

Bảng So Sánh Các Tiêu Chuẩn Phòng Sạch (Cleanroom Classes)

Cleanroom Classification according to EN ISO 14644-1 – particles per m³ (maximum limit)						
class	≥ 0.1 µm	≥ 0.2 µm	≥ 0.3 µm	≥ 0.5 µm	≥ 1.0 µm	≥ 5.0 µm
ISO 1	10					
ISO 2	100	24	10			
ISO 3	1 000	37	102	35		
ISO 4	10 000	2 370	1 020	352	83	
ISO 5	100 000	23 700	10 200	3 520	832	
ISO 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO 7				352 000	83 200	2 930
ISO 8				3 520 000	832 000	29 300
ISO 9				35 200 000	8 320 000	293 000

Cleanroom Classification acc. to US-FED-STD 209E – particles per ft³ (maximum limit)					
class	≥ 0.1 µm	≥ 0.2 µm	≥ 0.3 µm	≥ 0.5 µm	≥ 5.0 µm
1	35	7	3	1	
10	350	75	30	10	
100		750	300	100	
1 000				1 000	7
10 000				10 000	70
100 000				100 000	700

Note:
The US-FED-STD 209E has been withdrawn on 29/11/01 and hence is no longer valid!
1 ft³ = 0.0283168 m³

GMP Classification – particles per m³ (maximum limit)				
class	At rest		In operation	
	≥ 0.5 µm	≥ 5 µm	≥ 0.5 µm	≥ 5 µm
A	3 520	20	3 520	20
B	3 520	29	352 000	2 900
C	352 000	2 900	3 520 000	29 000
D	3 520 000	29 000	– not defined –	

GMP stands for Good Manufacturing Practice according to Directive (EU) 2003/94/EC, the so-called EU-GMP guideline, supplemented by Directive (EU) 2017/1572

Limits for microbiological contamination (operational)* according to GMP Classification				
class	air germ collector CFU/m³	contact plates Ø 90 mm CFU/4 hours**	contact plates Ø 55 mm 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	-

Notes
(*) these are average values
(**) single sedimentation plates can be exposed less than 4 hours
CFU: colony-forming unit

SCP classification (surface cleanliness) according to EN ISO 14644-9 – particles per m² (maximum limit)									
class	≥ 0.05 µm	≥ 0.1 µm	≥ 0.5 µm	≥ 1.0 µm	≥ 5.0 µm	≥ 10.0 µm	≥ 50.0 µm	≥ 100.0 µm	≥ 500.0 µm
SCP-class 1	(200)	100	20	(10)					
SCP-class 2	(2 000)	1 000	200	100	(20)				
SCP-class 3	(20 000)	10 000	2 000	1 000	200	(100)			
SCP-class 4	(200 000)	100 000	20 000	10 000	2 000	1 000	(200)	(100)	
SCP-class 5		1 000 000	200 000	100 000	20 000	10 000	2 000	1 000	(200)
SCP-class 6		(10 000 000)	2 000 000	1 000 000	200 000	100 000	20 000	10 000	2 000
SCP-class 7				10 000 000	2 000 000	1 000 000	200 000	100 000	20 000
SCP-class 8						10 000 000	2 000 000	1 000 000	200 000

Note:
Values in brackets should not be used for classification purposes – they only serve for orientation.
SCP stands for surface cleanliness by particle concentration.

ISO-ACC-classes according to EN ISO 14644-8			
ISO-ACC-class	concentration		
	g/m³	µg/m³	ng/m³
0	10 ⁰	10 ⁶ (1 000 000)	10 ⁹ (1 000 000 000)
-1	10 ⁻¹	10 ⁵ (100 000)	10 ⁸ (100 000 000)
-2	10 ⁻²	10 ⁴ (10 000)	10 ⁷ (10 000 000)
-3	10 ⁻³	10 ³ (1 000)	10 ⁶ (1 000 000)
-4	10 ⁻⁴	10 ² (100)	10 ⁵ (100 000)
-5	10 ⁻⁵	10 ¹ (10)	10 ⁴ (10 000)
-6	10 ⁻⁶	10 ⁰ (1)	10 ³ (1 000)
-7	10 ⁻⁷	10 ⁻¹ (0.1)	10 ² (100)
-8	10 ⁻⁸	10 ⁻² (0.01)	10 ¹ (10)
-9	10 ⁻⁹	10 ⁻³ (0.001)	10 ⁰ (1)
-10	10 ⁻¹⁰	10 ⁻⁴ (0.0001)	10 ⁻¹ (0.1)
-11	10 ⁻¹¹	10 ⁻⁵ (0.00001)	10 ⁻² (0.01)
-12	10 ⁻¹²	10 ⁻⁶ (0.000001)	10 ⁻³ (0.001)

Note:
ACC means here air cleanliness by chemical concentration

VDI Guidelines 2083 – Cleanroom technology (status February 2020) – Active ¹ / Active, checked ² / Active, checked, draft ³ (German / English version)	
Part 1	Particulate air cleanliness classes ³
Part 2	Stipulations regarding the checking and monitoring of continued compliance with specifications ¹
Part 3	Metrology and test methods of cleanroom air ³
Part 3.1	Metrology in cleanroom air – Monitoring ²
Part 4.2	Energy efficiency ²
Part 5.1	Cleanroom operation ²
Part 7	Ultrapure media – Quality, supply, distribution ¹
Part 8.1	Air cleanliness chemical concentration (ACC) ¹
Part 9.1	Compatibility with required cleanliness and surface cleanliness ²
Part 9.2	Consumables in the cleanroom ¹
Part 12	Safety and environmental aspects ²
Part 13.1	Quality, production and distribution of ultrapure water; Fundamentals ²
Part 13.2	Quality, production and distribution of ultrapure water; Microelectronics and other technical applications ²
Part 16.1	Barrier systems (isolators, mini-environments, cleanroom modules) – Effectiveness and certification ²
Part 17	Compatibility of materials with the required cleanliness ²
Part 18	Bio contamination control ²
Part 19	Tightness of containments, classification, planning and testing ¹
Part 20	Determination of desortions kinetic of materials after gassing ¹
Part 21	Cleaning validation ¹

Current projects ¹ / Draft in preparation ² / Active, reviewed, revision in progress ³ / Active, reviewed, revision draft ⁴	
Part 1.1	Purity in regards to nanoparticles ²
Part 4.1	Planning, construction and start-up of cleanrooms ³
Part 13.3	Quality, production and distribution of ultrapure water; Pharmacy and other life-science applications ⁴
Part 15	Personnel at the clean work place ³
Part 16.2	Barrier systems; Mini-environments ²
Part 22	Measurement of condensing airborne substances ¹
Part 23	Measurement/determination of film-like chemical contaminations, definition of criteria for supplied parts ¹

IEST (Institute of Environmental Sciences and Technology)	
Recommended Practices on non-durable products for cleanrooms and other controlled environments (in English)	
IEST-RP-CC003.4	Garments
IEST-RP-CC004.4	Wiping materials
IEST-RP-CC005.4	Gloves and Fingercots

Additionally further recommended practices (RPs) of the IEST exist on the subject of cleanroom/cleanroom technology.

Standard BS EN ISO 14644 – Cleanrooms and associated controlled environments (status May 2021)	
Part 1	Classification of air cleanliness based on particle concentration
Part 2	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
Part 3	Test method
Part 4	Design, Construction and Start-up
Part 5	Operations
Part 6	Vocabulary
Part 7	Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
Part 8	Classification of air cleanliness by chemical concentration (ACC)
Part 9	Classification of surface cleanliness by particle concentration
Part 10	Classification of surface cleanliness by chemical concentration
Part 12	Specifications for monitoring air cleanliness by nanoscale particle concentration ²
Part 13	Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications
Part 14	Assessment of suitability for use of equipment by airborne particle concentration
Part 15	Assessment of suitability for use of equipment and materials by airborne chemical concentration
Part 16	Energy efficiency in cleanrooms and separative devices
Part 17	Particle deposition rate applications

BS ISO 14644-12²

Book recommendations

Cleanroom Technology (2nd Edition, August 2011)	William Whyte	John Wiley & Sons, Inc.	ISBN 978-1-119-96559-6
GMP-Berater – Kapitel „Hygiene“	Gausepohl/Seyfarth	Maas & Peither GMP Verlag	ISBN 978-3-934971-03-5
Gute Hygiene Praxis (3rd revised and extended edition 2019)	Concept Heidelberg (Ed.)	Editio Cantor Verlag	ISBN 978-3-87193-465-0
Projektplanung Reinraumtechnik	Gail/Gommel/Weißsieker	Hüthig Verlag	ISBN 978-3-7785-4004-6
Reinraum in der pharmazeutischen Industrie (1st edition 2019)	Krebsbach (Ed.)	Editio Cantor Verlag	ISBN 978-3-87193-473-5
Reinraumtechnik (4th edition 2018)	Gail/Gommel/Hortig	Springer Verlag	ISBN 978-3-662-54914-8