There were four in the bed: Utilizing the IntaBio icIEF-MS system to expedite identification of capillary isoelectric focusing peaks

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Abstract

Charge heterogeneity is present in most biopharmaceutical protein products. Isolation and identification of charge variants separated using the specification method is an important part of product characterization and manufacturing control strategy development. For Capillary Isoelectric Focusing (cIEF), this is a major time commitment.

Since peak collection using cIEF separation has not been possible, liquid chromatography (LC) has typically been used as an orthogonal technique to achieve charge variant enrichment for further characterization. Drawbacks of this approach include the time investment in developing chromatography methods and because the 2 techniques do not use the same separation mechanism, chromatography fractions that appear to be pure by LC often result in a mixture of cIEF peaks, preventing definitive cIEF peak identification. We evaluated a pre-commercial icIEF-MS system from SCIEX for expediting cIEF peak identification. The IntaBio icIEF-MS system performs cIEF focusing, mobilizes each peak and sprays it into the mass spectrometer.

AstraZeneca tested the icIEF-MS with a monoclonal antibody that had undergone cIEF peak identification using our traditional chromatography platform. It took weeks of work to complete the analysis using chromatography enrichment while the IntaBio icIEF-MS system collected a similar dataset in a day! The results demonstrate the power of the IntaBio icIEF system to expedite cIEF peak identification through on-line focusing, mobilization and analysis without the need of an accompanying chromatography method.