

REVIEW

Strategies for capillary electrophoresis: Method development and validation for pharmaceutical and biological applications—Updated and completely revised edition

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Abstract

This review is in support of the development of selective, precise, fast, and validated capillary electrophoresis (CE) methods. It follows up a similar article from 1998, Watzig H, Degenhardt M, Kunkel A. “Strategies for capillary electrophoresis: method development and validation for pharmaceutical and biological applications,” pointing out which fundamentals are still valid and at the same time showing the enormous achievements in the last 25 years.

Abbreviations: ADC, antibody–drug conjugates; AIQ, analytical instrument qualification; APTS, 3-(aminopropyl)trimethoxysilane; AQbD, analytical quality by design; ATRP, atom transfer radical polymerization; BLA, biological license application; CE-FA, capillary electrophoresis frontal analysis; CMC, critical micellar concentration; COC, cyclic olefin copolymers; cosmo, cationic polymer–coated capillary; CS, chiral selector; DoE, design of experiments; DQ, design qualification; DS, dextran sulfate; eACA, ϵ -aminocaproic acid; EK, electrokinetic; EKS, electrokinetic supercharging; EME, electromembrane extraction; FASS, field-amplified sample stacking; FC, fluorocarbon; FESI, field-enhanced sample injection; FITC, fluorescein isothiocyanate; GO, graphene oxide; HD, hydrodynamic; HPMC, hydroxypropyl methylcellulose; HR, high reverse coatings; iCIEF, imaged capillary isoelectric focusing; iEK, insulator-based electrokinetics; IQ, installation qualification; LE, leading electrolyte; LN, low normal; LPA, linear polyacrylamide; MAPTAC, [3-(methacryloylamino)propyl]trimethylammonium; MCE, microchip electrophoresis; ms-ACE, mobility shift affinity capillary electrophoresis; μ TAS, micro-total analysis systems; OQ, operational qualification; PB, polybrene; PDMS, polydimethylsiloxane; PMMA, poly(methyl methacrylate); PSP, pseudostationary phases; PQ, performance qualification; PVA, polyvinyl alcohol; PVS, poly(vinyl sulfonate); QC, quality control; QCC, QC checks; RAFT, reversible addition-fragmentation chain transfer; SCARAF, surface-confined aqueous reversible addition-fragmentation chain transfer; SMIL, successive multiple polymer layers; SST, system suitability test; TE, terminating electrolyte; TEA, triethylamine; TETA, triethylenetetramine; T-EthA, triethanolamine.

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