Blaze by Intabio: An imaged cIEF-MS platform for biopharmaceutical quality attribute monitoring

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Video Abstract

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Abstract

Biopharmaceuticals, protein-based drugs manufactured by living cells, are some of the most powerful and effective drugs leading the fight against numerous diseases. But producing them is a notoriously difficult business. Growth conditions, purification procedures, and formulation requirements can unintentionally change the protein structure of these drugs, altering their efficacy and toxicity. Testing for these modifications is therefore crucial. But current methods are cumbersome and don't provide the throughput and real-time analytics that today's rapidly growing biopharma industry desperately needs to control their development and manufacturing efforts. Now, there's a solution. Introducing Intabio's Blaze system. The Blaze platform performs a comprehensive analysis of biopharmaceutical product quality with 100 times higher throughput than traditional approaches. The Blaze assay uses proprietary microchip technology to integrate three key functions: separation of protein isoforms by imaged capillary isoelectric focusing; UV absorption imaging of protein isoforms for quantitation; then electrospray ionization for delivering the separated isoforms to a connected mass spectrometer for peak identification. As such, Intabio's breakthrough Blaze system uniquely combines the analytical techniques of charge heterogeneity analysis, quantitation, and molecular mass characterization into one seamless process. The Blaze system includes a table-top instrument, a microchip-based consumable, reagent kits, and analytical software. In a recent study on a biosimilar of the cancer drug trastuzumab, the Blaze system demonstrated highly resolved charge variant separation, with a UV detection sensitivity less than 1% of the main peak. Electrospray ionization of the separated peaks to a connected mass spectrometer allowed for the characterization of antibody mass variants to a limit of detection below 1% composition. This approach provides substantial time and cost savings compared with today's labor-intensive methods involving chromatography and peptide mapping. That enables the analysis of multiple critical quality attributes in 15 minutes rather than in weeks. From screening of viable clones to process development to stability studies, Intabio's Blaze system is designed to meet the analytical needs of the biopharma industry. For more information, visit our page at www.intabio.com.