FLORIDA CLEANROOM SYSTEMS

ISO Class Cleanroom Manufacturing, Design, Build, Certification

ISO Cleanroom Particulate Classifications and Cleanroom Air Change Rates

Maximum Particulate M³

ISO CLASS	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm	209 E
ISO CLASS 1	10	2					
ISO CLASS 2	100	24	10	4			
ISO CLASS 3	1000	237	102	35	8		1
ISO CLASS 4	10,000	2,370	1,020	352	83		10
ISO CLASS 5	100,000	23,700	10,200	3,520	832	29	100
ISO CLASS 6	1,000,000	237,000	102,000	35,200	8,320	293	1,000
ISO CLASS 7				352,000	83,200	2,930	10,000
ISO CLASS 8				3,520,000	832,000	29,300	100,000
ISO CLASS 9				35,200,000	8,320,000	239,000	

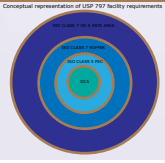
Cleanroom Air Change Rate Comparison

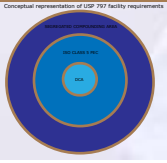
ISO CLASS	209 D	209 E METRIC	EUGGMP	BS 5295	Air Changes Per Hour	Average Airflow Velocity m/s (ft-min)	Ceiling Filter Coverage %
ISO CLASS 1						0.305 - 0.508 (60 - 100)	80% - 100%
ISO CLASS 2						0.305 - 0.508 (60 - 100)	80% - 100%
ISO CLASS 3	1	M 1.5		C	360 -540	0.305 - 0.457 (60 - 90)	60% - 100%
ISO CLASS 4	10	M 2.5		D	300 - 540	0.254 - 0.457 (50 - 90)	50% - 90%
ISO CLASS 5	100	M 3.5	A , B	E , F	240 - 480	0.203 - 0.406 (40 - 80)	35% - 70%
ISO CLASS 6	1,000	M 4.5		G , H	150 - 240	0.127 - 0.203 (25 - 40)	25% - 40%
ISO CLASS 7	10,000	M 5.5	C	J	60 - 90	0.051 - 0.076 (10 - 15)	15% - 20%
ISO CLASS 8	100,000	M 6.5	D	K	5 - 48	0.005 - 0.041 (1 - 8)	5% - 15%
ISO CLASS 9							

Locally Manufactured Velocity® Modular, Conventional, or Hybrid Cleanroom Systems
Designed and Engineered for Regulatory Compliance with FDA, cGMP, USP, ASTM Standards
ISO Class "One Source" Design Build Cleanroom Services ...

USP-797 Cleanroom Particulate Classifications and Cleanroom Air Change Rates

Non-Hazardous Drug Level ≥ + 0.02 - 0.05 WC				Hazardous Drug Level ≥ - 0.01 WC			
Volume	All			≥ 5 Per Week		< 5 Per Week	All
Low or Medium Risk		High Risk		Low or Medium or High Risk		Low or Medium or High Risk	Storage
Cleanroom	Anteroom	Cleanroom	Anteroom	Cleanroom	Anteroom		
ISO Class 7 ≥30 room ACPH or ≥15 room ACPH with recirculating Primary Control providing >15 ACPH	ISO Class 8 ≥20 room ACPH with positive pressure to adjacent areas except to the preparation room. Preparation room should be positive in relation to the anteroom	ISO Class 7 ≥30 room ACPH or ≥15 room ACPH with recirculating Primary Control providing >15 ACPH	ISO Class 8 ≥20 room ACPH with positive pressure to adjacent areas except to the preparation room. Preparation room should be positive in relation to the anteroom	ISO Class 7 ≥30 room ACPH or ≥15 room ACPH with recirculating Primary Control providing >15 ACPH No less than 0.01 inches water column negative to adjacent areas. Pressure indicating device must be installed and monitored.	ISO Class 7, ≥30 room ACPH positive pressure to adjacent areas including the preparation room. Preparation room should be negative in relation to the anteroom.	No negative pressure requirement if two tiers of containment (BSC and CSTD or CACI and CSTD) are used.	HD's must be stored in a room separate from non-hazardous drug storage and shall have sufficient general exhaust to outside of building. This storage may be in the hazardous drug compounding room at ≥ 12 room ACPH.





Abbreviations:
ACPH - Air Changes Per Hour, BSC - Biological Safety Cabinet , CAI - Compounding Aseptic Isolator, CACI - Compounding Aseptic Containment Isolator
CSTD - Closed System Vial Transfer Devices, FPM - Feet per Minute , ISO - International Standards Organization, LAFW - Laminar Air Flow Workbench

* 30 ACPH, + 0.02 WC, - 0.01 WC, will not meet FDA requirements for ISO 7 ACPH, FDA will require 60 - 90 ACPH with + 0.04 WC and - 0.20 WC pressurizations per ISO 14644-1

ISO Class Certified Cleanroom Construction

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