

Alcami Advantage

Imaged Capillary IsoElectricFocusing (iCE)

Introduction

Over the last fifteen years, the biopharmaceutical industry has experienced an exponential growth in the development of peptides and proteins for use as human drugs. The biological activities of these proteins are often dependent on the charge profile of the protein, which may vary as a result of deamidation, aggregation, fragmentation and glycation. Control and monitoring of lot-to-lot consistency and stability is required because charge profiles are sensitive to both process changes and degradation pathways. Additionally, this charge profile may serve as a “fingerprint” for identification. This is relevant for early product development through stability studies and lot release of peptides and proteins (preclinical through commercial) - including therapeutic proteins, monoclonal antibodies, and antibody-drug-conjugates (ADC) - for large pharma and virtual companies alike.



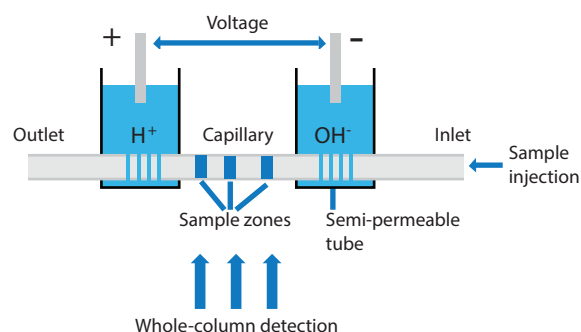
Limitations of Traditional Techniques and the Alcami Solution

Several methods are currently available for the characterization of charge variants. These methods include flat-bed gel isoelectric focusing and capillary isoelectric focusing. These methods suffer from various limitations: the flat-bed method is labor intensive, time consuming, few samples can be analyzed in a single gel and the manual analysis is somewhat subjective; traditional capillary isoelectric focusing, while similar to iCE requires a mobilization step that both increases the overall run time and results in loss of resolution.

Alcami Corporation recognized the industry needs and acquired a Protein Simple iCE3 system with Alcott autosampler, which focuses the protein in a pH gradient with continuous whole capillary imaging. This system facilitates rapid method optimization, high throughput, increased resolution and batch analysis. Alcami can provide identification testing and quantitation of isoforms to suit individual needs and time lines, including method development, validation and routine testing.

Summary

Alcami has a Protein Simple iCE3 system with back-end Empower integration to meet routine testing needs for charge heterogeneity analysis, as well as rapid method development/optimization and method validation.



Process Step	Traditional Flat-Bed	iCE3
Solution Prep/ Instrument Set-up	2 hours	2 hours
Run Time	45 minutes	10-15 minutes per sample
Fix Time	30 minutes	NA
Stain	15 minutes	NA
De-Stain	30 minutes	NA
Air Dry	overnight	NA
Scan/ Analyze	1 hour	30 minutes (Empower)
Samples per Run	3	Up to 48
Start to finish	2 days	1 day

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