

COMPRESSED AIR IN PHARMACEUTICAL ENVIRONMENTS

By Erica Geske



Compressed air is in a key component in many pharmaceutical manufacturing operations. Air power is used in processes such as tablet manufacturing, cleaning and drying, transporting products, packaging and more.¹

Because compressed air has such close proximity to products, extremely high air purity is required. Increasingly stringent regulations on purity have many pharmaceutical manufacturing operations using Clean Room Classifications as outlined by ISO 14644.

What is a clean room?

A clean room is classified by the maximum acceptable number of parts, by size, in the air per cubic meter. Clean rooms must meet stringent regulatory requirements and must be monitored regularly for compliance.

This often means clean rooms require more energy, air, and advanced technology to maintain the required conditions.²

CLEAN ROOM CLASSIFICATIONS^a

Clean Area Classification (0.5mm particles/ft ³)	ISO Designation ^b	≥ 0.5 mm particles/m ³	Microbiological Active Air Action Levels ^c (cfu/m ³)	Microbiological Settling Plates Action Levels (Diam 90mm; cfu/4hours ^{c&d})
100	5	3520	1 ^e	1 ^e
1000	6	35,200	7	3
10,000	7	352,000	10	5
100,000	8	3,520,000	100	50

a. All classifications based on data measured in the vicinity of exposed materials/articles during periods of activity.

b. ISO 14644-1 designations provide uniform particle concentration values for clean rooms in multiple industries. An ISO 5 particle concentration is equal to Class 100 and approximately equals EU Grade A.

c. Values represent recommended levels of environmental quality. You may find it appropriate to establish alternate microbiological action levels due to the nature of the operation or method of analysis.

d. The additional use of settling plates is optional.

e. Samples for Class 100 (ISO 5) environments should normally yield no microbiological contaminants.

RECOMMENDED LIMITS FOR MICROBIAL CONTAMINATION ^a				
Grade	Air Sample (cfu/m ³)	Settle Plates (Diam 90mm) cfm/4hours ^b	Contact Plates (Diam 55mm) cfm/plate	Glove Print 5 fingers cfm/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	–
D	200	100	50	–

a. These are average values.

b. Individual settle plates may be exposed for less than 4 hours.

Chart source: <https://www.airchecklab.com/resources/standards-specifications/microbial-cleanroom-compressed-air-classifications/>

What level of compressed air purity is required in your operation?

Air purity requirements depend on the application and the specific requirements of the clean room. The International Society for Pharmaceutical Engineers (ISPE) Good Practice Guide specifies, “in cases where the gas is entering a classified area, it is required to at least meet the room classification limits established for the cleanroom environment” (2016).

The recent US FDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice also recommends “compressed gas should be of appropriate purity... and it’s microbiological and particle quality after filtration should be equal to or better than that of the air in the environment into which the gas is introduced.”

Air purity is critical

Air compressors pull in ambient air. The purity of this air is highly impacted by environmental factors. For example, if the compressor is pulling ambient air from near a construction site, the particulates from the job site can be pulled into the compressor and contaminate the process air if the proper filtration and purity procedures are not followed.

This can pose a huge risk to the quality of products and the safety of the consumers. In addition, it can reduce the efficiency of the compressed air system and put additional wear and tear on each component.³

Increasing energy costs, repair costs and the likelihood of unplanned downtime.

That is why it is critical to not only have the appropriate system in place, but to monitor that system at all times to help ensure all purity requirements are being met.

Sullair can help

Sullair offers a broad line of oil free air compressors, air treatment products and compressor monitoring technology to meet your needs. And, the Sullair network of Authorized Distributors are true compressor experts ready to help you build a reliable and efficient system to help keep your operation running smoothly for years to come.

Sources:

1 *Applications in the pharmaceutical industry*. Retrieved from <https://www.bekotechnologies.com/en/en/solutions/industries/pharmaceutical-industry>.

2 *Key Differences Between a Controlled Environment and a Clean Room*. Retrieved from <https://high-techconversions.com/key-differences-between-a-controlled-environment-and-a-clean-room/>

3 *Whitepaper Compressed Air in the Pharmaceutical Industry*. Retrieved from https://www.beko-technologies.com/fileadmin/beko-technologies.com/Shared/Landing_page_Pharma/80-00012-whitepaper_pharma_int_display.pdf