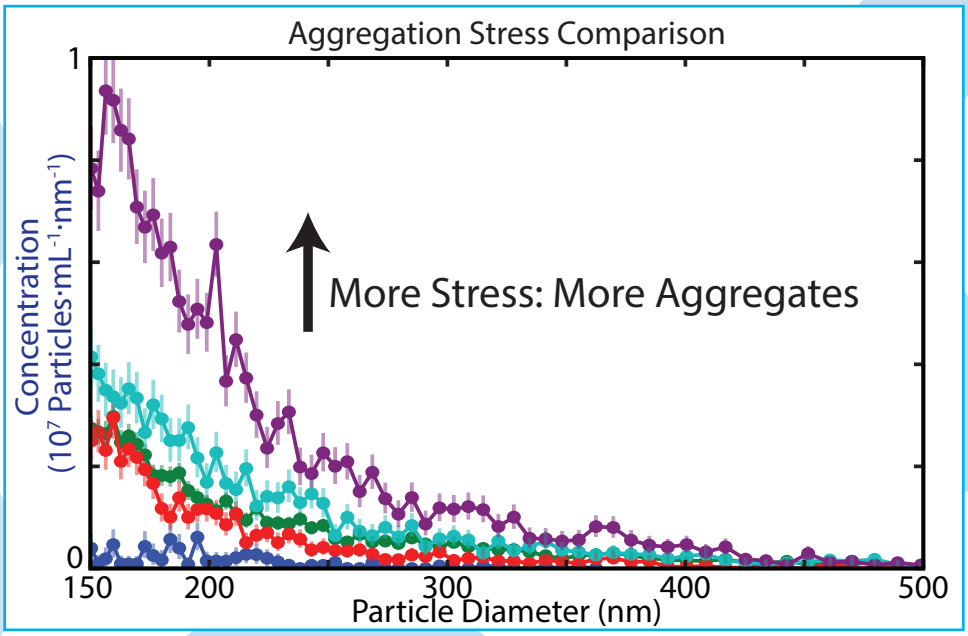
Spectradyne®
Particle Analysis

Nanoparticle Analysis of Protein Aggregates in Biologics

The Spectradyne nCS1 employs a novel implementation of the resistive pulse sensing method to count and size nanoparticles quickly and with high resolution. Sizing precision of ±3% is typically achieved, with measurement rates up to 10,000 particles/s.

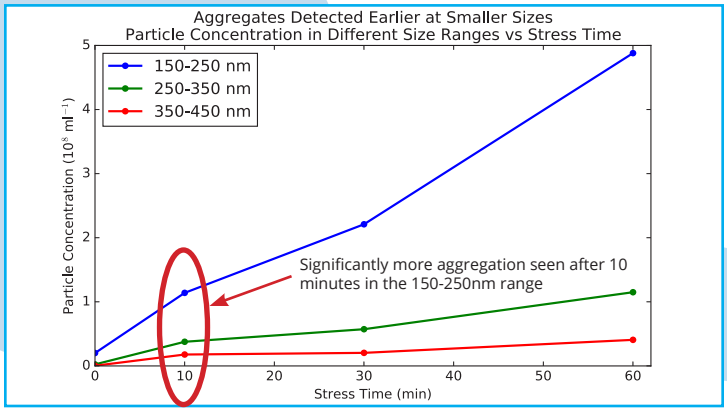
The nCS1 delivers two significant advantages for detecting aggregates in protein solutions: First, individual particle measurements (no ensemble-averaging) deliver accurate size distributions in highly polydisperse samples such as these. Second, the non-optical electrical detection method ensures that protein aggregates, which are low-index contrast materials, are accurately represented in the distribution.

Particulates in parenteral drug development and production have always been a serious issue. In biologics, the issue is compounded by reported impacts of aggregates and particles on the product's efficacy, safety and immunogenicity. FDA regulations strongly recommend in-depth characterization of the identity and quantity of particles in protein therapeutics.



While regulations require measurement of larger particles (>1µm), it is desirable to detect and characterize protein aggregates long before they are that large. Crucial decisions about formulation, processing, storage conditions, etc. must be made with an eye towards minimizing protein aggregation throughout the drug life-cycle.

The nCS1 is ideally suited for accurate quantification of submicron protein aggregates. The figure above demonstrates the power of the nCS1 to quantify protein aggregation in real-world samples. Five formulations that had been stressed to varying degrees (0, 10, 20, 30, and 60 minutes) were provided by a large biopharmaceutical customer and analyzed "as received" on the nCS1 - no dilution or additives were required. The quantitative results clearly show that increased stress causes more aggregates in this formulation. Furthermore, the lower figure shows that aggregation can be detected much sooner by looking at the smaller size ranges, in this case the 150-250nm diameter range. This ability to detect aggregation earlier can directly influence time-to-market, by reducing the time required to test multiple different formulations in early discovery.



Spectradyne's nCS1 provides accurate, high-resolution particle size and concentration distributions for particles of all material types. For more information or to arrange a demonstration of the technology, please visit our website or contact us by email.

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