Particulate Matter for Medical Devices

Whether analyzing an unknown contaminant, qualifying a raw material supplier, or investigating the impact of a process change on a powdered product, Eurofins Medical Device Testing provides the appropriate expertise and equipment for your product. Our laboratories can provide the detailed characterization of powders essential to ensure proper flowability during processing, prevent clogged feeder nozzles and distribute radiopacifiers.

Particle testing is required on medical devices to ensure patient safety. USP <788> is the most commonly used standard for medical device analysis of particulates. Eurofins Medical Device Testing's network of Labs performs particulate matter testing on a wide range of medical devices, such as implantable medical devices, infusion devices, syringes, bottles, vials, stoppers, needles, packaging, and gloves.

With over 30 years of particle analysis experience, Eurofins Medical Device Testing assists customers with a broad range of specialized apparatus to ensure the right instrumentation for every job. Our expert scientists provide accurate analysis and material characterization from nanometer scale particles to bulk powders greater than 1mm.

Choose Eurofins Medical Device Testing to help you:

- Characterize your raw material, in process, or finished powdered products
- Characterize and record contaminant particles with digital microscopy techniques
- Understand particle size distributions.
- Determine surface morphology
- Perform elemental analysis testing
- Qualify raw material suppliers
- Assess effects of process changes

Particulate Matter Testing

Sample Types

The Light Obscuration Test is based on the principle of light obscuration, and allows for automatic determination of the number of particles according to their size. The test is performed in a biological safety cabinet, under conditions that limit foreign particulate matter.

Volume requirements: USP<788> /EP 2.9.19/JP 6.07: A minimum of 25 mL sample solution is required to meet the harmonized requirements. If the fill volume is >25 mL and only 1 container is >25mL, then only 1 container is needed for testing. However, if the fill volume is <25mL, then a minimum of 10 are required. Dilution of the samples can be performed as required.

USP <787>: Can be used as an alternative to USP <788> and specifically addresses testing of therapeutic protein injections and related preparations. Smaller test volumes are allowed, and there is no specific volume requirement as compared to USP <788>. Specific sample handling instructions take into account potential issues associated with analysis of these types of materials.

Particle sizes: The compendial requirement is to enumerate particles at ≥10 µm and ≥25 µm, although particles in the range of ≥2 µm – 400 µm can also be enumerated.

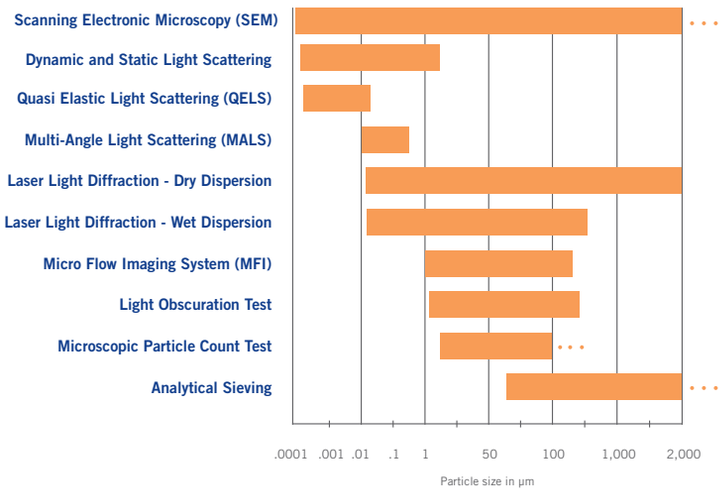
USP <789>: Used specifically to address testing of ophthalmic solutions and related preparations. The test volumes allowed are identical to USP <788>. Specific sample handling instructions take into account potential issues associated with analysis of these types of materials.

Particle sizes: The compendial requirement is to enumerate particles at ≥10 µm, ≥25 µm, and ≥50 µm.
Instrumentation: Testing utilizes our HIAC 9703+ Liquid Particle Counting System.

Microscopic Particle Count Test

Our experts will utilize a Microscopic Particle Count Test when certain test articles cannot be analyzed by the Light Obscuration method due to color, reduced clarity and/or viscosity. This method can also be utilized in the event the product does not meet the USP criteria for the Light Obscuration Method.

Volume requirements: A minimum of 25 mL sample solution is required to meet the harmonized USP/EP/JP requirements. If the fill volume is >25 mL then only 1 container is needed for testing. However, if the fill volume is <25 mL than a minimum of 10 containers are required. Dilution of samples can be performed as required.
Particle Size: The compendia requirement is to detect particles at ≥10 µm and ≥25 µm. Particles < 10µm cannot be accurately detected using the Microscopic Particle Count Method.



Instrumentation: Testing utilizes our Fein Optic IMA/ USP 788 Pharmaceutical Microscope.

Particle Size Testing

Dynamic Light Scattering

Particle size distribution of sub-micron particles is measured at a 90 degree scattering angle using Dynamic Light Scattering.

Volume requirements: 0.1 g – 0.5 g per sample determination.
Particle sizes: 0.0003 µm - 5 µm.
Instrumentation: Malvern Zetasizer Nano ZS90.

Multi-Angle Light Scattering (MALS)

A static light scattering technique which can be used in conjunction with Size Exclusion Chromatography (SEC) as an in-line detection technique or it can be used for non-fractionated samples in the batch mode of operation.

Volume requirements: Approximately 100 µg (i.e., 100 µL injection of 1 mg/mL solution for in-line SEC operation) and1,000 µg (Direct 1000 µL infusion of 1 mg/mL solution for batch mode operation).
Particle Sizes: 0.01 µm - 0.5µm.
Instrumentation: Wyatt Technologies HELEOS II.

Laser Light Diffraction

Particle size distribution is measured by the dispersion and absorption of light (red and blue) generated by a laser using either the wet or dry dispersion techniques.

Volume requirements: 0.1 g – 0.5 g per sample determination for wet dispersion. 0.5 g – 5 g per sample determination for dry dispersion.
Particle sizes: 0.01 µm – 600 µm for wet dispersion and 0.2 µm – 3,500 µm for dry dispersion.
Instrumentation: Malvern Mastersizer 3000 with Hydro MV wet dispersion unit and the Aero S dry dispersion unit, Malvern Mastersizer 2000, Microtrac S3500, Beckman Coulter LS 13 320

Zeta Potential (Electrophoretic Light Scattering)

Zeta potential is a measurement of the electrokinetic potential in colloidal dispersions. The Zeta Potential is measured at a 90 degree scattering angle using Electrophoretic Light Scattering.

Volume requirements: 0.1 g – 0.5 g per sample determination.
Particle sizes: 3.8 nm - 100 µm.
Instrumentation: Malvern Zetasizer Nano ZS90.

Analytical Sieving

Sieving is usually the method of choice for classification of the coarser grades of single powders or granules. It is a particularly attractive method in that powders and granules are classified only on the basis of particle size, and in most cases, the analysis can be carried out in the dry state. Mechanical sieving is most suitable where the majority of the particles are larger than about 75 µm. For smaller particles, other means of agitation such as air-jet sieving may be more appropriate.

Volume requirements: 10 g- 100 g is generally required per test. However, if the information needed to perform sieve testing for a specific material (i.e. sample amount, sieve sizes and sieve time) cannot be provided, then approximately 500 grams will be required in order to perform feasibility/endpoint determination to establish the appropriate parameters prior to testing the material.
Particle sizes: Certified ISO 3310-1, ASTM E-11 sieves in sizes ranging from 25 µm to 2,000 µm. Larger sizes up to 11.20 mm may be purchased upon request.
Instrumentation: Endecotts Octagon 200 Test Sieve Shaker, W.S. Tyler Model RX-29 Ro-Tap Shaker and-Hosokawa Micron AirJet Sieve (Version II).