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Cheat-Sheet: Clean-Room Classes

ISO 14644-1 Classes	Class 3	Class 4	Class 5	Class 6	Class 7	Class 8
Federal Standard	Class 1	Class 10	Class 100	Class 1000	Class 10000	Class 100000

➢ **Comparison of International Standards**

		Country and Standard				
USA 209D	USA 209E	Britain BS 5295	Australia AS 1386	France AFNOR NFX 44-101	Germany VDI 2083	ISO
		Date of Current Issue				
1988	1992	1989	1989	1981	1990	1999
1	M 1.5	C	0.035	-	1	3
10	M 2.5	D	0.35	-	2	4
100	M 3.5	E or F	3.5	4000	3	5
1000	M 4.5	G or H	35	-	4	6
10000	M 5.5	J	350	400000	5	7
100000	M 6.5	k	3500	4000000	6	8

➢ **EUGGMP 2002 Recommended Limits for Microbial Contamination**

Grade	Air Sample cfu/m3	Settle Plates Dia 90 mm cfu/m3	contact Plates Dia 55 mm cfu/m3	Glove Print 5 fingers cfu/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

Note :

Grade A and B correspond to with class 100, M 3.5, ISO 5
Grade C correspond to with class 10000, M 5.5, ISO 7
Grade D correspond to with class 100000, M 6.5, ISO 8

Merkformel:

Anzahl Nullen der Class + 3 = Grade

CLEAN ROOM MONITORING – REGULATORY STANDARDS

➢ **Air Classification as per Schedule M**

Grade	Maximum permitted number of particles / m3 equal or above			
	at rest		in operation	
	0.5µm	5.0µm	0.5µm	5.0µm
A	3,520	29	3,500	29
B	35,200	293	3,52,000	2,930
C	3,52,000	2,930	35,20,000	29,300
D	35,20,000	29,300	not defined	not defined

Note
Grade A and B correspond to with class 100, M 3.5, ISO 5
Grade C correspond to with class 10000, M 5.5, ISO 7
Grade D correspond to with class 100000, M 6.5, ISO 8

➢ **Air Classifications by USFDA guideline on Sterile Drug Products**

Clean Area Classification	<0.5 µm Particles/ft3	<0.5 µm Particles/mt3	Microbiological Limit	
			cfu/ft3	cfu/m3
100	100	3,500	<1	<3
1000	1000	35,000	<2	<7
10000	10000	350,000	<3	<18
100000	100000	3,500,000	<25	<88

➢ **Air Classifications as per WHO 2002**

Grade	Maximum Number Permitted / M3		
	Particles		Microorganisms
	0.5µm	5.0µm	
A (LAF)	3,500	0	<1
B	3,500	0	5
C	3,50,000	2,000	100
D	3,500,000	20,000	500

Note :

Grade A and B correspond to with class 100, M 3.5, ISO 5
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Grade D correspond to with class 100000, M 6.5, ISO 8

Grade	Maximum Permitted Number of Particles /m3 equal to or above			
	at rest		in operation	
	>= 0.5µm	>= 5.0µm	>= 0.5µm	>= 5.0µm
A	3500	0	3500	0
B	3500	0	350000	2000
C	350000	2000	3500000	20000
D	3500000	20000	not defined	not defined

Note :

Grade A and B correspond to with class 100, M 3.5, ISO 5
Grade C correspond to with class 10000, M 5.5, ISO 7
Grade D correspond to with class 100000, M 6.5, ISO 8

➢ **Cleanroom Environmental Monitoring**

Sr.No.	Test	Frequency
1	Particle Monitoring in air	6 monthly
2	HEPA Filter Integrity Testing	6 monthly
3	Air Changes Rate Calculation	6 monthly
4	Air Pressure Differentials	Daily
5	Temperature and Humidity	Daily
6	Microbiological monitoring by settle plates and / or swabs in aseptic areas	Daily, and at decreased frequency in other areas

➢ **Cleanroom Industry Design Thumb Rule**

ISO Class	Controls	Air Velocity at table level in FPM	Air Changes Rate per Hour	HEPA Coverage as % of Ceiling
1	Stringent	70 - 130	>750	100
2	Stringent	70 - 130	>750	100
3	Stringent	70 - 130	>750	100
4	Stringent	70 - 110	500 - 600	100
5	Stringent	70 – 90	150 - 400	100
6	Intermediate	25 – 40	60 – 100	33 – 40
7	Intermediate	10 – 15	25 – 40	10 – 15
8	Less Stringent	3 – 5	10 – 15	05 – 10

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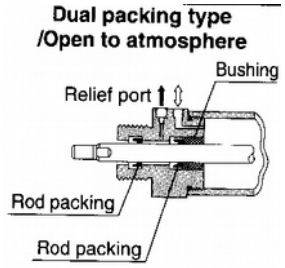

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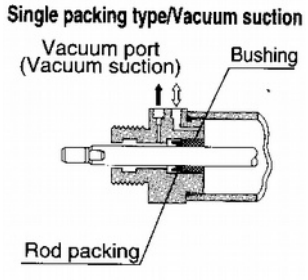

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➢ **Federal Standard 209E Class Limits**

Class Name		>= 0.1µm		>= 0.2µm		>= 0.3µm		>= 0.5µm		>=5.0µm	
Volume Units											
SI	English	m3	ft3	m3	ft3	m3	ft3	m3	ft3	m3	ft3
M 1		350	9.91	75.7	2.14	30.9	0.875	10.0	0.283	--	--
M 1.5	1	1240	35	265	7.50	106	3.00	35.3	1.00	--	--
M 2		3500	99.1	757	21.4	309	8.75	100	2.83	--	--
M 2.5	10	12400	350	2650	75.0	1060	30.0	353	10.0	--	--
M 3		35000	991	7570	214	3090	87.5	1000	28.3	--	--
M 3.5	100	--	--	26500	750	10600	300	3530	100	--	--
M 4		--	--	75700	2140	30900	875	10000	283	--	--
M 4.5	1000	--	--	--	--	--	--	35300	1000	247	7.00
M 5		--	--	--	--	--	--	100000	2830	618	17.5
M 5.5	10000	--	--	--	--	--	--	353000	10000	2470	70.0
M 6		--	--	--	--	--	--	1000000	28300	6180	175
M 6.5	100000	--	--	--	--	--	--	3350000	100000	24700	700
M 7		--	--	--	--	--	--	10000000	283000	61800	1750

➢ **ISO Standard 14644-1 Class Limits**

ISO Classification Number	Maximum concentration limits(Particles/m3 of air) for particles equal to and larger than the considered sizes shown below					
	>= 0.1µm	>= 0.2µm	>= 0.3µm	>= 0.5µm	>= 1.0µm	>= 5.0µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1000	237	102	35	8	
ISO Class 4	10000	2370	1020	352	83	
ISO Class 5	100000	23700	10200	3520	832	29
ISO Class 6	1000000	237000	102000	35200	8320	293
ISO Class 7				352000	83200	2930
ISO Class 8				3520000	832000	29300

Types of Operations for Aseptic Preparations

Grade Types of Opeartions for Aseptic Preparations

A Aseptic preparation and filling
B Background room conditions for activities requiring Grade A
C Preparation of Solution to be filtered
D Handling of components after washing

Note :
Grade A and B correspond to with class 100, M 3.5, ISO 5
Grade C correspond to with class 10000, M 5.5, ISO 7
Grade D correspond to with class 100000, M 6.5, ISO 8

➢ **Particles in Outdoor Air**

Size in Microns	Number of Particles/m3 on Outdoor Air		
	Dirty	Normal	Clean
>0.1	10000000000	3000000000	500000000
>0.3	300000000	90000000	20000000
>0.5	30000000	7000000	1000000

➢ **Schedule of Mandatory Tests to Demonstrate Continuing Compliance in Cleanrooms**

Test Parameter	Class	Maximum Time Interval
Particle Count Test	<= ISO 5	6 months
	> ISO 5	12 months
Air Pressure Difference	All Classes	12 months
Airflow	All Classes	12 months

➢ **Schedule of Optional Tests to Demonstrate Continuing Compliance in Cleanrooms**

Test Parameter	Class	Maximum Time Interval
Installed Filter Leakage	All Classes	24 months
Containment Leakage	All Classes	24 months
Recovery	All Classes	24 months
Airflow Visualization	All Classes	24 months

➢ **Special Requirements for ISO Class 3 Cleanrooms**

Special Requirements for ISO Class 3 Cleanrooms	
Air Quality	Total Hydrocarbons <1 ppm; Na <0.1 µg/m3
Fresh Air Intake	0.5 m3 /min per sqm of cleanroom floor area
Vibration	<0.1 µ (Building); <0.01 µ (Equipment) rms
Noise	< 55 dbA
Temperature	.1 degree C
Humidity	< 2%
Magnetic field var	< 1 mG
Static charge	< 50 v