

**Analytical Platform for Monitoring Aggregation of Monoclonal Antibody
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Abstract:

An analytical platform for the estimation as well as characterization of aggregates over the complete size spectrum (from invisible monomer to visible precipitates) was developed. Two mAb samples were incubated at 30°C in different buffer systems of protein A chromatography for observing degradation due to aggregation. The aggregation in these samples was quantified by size exclusion chromatography (SEC), dynamic light scattering (DLS), and micro flow imaging (MFI). The results obtained from various characterization tools were analysed in various size ranges - size exclusion chromatography (SEC) (1 nm - 25 nm), dynamic light scattering (DLS) (10 nm - 5 µm), and micro flow imaging (MFI) (2 µm - 300 µm). Since each characterization tool covers a particular size range, data from multiple tools was collected in the “hand- over” regions to demonstrate accuracy of the platform. Based on the observations from the experiments, an analytical platform has been proposed covering the whole size spectrum that would be of utility to those engaged in formulation development as well as other aspects related to stability of biotherapeutic products.