text{ Liter}$ $V_s = 6.9 \text{ Liter}$
Required Sample Volume in Liter	690 Liters		6.9 Liters	
Times for particle counter operation to get air as per sample volume Capacity of Particle Counter- 28.3 liter/min.	28.3 liter/min = 25 minute 100 liter/min = 6.9 = 7 minute		28.3 liter/min = 01 minute 100 liter/min = 01 minute	
C	3,52,000	2,900	35, 20,000	29,000
Formula		$V_s = 20 / C_{n,m} \times 1000$ $V_s = 20/2900 \times 1000$ $V_s = 6.89 \text{ Liter}$ $V_s = 6.9 \text{ Liter}$		$V_s = 20 / C_{n,m} \times 1000$ $V_s = 20/29000 \times 1000$ $V_s = 0.689 \text{ Liter}$ $V_s = 0.69 \text{ Liter}$
Required Sample Volume in Liter	6.9 Liters		0.69 Liters	
Times for particle counter operation to get air as per sample volume Capacity of Particle Counter- 28.3 liter/min.	28.3 liter/min = 01 minute 100 liter/min = 01 minute		28.3 liter/min = 01 minute 100 liter/min = 01 minute	
D	35,20,000	29,000	Not Defined	Not Defined
Formula		$V_s = 20 / C_{n,m} \times 1000$ $V_s = 20/29000 \times 1000$ $V_s = 0.689 \text{ Liter}$ $V_s = 0.69 \text{ Liter}$	Not Defined	Not Defined
Required Sample Volume in Liter	0.69 Liters			
Times for particle counter operation to get air as per sample volume Capacity of Particle Counter- 28.3 liter/min.	28.3 liter/min = 01 minute 100 liter/min = 01 minute		Not Defined Not Defined	