

# Preface

This book is addressed to the readers who wish to understand and improve their experimental skills on a fast-growing field of analytical science: capillary electrophoresis–mass spectrometry (CE-MS) for the analysis of protein therapeutics. With the recent advancement on the coupling of capillary electrophoresis with mass spectrometry, this book serves as a timely reference for analytical scientists who are adopting CE-MS technology for their protein therapeutics analysis work.

Unlike optical detectors used in traditional CE experiments, mass spectrometry is a highly sophisticated technology. The technical expertise required for effective use of CE-MS is normally developed through a number of years. This book contains a concentrated form of knowledge and experience with the hope of shortening the learning period for biopharmaceutical peers in this regard. However, one needs to bear in mind that, with the current pace of technology progressing, no books can be substitute for a great deal of time spent in the labs. Development of a good CE-MS method can be time-consuming. Taking CE-MS-based protein top-down sequencing as an example, in addition to CE separation conditions and MS instrument parameters, data acquisition method and data analysis software are also of paramount importance for the project success.

As CE-MS continues to evolve, now there are a number of systems under the broad term of CE-MS, namely capillary zone electrophoresis–electrospray ionization mass spectrometry (CZE-ESI-MS), capillary zone electrophoresis–matrix-assisted laser desorption/ionization mass spectrometry (CZE-MALDI-MS), capillary isoelectric focusing–matrix-assisted laser desorption/ionization mass spectrometry (cIEF-MALDI-MS), capillary isoelectric focusing–electrospray ionization mass spectrometry (cIEF-ESI-MS), micellar electrokinetic chromatography–electrospray ionization mass spectrometry (MEKC-ESI-MS), and chip-based microfluidics CE-MS. In this book we keep our focus on CZE-ESI-MS, as it is currently the most developed system and has become readily accessible on many instrument platforms.

Recombinant protein therapeutics has become the driving force for global biopharmaceutical industry. These molecules are much more difficult to characterize and monitor than small molecule drugs. Chapters 3–7 cover the topics that are

critical for evaluating drug efficacy, safety, purity, and stability. In particular, these chapters deal with the application of CE-MS on recombinant therapeutic protein pharmacokinetics and drug metabolism (PKDM) analysis, host cell protein impurities, post-translational modifications, and Top-Down sequencing.

This book provides the reader updated information on the forefront of technology advancement in CE-MS for protein therapeutics characterization. Special thanks to Brian P. Halm and Merry Stuber in Springer for their assistance and guidance throughout the cycle of this book production.

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