

Consistency as the True Measure of Cleanroom Wiper Quality

Introduction

The modern cleanroom is engineered to maintain low levels of contamination within while also preventing impurities from entering the controlled environment. “Contamination” may have different meanings in various controlled areas – while a pharmaceutical company may consider only large fibers a threat, trace levels of elemental contamination could devastate semiconductor production.

Widely recognized as a cleanroom essential, wipers are used in multiple industries as an element of cleanroom protocol for proper maintenance. Purity is critical as wipers themselves can serve as a source of contamination if improperly evaluated.

Measuring Wiper Quality

Cleanroom wiper quality is measured using a range of performance characteristics such as fabric substrate, micro-structure or sorption capacity using standard test protocols. The three main types of contamination being assessed are particles and fibers, ions, and non-volatile extractable matter.

Particles and Fibers

Particles and fibers are measured by first extracting particles into a solution and then counting them. This solution can be pure water, or water based with an additive that lowers surface tension. The motion used to move particles from the wiper to the solution will vary the quantity of particles being counted, with a more vigorous motion resulting in an increased number of particles.

Ions

Even once wiper fabric has been processed, extractable or leachable ions often remain. Typical cations include sodium, potassium, calcium, magnesium and ammonium, while typical anions are chloride, fluoride, nitrate, sulfide and phosphate. Wipers are soaked at a specific temperature and for a given time to extract the ions for measurements. Varying temperature and time periods offer different information about the wiper. Extractions performed at elevated temperatures for a short time estimate the maximum ion contamination the wiper contains.

Extractable Matter

Additives and oils used in fabric manufacturing can linger on wipers once the fabric is processed. To measure these contaminants, the wiper is soaked in solvent of a given temperature for a specified time. Again, the time and temperature of the extraction will impact the amount of matter extracted from the wiper. Extracting the wiper at or near the solvent’s boiling point will remove more material.

Wiper Testing and Statistical Process Control

Wiper manufacturers generate data to monitor contaminants as part of their statistical process control program, and data is analyzed to measure cleaning process viability with a goal of maintaining control and improving quality. To acquire data, generally a single representative sample is analyzed, which over time leads to data trending.

Statistical Treatment

If the cleaning process has been changed, statically results are affected by the difference of the means (average) of the data sets, the variability (standard deviation) in the data set, and the acceptable risk level. This statistical treatment can be used to compare various extraction processes, temperatures, solvents and more. The number of data points needed in each data set is a function of a difference of the data set means and overall standard deviation of these data sets. It is clear, however, that analysis of just a few data points is insufficient to determine if output has been significantly changed, as these differences are more easily analyzed when variability is lowest.

Anatomy of a Consistency Chart

Consistency charts provide a reliable way to evaluate many large sets of data, the components of which are determined by individual data points from the data set. The components of the consistency chart are determined through the data points themselves, as follows:

1. Line: Represents the median value of a ranked data set.
2. Box: Represents a range of values which encompasses 50% of the data.
3. Whisker: Represents a range of values which encompasses 25% of the data.
4. Outlier: Represents points that vary significantly from the rest of the data set.

Consistency charts are constructed through the following:

1. Data set values are ranked from highest to lowest.
2. Ranked data are divided into quartiles.
3. A box is constructed using the first and third quartile values.
4. The whisker ends are defined:

$$W_u = Q3 + 1.5 \times IQR$$

$$W_l = Q1 - 1.5 \times IQR$$

where W_u and W_l are the upper and lower whisker values, respectively; Q1 and Q3 are the first and third quarters respectively, and IQR is Intra-Quartile Range, or the difference between Q3 and Q1.

5. The outliers are determined and indicated with an asterisk.

Once the chart is assembled it presents a statistically reliable representation of the data values for a given wiper. Lower medians with smaller boxes and shorter whiskers indicate a clean, consistent wiper.

How to Evaluate a Cleanroom Wiper

1. Comparative assessment of cleanroom wipers

“Typical values” are often used in comparing cleanroom wipers across a range of performance test measurements. These values, however, are simply singular data points from a specific product lot and are not necessarily representative of the actual product. Unbiased assessment is best achieved through consistency charts developed over time.

2. Effect of Automation on Consistency of Cleanroom Wipers

A “fully automated” product is one that is manufactured in an automated environment free of human contact, thereby vastly reducing variability in the process. Because human contact also introduces particulate burdens to the product, a “hands-free” environment in combination with complete automation will produce a much cleaner and more consistent wiper.

Conclusions

Unbiased scientific assessment is a necessary component of cleanroom wiper production. Consistency chart comparison ensures reliable selection of the proper wiper. Quality should be evaluated through a statistically valid assessment over an extended period using a predefined process.

This article is based on an original Texwipe publication by Sandeep Kalekar and Jay Postlewaite.