eurofins | BioPharma Product Testing



Particulate Matter Testing

Eurofins BioPharma Product Testing is well-versed in testing particulate matter ranging from <.01 µm to >3,000 µm and uses a variety of techniques to develop and validate particle size methods. Our scientists are experienced in using orthogonal techniques to address a wide range of product and formulation issues—from protein aggregation through extraneous matter contamination.

Why Choose Eurofins BioPharma Product Testing?

- We offer a broad set of orthogonal methods covering the entire particle size range.
- Direct interaction with our technical staff will ensure a testing strategy appropriate for your product formulation.
- Our more than 30-year history of cGMP regulatory compliance ensures delivery of the highest quality data.

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.

Quasi Elastic Light Scattering (QELS)

This test measures and uses molecular motion to determine the diffusion coefficient of a molecule in solution. The diffusion coefficient for a spherical particle is directly related to its "hydrodynamic radius."
Volume requirements: Approximately 100 µg (i.e., 100 µL injection of 1 mg/mL solution for in-line SEC operation).
Particle Sizes: Approximately 0.0005 µm – .03 µm.
Instrumentation: WyattQELS, which is embedded within Wyatt HELEOS II.

Multi-Angle Light Scattering (MALS)

A static light scattering technique 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: .01 µm – .5 µm.
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 0.02 µm – 3,500 µm for dry dispersion.
Instrumentation: Malvern Mastersizer 2000 with Hydro 2000S wet dispersion unit and the Scirocco 2000 dry dispersion unit; Malvern Mastersizer 3000 with Hydro MV wet dispersion unit and the Aero S dry dispersion unit.

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 µm – 100 µm.
Instrumentation: Malvern Zetasizer Nano ZS90.

Micro Flow Imaging System (MFI)

Flow cell and digital photography are used to individually image, size, and count particles in liquid formulations. Using an autosampler or by manual injection, the sample is passed through the flow cell and pictures are captured after automatic illumination and precision focusing. MVSS software is used to process the captured images and determines the particle size and count within a desired particle size range. MVAS software is also used to identify the sample particle's morphology and shape attributes that traditional light obscuration (LO) and size exclusion chromatography (SEC) technologies are not able to detect.
Volume requirements:
1.0 – 2.0 mL per sample (5200 Model)
1.0 – 6.0 mL per sample (5100 Model)
Particle Sizes:
1 µm – 70 µm (5200 with 100 µm flow cell)
2 µm – 300 µm (5100 with 400 µm flow cell)
Instrumentation: Protein Simple MFI 5100 Micro Flow Imaging System (comprised of MFI 5100 Flow Microscope, MFI View System Software (MVSS) and MFI View Analysis Suite (MVAS) Software).

Light Obscuration Test

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



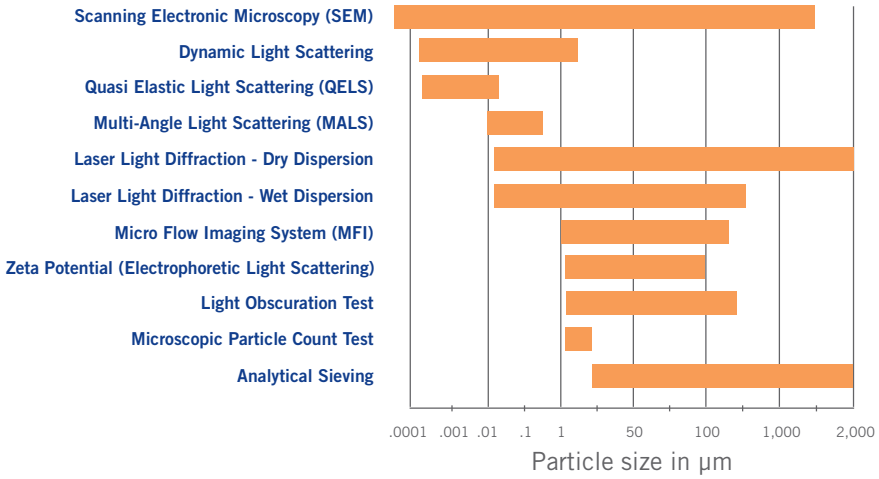
Volume requirements:
USP <788>/EP 2.9.19/JP 6.07: A minimum of 25 mL pooled sample solution is required to meet the harmonized USP/EP/JP requirements. Dilutions of samples can be performed as required.
USP <787>: Can be used as an alternative to USP <788> and specifically addresses testing of therapeutic 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.
Instrumentation: HIAC 9703+ Liquid Particle Counting System.

Microscopic Particle Count Test

Utilized 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 a product does not meet the USP criteria for the Light Obscuration Method.
Volume requirements: A minimum of 10 containers is required to meet USP/EP/JP requirements. An alternate number of containers can be analyzed and dilutions of samples can be prepared if warranted.
Particle sizes: The compendial requirement is to detect particles at ≥10 µm and ≥25 µm. Particles <10 µm cannot be accurately detected using the Microscopic Method.
Instrumentation: Olympus BMAX BX60 microscope, equipped with an internal episcopic brightfield illuminator, a circular diameter graticule and an external focusable auxiliary illuminator.

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 g 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).



Comprehensive GMP Testing Services

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