Viable and Non-viable Particulates

Viable and non-viable particulate level requirements are typically controlled through adequate system design and utilization of critical use-point filtration and maintenance. Compressed air and nitrogen systems are typically designed, controlled and maintained in a dry state, therefore significantly reducing the risk of microbial growth. Filter selection is dependant on the intended use of the compressed air or nitrogen and the particulate requirements defined during the system design phase.

Particulate levels of compressed air or nitrogen used in aseptic or sterile applications are controlled using sterilizing-grade (0.22µm, micro-retentive) point of use filters. Due to the criticality of application, these filters are typically integrity tested before and after use.

Particulate removal for compressed air or nitrogen used in non-sterile applications is often conducted using either critical point of use or supply-line particulate filters. These are typically in the range of 0.45-5.0µm pore-size. While integrity testing of filters used in non-sterile applications is not required, a filter inspection and replacement schedule (e.g. every 6-12 months) is typically established.

Where particulate filters are not located at the critical point of use, it is important to consider the potential for particulate contamination of the system to occur during maintenance activities, conducted down-stream of the supply-particulate filters to the actual use point(s). In these cases, the distribution piping downstream of the installed supply-line filter may have particulate testing performed prior to the system being used for production use. It is recommended that filters be located as close as is practical to the intended critical point of use.

Moisture Content

If moisture content testing is determined to be necessary, limits for moisture may include applicable EP pharmacopoeia limits. [5] Moisture levels are typically controlled via adequate system design, operation and maintenance. They are typically monitored continuously using on-line instrumentation and associated alarms. For air and nitrogen systems where the level of moisture is considered critical, the instrumentation and alarms associated with the monitoring of moisture levels are commissioned and qualified.

Oil-mist & Hydrocarbons (as part of Oil-Mist)

Oil-mist within compressed air and nitrogen systems is typically controlled by using oil-free compressors. Some compressors are ‘oil-free’ but there may still be components within the compressor that utilize oil. Removal of oil-mist from these systems is performed through the use of coalescing filters located in the distribution system. Where these design controls are in place, oil-mist is not expected to be present in the system and no routine testing or monitoring is therefore recommended.

Nitrogen System Purity

Purity of nitrogen generated on-site using PSA systems is typically monitored through the use of on-line continuous oxygen and moisture-content monitoring with associated alarms.

Other Potential Contaminants

During the design and construction phases consider other potential contaminants, such as cutting oils or cleaning agents used in system construction or subsequent maintenance activities. A risk-assessment can be conducted to assess the likelihood of other contaminants being present and to assist with the elimination of their sources, or development of a testing strategy if necessary.

