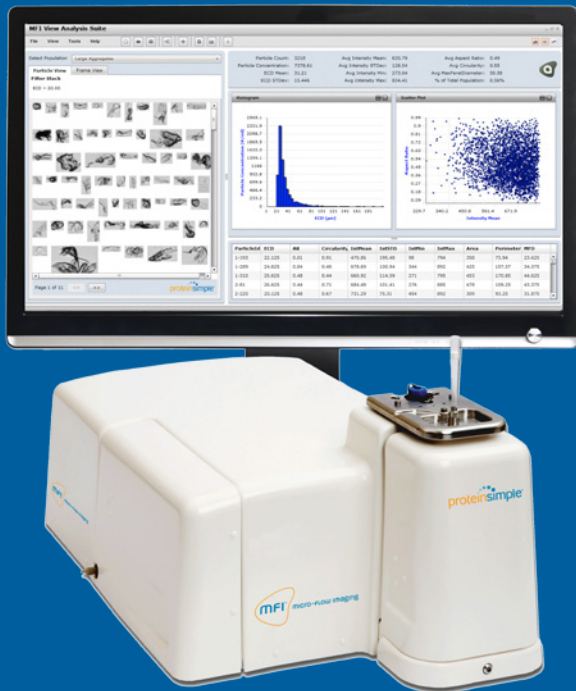


See sub-visible particles.
Micro-Flow Imaging.



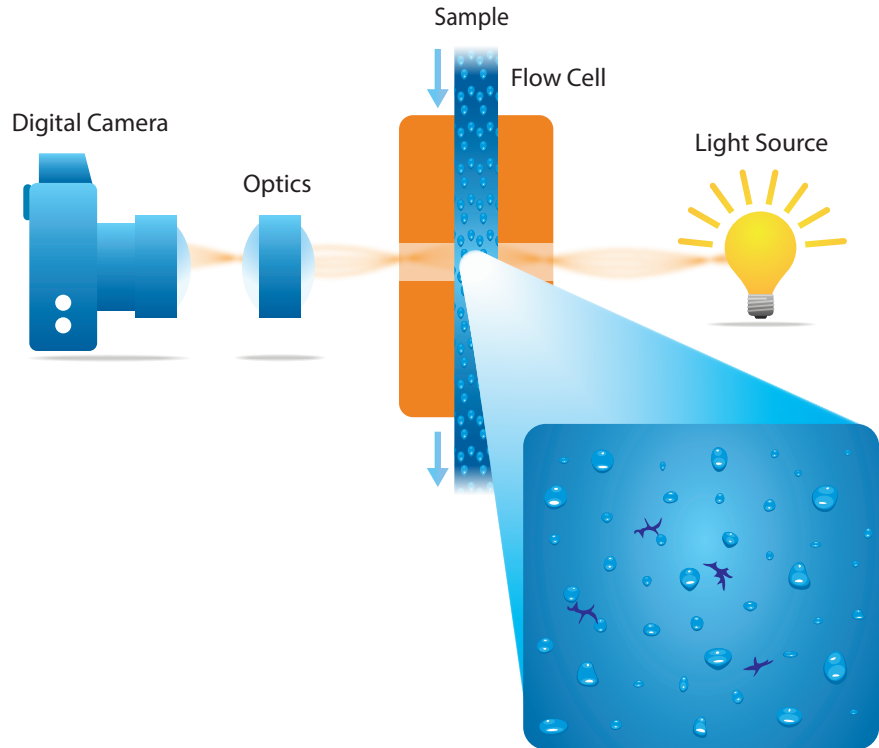


The MFI 5000 Series

Do you need to answer tough questions about sub-visible particles? Regulatory agencies are concerned about undesired side effects and reduced efficacy and require them to be well-characterized in biopharmaceutical formulations. But as their name implies, doing that can sometimes be a challenge. The MFI 5000 Series detects, quantitates and differentiates particles that you may not see now. Can't beat that, right?

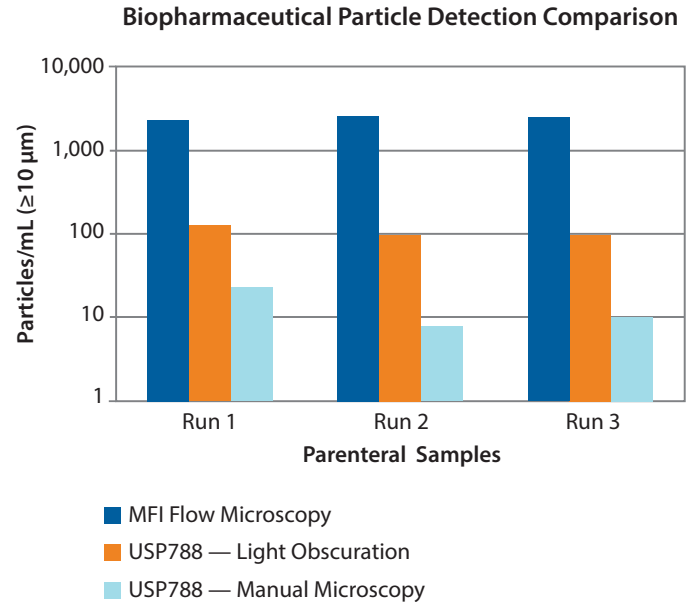
How MFI™ Works

Micro-Flow Imaging™ combines the direct imaging capabilities of digital microscopy with the precise control of microfluidics. What does that get you? High resolution images with 85% sampling efficiency... more precise counts and sizing with full morphological detail for all sub-visible particles in your sample... the complete confidence that you can accurately identify every possible type — from protein aggregates to air bubbles.



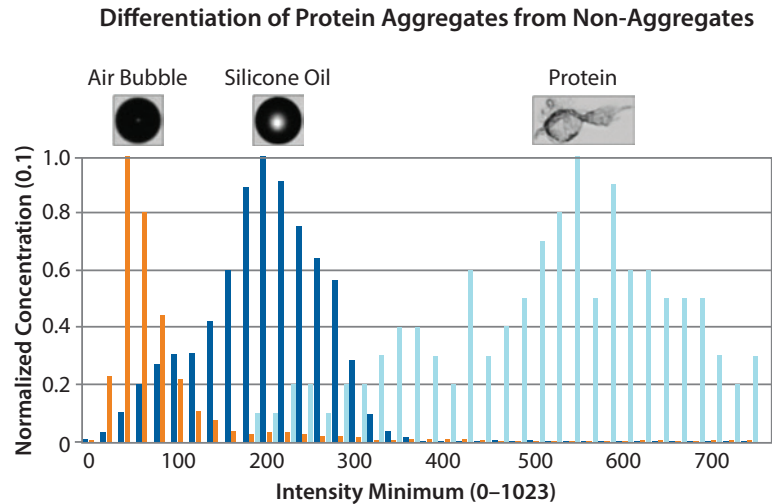
Detect

MFI is just more sensitive than other technologies, so it can easily detect translucent and transparent sub-visible particles. It's also much less affected by a particle's optical properties, giving you more accurate sizing even in viscous and highly concentrated solutions. End result? A more realistic picture of what's actually in your sample. Armed with better information, you'll quickly be on the best path to improving product quality and safety.



Classify

Protein aggregate, silicone micro-droplet, air bubble or something else? The MFI 5000 Series gives you the size, concentration and image for each particle in just one test, and then lets you isolate them by different sub-populations. When you can group data by specific characteristics like size range, count, intensity, transparency and shape, you'll always know exactly which particles you're dealing with.



Optimize

The MFI 5000 Series gives you a lot more insight into how to minimize particulates. Now you can monitor changes in particle groups over time, or even evaluate the impact of process variables on their formation. As an added bonus, MFI can address USP <788> guidelines for sub-visible particle analysis in both protein formulations and small molecules. But here's the true test: development and quality control groups in the world's largest pharmaceutical companies use MFI to do all these things, every day.

Define Settings for Particle Analysis with User-Created Filters

The screenshot displays the MFI 5000 Series software interface. The top section shows a 'Tree View' for 'proteinsample' with a filter tree for 'Circularity >= 0.90' and 'Circularity <= 0.90'. The bottom section shows a 'Particle List' table with columns for ParticleID, ECD, AR, Circularity, DiffMean, SRETD, DiffIn, DiffEx, Area, Perimeter, and MSD. The 'Particle Properties' section on the right shows 'Active Filter: ECD >= 10.00 AND Circularity >= 0.90' and various statistical data points.

ParticleID	ECD	AR	Circularity	DiffMean	SRETD	DiffIn	DiffEx	Area	Perimeter	MSD
72-2	10.375	0.96	0.93	666.96	182.05	352	1020	232	58.28	16.129
92-0	10.875	0.97	0.91	714.69	146.3	431	1019	134	44.97	10.625
108-7	10.625	0.97	0.91	663.9	202.74	336	1019	296	58.04	15.076
141-12	10.875	0.96	0.93	649.58	229.33	278	1020	239	58.87	16.125
154-13	10.875	0.96	0.91	639.05	216.66	244	1019	219	57.87	15.125
164-3	10.375	0.96	0.93	647.83	143.56	314	974	134	42.38	10.125
187-22	10.375	0.97	0.91	606.54	195.58	207	988	127	43.6	10.125

Automate

Sometimes analyzing a few samples is all you need. But when it's time to scale up for routine testing, the Bot1 Autosampler lets you do just that. The only automated particle analysis platform available today, it handles sample loading, washing, and rinsing on up to 96 samples and boosts overall standardization in the process. Not sure what your sample load will be? Add a Bot1 to your MFI 5000 Series system at any time.



Specifications

DESCRIPTION	MFI 5100	MFI 5200
Size Range	2 µm to 300 µm	1 µm to 70 µm
Percent of Sample Analyzed	>85% – entire size range	>85% – entire size range
Depth of Field (DOF)	400 µm	100 µm
Flow Cell Depth	400 µm – <i>DOF matched</i>	100 µm – <i>DOF matched</i>
Analysis Rate	200 µL/min	150 µL/min
Maximum Concentration (@2.5 µm)	175,000 particles/mL	900,000 particles/mL
Automation	High Throughput Bot1 Autosampler (optional)	
Sample Loading Options	<ul style="list-style-type: none"> • Pipette tip: 1 mL manual insertion, 1 mL Autosampler • Syringe barrel: 2 mL, 10 mL, 20 mL manual insertion • BD Hypak™ Syringe Introduction Adapter: 1 mL, 2 mL 	
Flow Cell Coatings	Non-coated, hydrophobic, custom	
Precision Stirring	<ul style="list-style-type: none"> • Variable speed control: 200–2,000 RPM • Compatible with syringe barrel usage 	
Data Output	<ul style="list-style-type: none"> • Chart formats: histograms, scatterplots, trend charts • Image formats: uncompressed TIFF (analysis), compressed JPG (storage) 	
Particle Count Parameters	Particle count, concentration, mass, volume	
Morphology Parameters	Size (ECD), maximum feret diameter, aspect ratio, circularity, area, perimeter, intensity	
Customized Analysis Filters	Combine two or more image and count parameters in a filter, for up to 511 different custom analysis filters	
MFI View System Software (MVSS) <i>See product brochure for full details</i>	<ul style="list-style-type: none"> • Method-based analysis protocols • Time-resolved analysis and data compression for storage • 21CFR Part 11 enabling features • Secure access with comprehensive audit/log files • Fully compatible with MFI View Analysis Suite (MVAS) 	
MFI View Analysis Suite (MVAS) <i>See product brochure for full details</i>	<ul style="list-style-type: none"> • Review images, parametric data and trend charts • Isolate sub-populations using “find-similar” function • Create multi-node filters with real-time feedback • Overlay and compare data sets • Generate comprehensive reports with multiple categories • Create analysis templates for repeat use 	

What real users are saying:

“Particle counting [using MFI] may be the most sensitive technique available for the detection of aggregated protein.”
2011, *Journal of Pharmaceutical Sciences*, 100(2):492–503.

“Subvisible particle analysis using MFI can help present a more complete picture of the solution and in some cases also help to identify the origins of the particles.”
2011, *Journal of Pharmaceutical Sciences*, 100(7):2563–73.



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