Optimizing DLS Measurements for Protein Drugs and Biotherapeutics

Testa Analytical has published a study that investigates parameters that can be tweaked to improve Dynamic Light Scattering (DLS) measurement quality when analyzing monomeric and aggregated monoclonal antibodies.

One of the fastest growing classes
of pharmaceutically active biologics are monoclonal antibodies. These highly versatile proteins are used as the major functional element in immunoassays and other rapid diagnostics, in vaccine production, and as the primary component in a growing number of next generation injectable protein drugs.

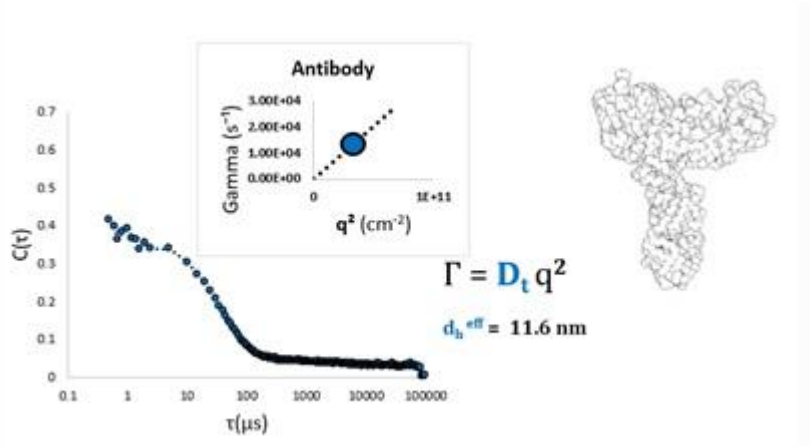

Image A: Dilute monoclonal antibody measured at a ninety-degree scattering angle shows a single effective diameter of around 11.6 nm ;

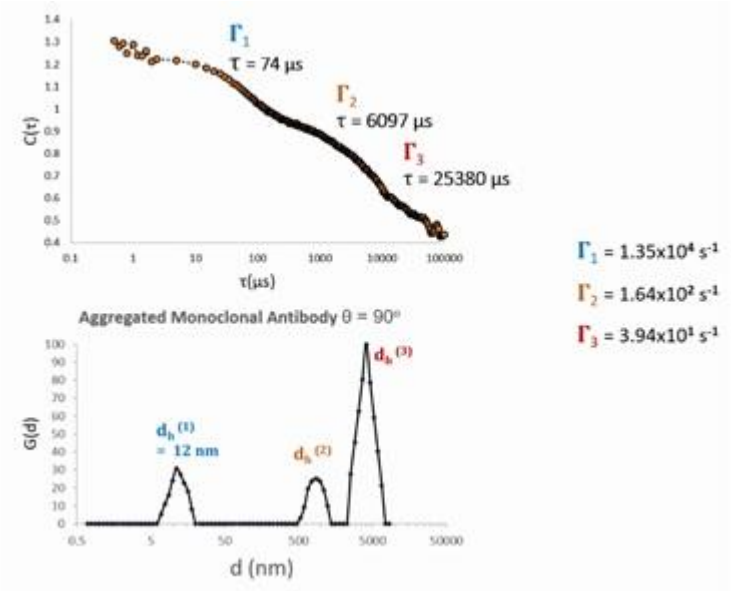

Image B: DLS of chemically stressed monoclonal antibody produces a correlation function with 2-3 major components, where the dominant component is aggregated protein

When manufacturing
such protein drugs and biotherapeutics it is essential that the monoclonal antibodies remain intact, and monomeric. Failure to adhere to these strict and exacting standards can compromise the processability, activity, and shelf stability of antibody-based products. As a consequence monoclonal antibody based products are typically expensive to manufacture and therefore the need for a reliable analytical method for quality control is highly desirable.

In the study,
experimental data is shown comparing the DLS results for a common protein (Bovine Serum Albumin) and a commercially available pharmaceutical-grade monoclonal antibody.
The authors show that selecting an optimal dynamic light scattering angle is key to accurately measuring challenging biological samples such as monoclonal antibodies.

In addition, they demonstrate
that making multi-angle DLS measurements can be informative, especially when starting with unknown mixtures of aggregated and monomeric protein. However, this is often unnecessary for stable, homogenous protein samples. Overall, This new study demonstrates how when DLS is used to its full potential, aggregation of proteins can be detected and the size of monomeric protein can be determined to a very high degree of certainty.

To read the study in full
please visit https://www.testa-analytical.com/papers/paper22.html or contact Testa Analytical Solutions on +49-30-864-24076 / info@testa-analytical.com.

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