Development of orthogonal NISTmAb size heterogeneity control methods.

The NISTmAb is a monoclonal antibody Reference Material from the National Institute of Standards and Technology; it is a standard to evaluate the performance of size-exclusion chromatography, gel filtration, and other methods. In this study, we developed orthogonal methods to control size heterogeneity in NISTmAb. The methods include size exclusion chromatography (SEC) and gel filtration chromatography (GFC), which provide complementary information for the characterization of NISTmAb samples.

The SEC method was performed using a Superdex 200 column, and the GFC method was performed using a Superdex 300 column. The SEC method was used to determine the molecular weight of the NISTmAb, while the GFC method was used to determine the monomer and dimer concentration of the NISTmAb. The results showed that the SEC method could accurately determine the molecular weight of the NISTmAb, while the GFC method could accurately determine the monomer and dimer concentration of the NISTmAb.

The abstract also discussed the potential applications of these methods in the quality control of monoclonal antibody products. The methods developed in this study can be used to evaluate the performance of size exclusion chromatography, gel filtration, and other methods. The methods can also be used to evaluate the quality of monoclonal antibody products, which is important for the pharmaceutical industry.