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Edition 5

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A New Form of Protein Aggregate Signals the Onset of Polysorbate Degradation

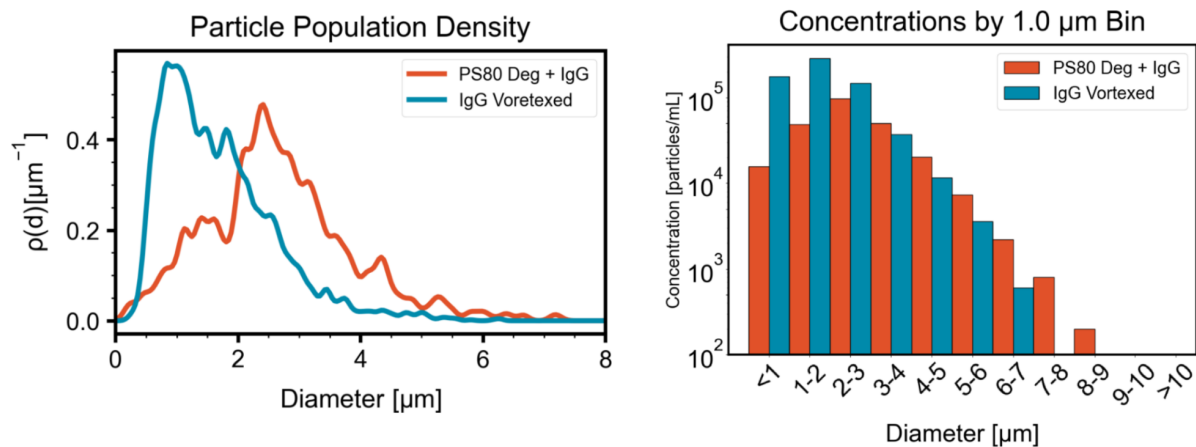
Early detection of polysorbate degradation can be challenging in all stages of drug development and manufacturing. xSight's ability to give accurate counts, size and composition of particles well below 1 μm enables earlier detection of polysorbate degradation, before it becomes a problem.

The data below shows the unique way xSight with Total Holographic Characterization detects this phenomenon. When polysorbate degrades, instigating protein aggregation, the aggregation behavior has a unique THC signature. With mechanical or thermal stress, protein aggregate concentrations increase as they get smaller. With

aggregation induced by polysorbate degradation, there is a distinct peak in the size range of 2-3 μm .

With xSight's sensitivity in this smaller size range, as well as xSight's higher resolution of particle size distribution, it's easy to tell when you have polysorbate degradation. This unique feature occurs with PS20 and PS80.

xSight's high resolution identifies early warning signs of polysorbate degradation in biologics



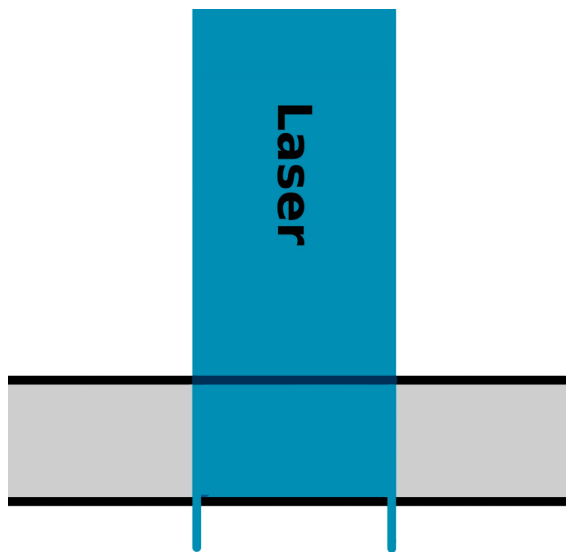
- Shown above are two plots of the same measurements of protein aggregates using xSight.
- On the left is xSight's particle density distribution as a function of particle size.
- On the right is a bar chart plot with size bins of 1 μm typically used by other techniques.
- The plot on the left shows a stark difference between the size distribution of protein aggregates caused by mechanical stress compared to the size distribution caused by exposure to polysorbate degradants. This difference is harder to distinguish in the plot on the right.



xSight: Quality Confirmation in Every Measurement

With xSight, there is no need to run standards or perform calibration to ensure accurate results. Every measurement with xSight contains an inherent quality check: the Velocity Profile of the particles.

xSight carefully controls the flow of sample through xCells, our custom microfluidic sample chips, to maintain precise flow volumes, which deliver accurate concentrations. As long as the velocity profile is parabolic and within specifications, concentration, size and refractive index of each particle is accurate and reliable.



New Review Article about Particle Characterization Technologies

Congratulations to our customers at [Merck](#) have published a comprehensive review of particle characterization technologies, including Spheryx's xSight with Total Holographic Characterization (THC).

xSight uses THC to detect, identify and quantify sub-visible particles in the size range of 500 nm - 10 μ m. xSight has 10x greater sensitivity in this size range and enables you to detect issues before they become problems. Monitor multiple particle types simultaneously in a single measurement - even when they are the same size and shape. Click the link below to read the article!

[Read the Article Here](#)

USP BioPharma Webinar with Spheryx CEO Laura Philips on Silicone Oil Detection

Earlier this month, Spheryx CEO Laura Philips participated in the BioPharma Webinar "Addressing Subvisible Silicone Oil Droplets-Industry Challenges, Analytical Strategies, and USP's Rationale for a New General Informational Chapter" with USP's Desmond Hunt and Yokogawa Fluid Imaging Technologies' Tyler Carter including a live Q&A session. Click the link below to watch the free recording!

[Watch the Webinar Here](#)

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About Spheryx, Inc.

Spheryx, Inc. is a privately held analytical services and instruments company providing Total Holographic Characterization® of colloidal materials. Spheryx's proprietary technology uses holographic video microscopy to characterize each particle in colloidal dispersions and multi-component colloidal mixtures, offering unprecedented insights into these materials' characteristics. Applications include R&D, quality assurance and manufacturing process control across a broad spectrum of industries, where characterization of colloids can enhance innovation, improve safety and reduce costs. For more information: <https://www.spheryx.solutions/>

Note: This news release contains forward-looking statements regarding future events. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or result to differ materially.

Contact:

Laura Philips, CEO

lphilips@spheryx.solutions

917-773-8553



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Our mailing address is:

Spheryx, Inc.

330 E 38th St

#48J

New York, Ny 10016

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