Ultra-Fast pH-Gradient Ion Exchange Chromatography for the Separation of Monoclonal Antibody Charge Variants

Authors : Robert van Ling, Alexander Schwahn, Shanhua Lin, Ken Cook, Frank Steiner, Rowan Moore, Mauro de Pra Abstract : Purpose: Demonstration of fast high resolution charge variant analysis for monoclonal antibody (mAb) therapeutics within 5 minutes. Methods: Three commercially available mAbs were used for all experiments. The charge variants of therapeutic mAbs (Bevacizumab, Cetuximab, Infliximab, and Trastuzumab) are analyzed on a strong cation exchange column with a linear pH gradient separation method. The linear gradient from pH 5.6 to pH 10.2 is generated over time by running a linear pump gradient from 100% Thermo Scientific[™] CX-1 pH Gradient Buffer A (pH 5.6) to 100% CX-1 pH Gradient Buffer B (pH 10.2), using the Thermo Scientific[™] Vanquish[™] UHPLC system. Results: The pH gradient method is generally applicable to monoclonal antibody charge variant analysis. In conjunction with state-of-the-art column and UHPLC technology, ultra fast high-resolution separations are consistently achieved in under 5 minutes for all mAbs analyzed. Conclusion: The linear pH gradient method is a platform method for mAb charge variant analysis. The linear pH gradient method can be easily optimized to improve separations and shorten cycle times. Ultra-fast charge variant separation is facilitated with UHPLC that complements, and in some instances outperforms CE approaches in terms of both resolution and throughput. **Keywords :** charge variants, ion exchange chromatography, monoclonal antibody, UHPLC

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