Micro Measurement Laboratories, Inc.

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# **Particulate Matter Testing**

Particulate Matter Testing is required to quantify the amount of intrinsic, extrinsic, and inherent particulate to demonstrate a clean manufacturing process and stability for drug products, medical devices, and other products where Particulate Matter may be considered a Critical Quality Attribute.

Micro Measurement Laboratories offers expert support for Particulate Matter Testing requirements from method development to lot release testing, using multiple state-of-the art techniques and decades of experience.



In Particulate Contamination Testing applications, MML customers are seeking to determine the quantity of unexpected and/or unwanted contaminant particles present in or on the surface of the sample. A combination of automated particle counting instrumentation (LO) and optical microscopy (MM) is used for these applications.

In Particle Size Distribution applications, sometimes called Material Characterization, the product itself is made up of particles. In these cases the purpose of the testing is usually two-fold: material performance is characterized in addition to testing for product quality. To name just a few examples, in API powders, lipid emulsions, paint pigments, soft-drink syrup concentrates, CMP slurries, and colloid applications, the mean size of the particle size distribution (PSD) is critical to product performance, but it's not the entire picture.

Rely on the team at Micro Measurement Labs to identify unknown contaminant particles in your facility or process. We provide particle isolation and identification services by optical microscopy, Fourier-Transform/Infra-Red (FT-IR), or Raman spectroscopy.

## Call us at (847) 459-6540

#### Visit us at www.mmlabs.com

\* Additional services billed separately

#### **Highest Quality & Reliability**

- Testing performed in a cGMP laboratory.
- Sample preparation and testing performed in ISO Class 5 clean areas.

#### Support for Many Compendial Tests, Including:

- USP <1>, <788>, USP <789>, USP <787>, USP <729>
- ISO 8871-3, ISO 8536, ISO 14708
- BS EN 45502, ASTM
- ASTM Chapters And Many Other Industry Methods

### Support for Particulate Matter Testing Throughout Whole Process

- Method Development services
- Method Validation and Verification services
- Lot release testing services
- Root Cause Investigations
- We have experience with nearly every drug, device, and container type
- We offer a large variety of instrumentation and techniques for use in testing
- We will identify virtually any particle<sup>\*</sup> of concern in or on samples to address your site-specific particle concerns

#### When the Regulators Come...You Will Be Ready

- 30+ years of experience with Particulate Matter testing
- Our staff is comprised of engineers and scientists who are award-winning authors and regular conference speakers
- Professional organizations use our services to support their product evaluations
- We continue to participate, contribute, and share information on particulate matter testing through workshops, forums, presentations, and papers
- Ask about our NIST PQ Check Particle Size and Count standards and Custom made Certified Challenge Sets to Qualify Visual Inspections.

ACCURATE. EXPERT. STATE OF THE ART

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