

Rapid Fingerprinting of a Highly Glycosylated Fusion Protein by Microfluidic Chip-based Capillary Electrophoresis–Mass Spectrometry

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Technical Note

Abstract

Protein glycosylation can impact the efficacy, safety and pharmacokinetics of therapeutic proteins. Achieving uniform and consistent protein glycosylation is an important requirement for product quality control at all stages of therapeutic protein drug discovery and development. The development of a new microfluidic capillary electrophoresis (CE) device compatible with mass spectrometry (MS) offers a fast and sensitive orthogonal mode of high-resolution separation with MS characterization. Here, we describe a fast and robust chip-based CE-MS method for intact glycosylation fingerprinting of a therapeutic fusion protein with complex sialylated N and O-linked glycoforms. The method effectively separates multiple sialylated glycoforms and offers a rapid detection of changes in glycosylation profile in 6 minutes.

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