



Essentials of Particulate Testing: USP <788> and AAMI TIR42

While there are many standards available for particulate testing, USP <788> and AAMI TIR42 are the most important. This is especially true for vascular devices.

Start with the Proper Standards

USP <788> is a good starting point for sizing and enumeration, and AAMI TIR42 provides general guidance on analytical methods for identifying and developing specifications for particulate contamination.

Use Qualified Cleanrooms

The first step to particle analysis is the isolation of the foreign particles, or native particles of interest. A clean environment is the key. The facilities at Eurofins EAG Laboratories are well equipped to perform particulate analysis with cleanrooms that are qualified and validated to meet ICH and/or USP requirements. EAG has ISO 7 and ISO 5 cleanrooms.

Customize Sample Preparation

Another key part to particle collection is sample preparation. In recent years, a simulated-use model has been recommended over a simple beaker method. The simulated-use model as described in ASTM F2394 is typically utilized for cardiovascular medical devices. However, EAG can use a custom model if needed.

Both AAMI TIR42 and USP <788> outline particle counting and sizing by light obscuration or light microscopy on collected particulate extracts. There are pros and cons to each method.

Determine Counting and Sizing Method

Light Obscuration

The most efficient way to size and count particulate matter

- Challenges with large aspect ratios (e.g. fibers) and high density particulates
- Cloudy or viscous solution leads to inaccurate particle detection

Light Microscopy (Manual or Automatic)

- Sample is filtered, thus isolation of the particulate matter for chemical characterization is possible: Raman, FTIR, SEM-EDX, etc.
- Morphology: Naked eye and 2.5X optical for visible particles
- Optical microscopy 20x or larger
- Automated sizing and counting may be achieved with optical microscope
- In addition to particle size and counts, a visual assessment of the particulates under the optical microscope can also provide information on morphology, color, and shape

Our Capabilities

The device testing services at EAG include multiple Keyence Optical microscopes, Renishaw Qontor Confocal Raman Microscopes, and Thermo Scientific Apreo 2 SEM-EDX instruments. Our scientists have the capability to perform manual or automatic particle counting and sizing. The Keyence and Raman microscopes are located within EAG's three ISO 7 cleanrooms.

Chemical and Elemental Identification

AAMI TIR42 encourages identification of foreign particulates, especially for visible or large sized particles. EAG can assist with chemical identification using FTIR and/or Raman spectroscopy for chemical identification and SEM-EDX for elemental analysis. To perform chemical and elemental identification, particulates will be filtered in an ISO 5 clean space. Identification of the foreign particulates can be obtained using the following techniques as outlined in AAMI TIR42:

FTIR Spectroscopy

- Suitable for samples that are observed to contain few and/or larger particulates
- Custom libraries can be built using reference standards to optimize library matches for samples

Raman Spectroscopy

- Renishaw Qontor Confocal Raman Microscopes located in ISO 7 cleanrooms have the capability to stitch, map, count, size, and identify chemical profile of particulates on an entire filter
- Particulate package (count, size, and chemical ID) is suitable for samples that are expected to contain 100s to 1000s of particles, or particles are too small for physical isolation for FTIR analysis
 - » EAG performs method development to optimize method settings to survey the entire filter
 - » Custom libraries can be built using reference standards to optimize library matches for samples
- Ideal for particles around 10 μm and larger

Energy Dispersive X-ray Spectroscopy

- Elemental profile can be performed on an isolated particle or directly on filters prepared from simulated use extracts
- Aztek feature mapping (automated)
 - » Can be packaged to provide size, count, and elemental profile for particles 1 μm to 500 μm

Additional Techniques

- X-Ray Diffraction, Time-of-Flight Secondary Ion Mass Spectrometry, X-Ray Photoelectron Spectroscopy and Auger Electron Spectroscopy



Manual and Automated Analysis

While chemical information can be obtained in a manual or automated manner, there are pros and cons to both. Automated analyses are considered more efficient for numerous particles, but it is not effective in identifying particle overlap or morphology. Both manual and automated particle analyses are available at EAG, and can be customized based on the goals of the testing.

Knowledgeable, Flexible Testing Support

EAG uses the newly updated AAMI TIR42:2021 as guidance, as it is fully recognized by FDA, to provide particle analysis testing. EAG also assists clients by interpreting the results, identifying contamination sources and applying acceptable particle limits.

EAG is ISO 9001:2015 and ISO 17025 accredited; FDA-registered and DEA Licensed, and offers analytical support for materials characterization, failure analysis, particle identification, contaminant identification, analyte quantitation, and ISO 10993-18 chemical characterization.

Contact our team for help with your device testing needs.
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