



ISO Classes for Compressed Air Quality

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Knowing the proper air quality level required when considering FDA enforced cGMP is important. Compressed air is required in many applications in the pharmaceutical industry, for example, for breathing air, operation of equipment and instrument air. Review the compressed air application and determine the appropriate level of air quality the application requires.

How do I determine what is the appropriate ISO 8573 Class for compressed air used in my pharmaceutical production processes?

In most cases you want the compressed air to be at least as clean as the air in the room where it is being used. In semiconductor work this may be very clean, such as class 2, 1 or even 0. In the semiconductor industry even the smallest particle on the surface of a piece of ultra pure silicon can potentially destroy the resultant IC or Processor. But, in the case of pharmaceutical manufacturing the situation is quite different. Rarely would the presence of a small number of nonviable particles adversely effect the performance of a pharmaceutical product. Many of these products, particularly tablets, may actually shed many particles from their surface. So, in a case where the air is being used in the production of tablets, it would be foolish to specify Class 1 or 2 in compressed air.

But wouldn't it still be a good idea to go for the highest Class possible even if I don't really need it?

It might be if it weren't for the high cost of producing and especially testing for these higher classes of compressed air. The instrumentation and expertise required to test these Classes would greatly increase the cost of the air you produce without producing any real gain in the quality of the resultant product. It is generally not too much more expensive to filter the air to the extent necessary to keep particle count low, but the testing required to verify compliance with Class 1 or 2 can be quite costly. So one might want to do the kind of filtering that could potentially produce these higher Classes of compressed air, but not actually specify and then have to test to a higher Class than is really needed. In most cases, it is probably sufficient to do total weight of



particulate in a given volume of air rather than doing particle counting and size distribution. All of these questions and answers are generalities and not very specific because there are so many different products and conditions involved. Keep in mind that the ISO Classes were not developed specifically for the pharmaceutical industry and may not be the best guide to use when trying to specify the quality of compressed process air needed.

There are a variety of standards that govern compressed air. The quality of air required throughout a compressed air system can vary. A laboratory such as TRI can assist you with testing the quality of air for every application from breathing air to direct product contact or indirect product. Below is a table with values that some pharmaceutical companies have used.

The air used in the manufacturing processes should be evaluated by a qualified product engineer to determine the appropriate requirements to protect the safety of the employees and the integrity of the products.

General Guidelines for:	Employee Breathing Air	Indirect Product Contact	Direct Product Contact
Oil mist/particulate (matter)	Grade D	1 mg/m ³	0.1 mg/m ³
Moisture/Dew Point	Grade D	1267ppmv/0 degF	67ppmv/-50degF
Gaseous Hydrocarbons (minus methane)	Grade D	5ppm	2ppm
Halogenated Hydrocarbons	GradeD	5ppm	1ppm

I recommend developing an air quality program for validation that is repeatable for verification and compliance for FDA enforced cGMP. Compressed or process air lines should be tested on a routine or regular basis. A thorough evaluation of the application and manufacturing process is required to ensure the appropriate solution, both technically and financially.



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