

Flow Imaging Microscopy with Light Obscuration

OVERVIEW

With the introduction of the FlowCam LO, the biopharmaceutical industry has the option to streamline drug development and fine tune testing with a single instrument. By integrating a light obscuration component into a standard FlowCam, you get two analyses, and two data sets for your drug product testing.

While analysis using light obscuration instrumentation is standard, the FDA has long made clear that size data alone, collected with light obscuration, is not adequate to ensure safe and effective drugs, and that it is also necessary to provide validation and imaging data using orthogonal methods.

The FlowCam LO provides:

1. USP <787/788> compliance with Light Obscuration
2. Flow Imaging Microscopy validation of particle types with images
3. Identification of additional particles missed by LO alone
4. Greater understanding of drug product formulation



BENEFITS

Streamline drug development

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Collect and process data with FIM and LO at the same time

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Reconcile data from a single sample, and a single run with two different technologies

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Minimize required sample volume to as little as 250 µL

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Have greater confidence in your data

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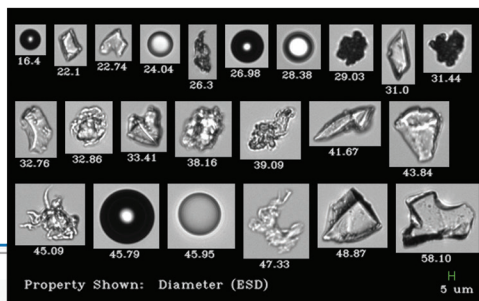
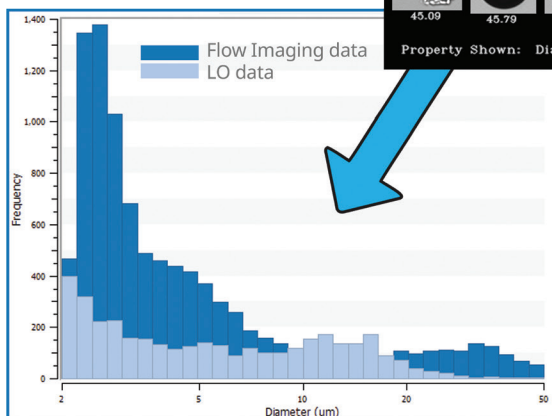
Build particle libraries and automate classification

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Confirm the presence of inherent particles and reduce presence of intrinsic/extrinsic particles

Size alone isn't enough: What's behind the data?

Reconcile your data with a single instrument:
Meet compliance standards and verify with images.



- Protein aggregates
- Silicone oil
- Glass Shards
- Bubbles

Flow Imaging Microscopy with Light Obscuration

Specifications	
Particle Size Range	2 µm to 70 µm
Magnification	10X
Flow Cell	<i>Flow Imaging Module:</i> 80 µm x 700 µm quartz flow cell <i>LO Module:</i> 1 mm x 0.4 mm quartz flow cell
Sample Volume Range	250 µL - 2 mL
Sample Processing Capability	0.2 mL/minute
Measured Parameters	<p><i>Basic Shape Parameters:</i> Area, Aspect Ratio (width/length), Area Based Diameter (ABD), Equivalent Spherical Diameter (ESD), Length, Volume (ABD-based), Volume (ESD-based), Width, 3 Biovolume Measurements</p> <p><i>Advanced Morphology Parameters:</i> Area (Filled), Circle Fit, Circularity, Circularity (Hu), Compactness, Convex Perimeter, Convexity, Elongation, Fiber Curl, Fiber Straightness, Geodesic Aspect Ratio, Geodesic Length, Geodesic Thickness, Perimeter, Roughness, Symmetry</p> <p><i>Gray Scale and Color Measurements:</i> Average Blue, Average Green, Average Red, Blue/Green Ratio, Red/Blue Ratio, Red/Green Ratio, Edge Gradient, Intensity, Sigma Intensity, Sum Intensity, Transparency</p>
Flow Imaging Module Camera	High resolution (1920 x 1200 pixels), CMOS sensor, Color or Monochrome, Resolution < 10%
Frame Rate	Shutter Speed up to 100 frames per second.
LO Light Source	Solid-state laser diode, 785 nm
LO Detection Method	Light extinction
Fluidics	Micro-syringe pump with 2.5 mL syringe
Software	VisualSpreadsheet®: Interactive, image-based analytical software that generates 40+ measurements per particle. Filter, sort, and classify data based on user-defined criteria. Create libraries to automate classification for future sample analyses.

REQUEST A FREE SAMPLE ANALYSIS

Send us your sample and we will provide:

- A web-based, interactive presentation of results
- Histograms and scattergrams showing size and distribution of particles
- A Microsoft Excel spreadsheet with measurement data, including count, length, width, and ESD
- Digital images of your particles

