

CMP Scientific's CR3520 cIEF-MS Workflow Used in Biopharma Customer's BLA Submission

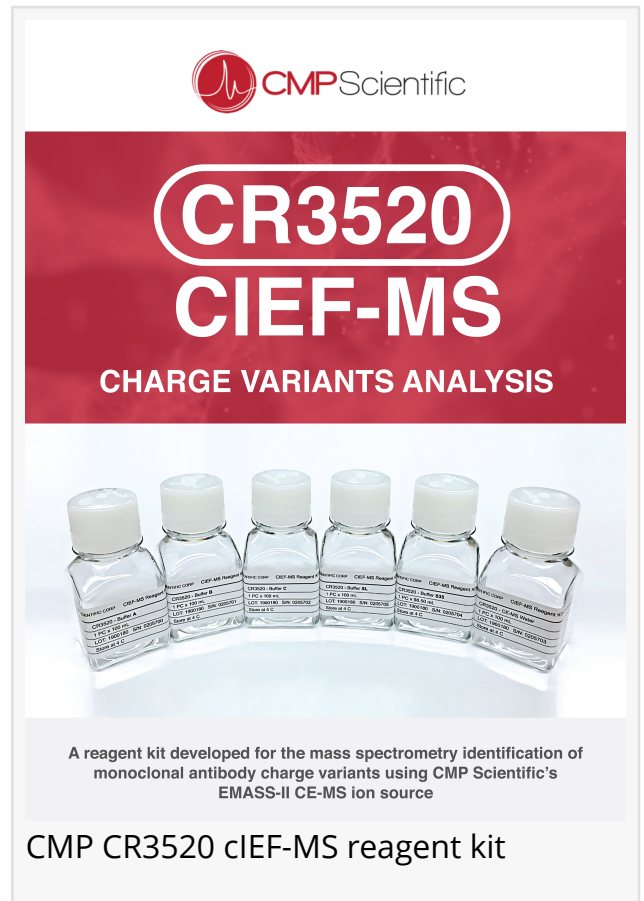
Analytical data generated with CMP CE-MS technology included in a Biologics License Application to the U.S. FDA

BROOKLYN, NY, UNITED STATES, July 22, 2025 /EINPresswire.com/ -- [CMP Scientific](#) is pleased to announce that its [CR3520 cIEF-MS](#) workflow was utilized by a biopharmaceutical customer to generate analytical data included in a Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA). This marks an important step forward for the use of CMP CE-MS technologies in regulatory-supporting applications for biologics development.

Online cIEF-MS, or capillary isoelectric focusing–mass spectrometry, combines the high-resolution separation capabilities of cIEF with the sensitive detection and structural characterization offered by mass spectrometry. This powerful technique enables simultaneous analysis of isoelectric points and molecular weights of biological molecules.

The use of CMP's technology in a BLA submission highlights the growing interest in advanced analytical tools among biopharma companies for the development of complex biologics such as monoclonal antibodies (mAbs), biosimilars, and recombinant proteins. As expectations for the characterization of critical quality attributes (CQAs) increase, charge variant analysis has become an essential focus for product development and lifecycle management.

Traditional techniques like cation exchange chromatography require additional off-line mass spectrometry steps to identify the nature of charge variants, often resulting in time-consuming and labor-intensive workflows. This has created a demand for integrated analytical platforms that combine separation and identification in a streamlined process.



CMP Scientific's CR3520 cIEF-MS system is designed to meet this demand by delivering a fully automated, online cIEF-MS workflow. The system enables precise identification of charge variants in a single run. At the core of the CR3520 is CMP's proprietary capillary-based [EMASS-II CE-MS](#) interface, which seamlessly integrates high-resolution cIEF separation with mass spectrometric detection - supporting rapid, accurate molecular characterization.

The CR3520 workflow is supported by a complete suite of application-specific consumables, including separation capillaries, emitters, and reagent kits optimized for monoclonal antibodies and other biotherapeutics. This integrated approach simplifies the analytical process while improving performance metrics such as robustness, reproducibility, and ease of use.

Unlike conventional analytic techniques, the CR3520 delivers results in hours rather than days or weeks, reducing analytical turnaround time while improving data quality. Its automation-friendly design and minimal sample preparation have made it a valuable tool for both analytical development and quality control environments. These capabilities are increasingly important as biopharma companies seek to streamline development timelines and meet evolving regulatory expectations.

"This is a significant milestone for CMP Scientific," said James Xia, CEO of CMP Scientific. "Seeing our CR3520 system used in support of a BLA submission underscores the platform's value to biopharma customers navigating complex regulatory landscapes. It demonstrates that CMP CE-MS has matured into a fit-for-purpose technology that supports comprehensive biologics characterization."

CMP Scientific's technology is being adopted by leading biopharmaceutical and biotechnology companies for critical applications such as charge variant analysis, product and process characterization, comparability studies, and in-depth structural elucidation of biologics including bispecific antibodies and antibody-drug conjugates (ADCs). Its ability to directly correlate charge variants with molecular identity provides deeper insights into product heterogeneity, supporting better control and consistency in biologic development.

CMP Scientific remains committed to advancing the field of CE-MS and empowering biopharma innovators with the tools they need for faster, smarter, and more confident decision-making. Visit www.cmpscientific.com for more information.

James Xia
CMP Scientific Corp
+1 718-360-7803
james.xia@cmpscientific.com
Visit us on social media:
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