SAMPLING COMPRESSED GASES USING A HIGH PRESSURE DIFFUSER

APPLICATION NOTE HPD-001 (US)

Compressed air is used abundantly in pharmaceutical and electronics cleanrooms. Some uses of compressed gases include: de-dusting, spray-coating tablets, over-pressurizing mixing and holding tanks, driving liquids through fill lines and filters, and operating control valves. However, compressed gases can be a source of contamination if not sufficiently clean. Leading facilities will therefore routinely test their compressed gases.

Measuring the cleanliness of compressed gas is challenging. The high pressure of a compressed gas system can overwhelm a particle counter, forcing more air through the particle counter than it was designed for. The higher flow rate will cause errors in the particle measurements and could even damage the particle counter. In this instance, a high pressure diffuser accessory is used to reduce the pressure of the compressed gas system to a level suitable for measurement with particle counters.

Gas Cleanliness Levels

ISO 8573-1:-2010 defines acceptable levels of contamination in compressed air systems, with limits as shown in Table 1.

Table 1. ISO 8573-1:2010 Compressed Air Contaminants and Purity Classes

ISO 8573-1:2010 Class	Solid Particulate				Water			Oil
	Maximum number of particles per m^3			Concentration	Pressure Dewpoint		Liquid	Aerosol, liquid and vapor
	0.1 - 0.5 µm	0.5 – 1.0 µm	1.0 – 5.0 µm	mg/m^3	°C	°F	g/m^3	mg/m^3
0	As specified by the user and more stringent than Class 1							
1	≤ 20,000	≤ 400	≤ 10	-	≤ -70	≤ -94		0.01
2	≤ 400,000	≤ 6,000	≤ 100	-	≤ -40	≤ -40		0.1
3	-	≤ 90,000	≤ 1,000	-	≤ -20	≤ -4		1
4	-	-	≤ 10,000	-	≤ +3	≤ 37		5
5	-	-	≤ 100,000	-	≤ +7	≤ 45		-
6	-	-	-	≤ 5	≤ +10	≤ 50		-
7	-	-	-	5 – 10			≤ 0.5	-
8	-	-	-	-			0.5 – 5	-
9	-	-	-	-			5 – 10	-
X				>10			>10	>10

A compressed air system can have different purity classes for particulates, water and oil. In fact, the rating for each contaminant is properly listed using the format *ISO 8573-1:2010 (Particles:Water:Oil).* For example, a compressed air system of Class 2 for particulates, Class 4 for water and Class 1 for oil would be listed as ISO 8573-1:2010 (2:4:1). Many electronics cleanrooms require less contamination than the ISO 8573-1 limits for particulates; these facilities specify their own limits by particle size.

The particulate limits for compressed gases in ISO 8573-1:2010 differ from the particulate limits for cleanrooms from ISO 14644-1:2014. Cleanroom personnel should determine the appropriate Class of compressed air for a cleanroom based on established risk assessment tools such as Hazard Analysis Critical Control Points (HACCP), Failure Mode Effects Analysis (FMEA), or Fault Tree Analysis (FTA). Specifying compressed air to be cleaner than the surrounding clean space may not be cost-effective, whereas specifying insufficiently clean air may introduce contamination. For pharmaceutical applications, the US Food and Drug Administration requires compressed gases to be at least as clean as the area into which the gases are introduced.*

Filtering Exhaust Air

If the compressed gas supply is cut off, flow through a high pressure diffuser accessory will reverse and enter through the exhaust port. If the air brought in through the exhaust is not as clean as the compressed gas, this will introduce contamination into the high pressure diffuser accessory and potentially bias future readings. TSI Models 7950 and 7955 High Pressure Diffuser Accessories have a filter across the exhaust air to ensure only clean air enters the high pressure diffuser accessory under this scenario.

Conditioning Sample Air

Compressed air used in electronics applications may be so dry that it will actually abrade a particle counter's fan and optics. Adding humidity to the air sample allows the air to flow smoothly, without damaging the particle counter. HEPA-filtered room air normally has enough moisture to add sufficient humidity to the sampled air stream without over diluting the sample.

Adding bleed air to humidify the sample airstream will also reduce the measured particle concentration. A well-designed high pressure diffuser will limit the amount of bleed air to be no more than 20% of the sample airstream, meaning the particle concentration measurements could be up to 20% lower than the true particle concentration of the compressed airstream. However, a well-implemented compressed air system should not be near its upper limit of particle concentration. The particle concentration of the compressed air system should only approach or exceed relevant limits if there is a significant issue with the filters or other equipment in the compressed gas lines. Thus, the results of testing a compressed air system should be interpreted using pass/fail criteria rather than trending the absolute measurement.

Conclusion

Compressed gases used in cleanrooms should be tested to ensure they do not contribute unwanted contamination. High pressure diffusers reduce the pressure of a compressed gas system. This allows a particle counter to accurately measure the particulate concentration when other factors such as pressure safety, humidity and gas compatibility are considered.

*fda.gov, "Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice." N.p., 2004. Web. 2 Sept. 2015.

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HPD-001 Rev. A (1/13/2017) US Printed in U.S.A.