Compressed Air Testing for Pharmaceutical Industry

Compressed Air Contamination is Hazardous to Health and Your Product !!

AES LABORATORIES (P) LTD.

analyzing today for an assured tomorrow...

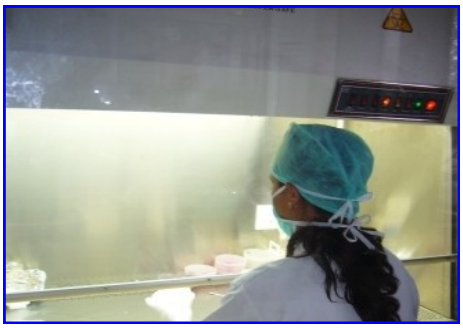
AN NABL ACCREDITED LABORATORY

Compressed air is a Critical Process Parameter (CPP) whose variability has an impact on the Critical Quality Attribute (CQA) and therefore should be monitored or controlled to ensure the process produces the desired quality. During commercial manufacturing, a well-defined system for process performance and product quality monitoring should be applied to assure performance within a state of control and to identify improvement areas. Quality risk management should include facilities, equipment, and utilities.

Why test compressed air quality?

Clean Dry Air is essential for many types of applications. Air compressors draw in large volumes of air from the surrounding atmosphere containing contaminants. The air compressor itself can also add contaminants. Process air contamination found in automotive spray paint air lines, powder coating air lines, pharmaceutical processing air lines or food processing air lines can affect product quality. A major problem in compressed air systems is the presence of oil and solid contaminants which can affect air quality and lead to scaling, instruments clogging, valves sticking and process contamination. 1m^3 of compressor intake air can contain up to 180 million particles of dirt. Besides these particles of dirt, the intake air can also contain 50 – 80% water vapour and oil in the form of unburnt hydrocarbons from machinery and waste gases. In addition, tiny amounts of lubricating oil and dust from the compressor can get into the compressed air network. When compressed to 10 bar for example, the concentration of these harmful substances increases eleven -fold, i. e. 1 m^3 of compressed air can contains up to 2 billion particles of dirt. Depending on the application, these particles of dirt will have to be removed until the compressed air becomes absolutely dry, oil-free and sterile.

Unlike the food industry, the pharmaceutical industry does not have a clear-cut guideline or regulation that specifically addresses compressed air quality requirements, testing frequency, or number of samples. The individual manufacturer is responsible for assessing the risk and affect that a contaminated compressed air supply could have on the final product. An important international standard, **ISO 8573-1**, provides a variety of Purity Classes that can be incorporated into a robust quality assurance plan for this critical utility. Testing and monitoring of compressed air is vital to assuring the quality and safety of the product.



AES is an NABL accredited laboratory established in 1983. We offer baseline testing of compressed air for parameters including viable aerobic count, non-viable count or particulate count, dew point, water vapor and oil mist. Our team of trained and experienced samplers ensure that proper protocols are followed during sample collection and transportation back to the laboratory. Our stringent quality control guidelines ensure that our lab meets the highest standards of quality and can deliver reliable, consistent laboratory test results. We have a great team of experts ready to answer your questions and help you get started with your air quality assurance program. AES is currently providing independent laboratory support for many pharmaceutical companies.

To find out more about our compressed air testing services or to get a quote, please do contact us.

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