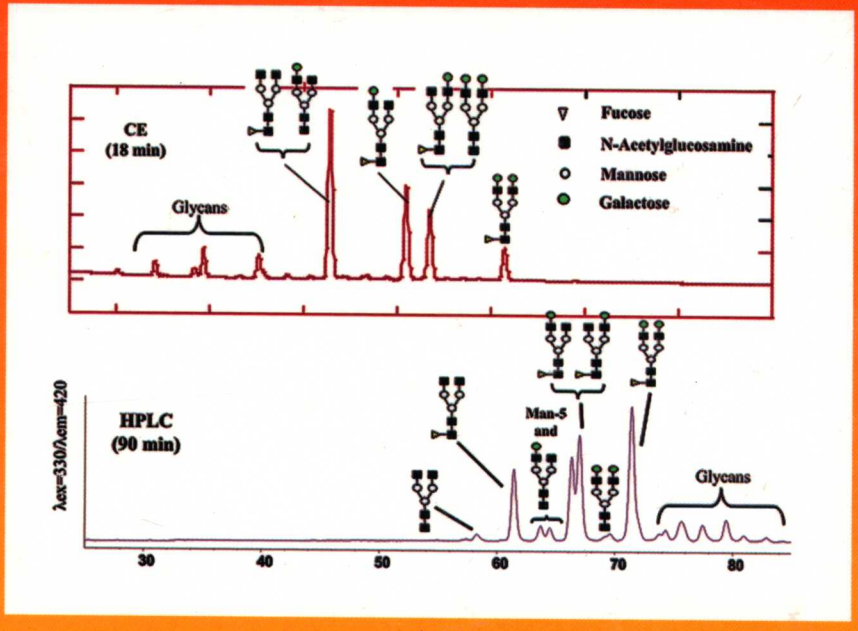
CAPILLARY ELECTROPHORESIS METHODS FOR PHARMACEUTICAL ANALYSIS

Edited by
Satinder Ahuja
M. Ilias Jimidar



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CAPILLARY ELECTROPHORESIS METHODS FOR PHARMACEUTICAL ANALYSIS

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SEPARATION SCIENCE AND TECHNOLOGY

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PREFACE

Capillary electrophoresis (CE) using fused-silica capillaries with internal diameter in the micrometer range was introduced in 1981 and was received with great enthusiasm in the separations world because it promised high separation efficiency, a large degree of flexibility during method development, and a low cost of operation. After a better understanding of the fundamentals was developed, the focus shifted to some real applications. Many papers describing highly efficient separation methods have been published in the last two decades. CE offers several advantages over high-performance liquid chromatography (HPLC), a technique commonly used in the pharmaceutical industry. These include simplicity, smaller sample size, rapid analysis, automation, ruggedness, different mechanisms for selectivity, and low cost. Furthermore, CE offers higher efficiency than HPLC and thus greater resolution power for separating various components. These advantages make CE a very attractive tool in the research and development of pharmaceuticals, quality control, and stability studies.

This book has been planned to provide busy pharmaceutical scientists a complete yet concise reference guide for utilizing the versatility of CE in new drug development and quality control. The text can be broadly classified in five major sections:

- Overview, theory, and instrumentation (Chapters 1–3)
- CE methods and practices (Chapters 4–6)
- Regulatory aspects (Chapters 7–11)
- Applications (Chapters 12–16)
- New developments (Chapters 17 and 18)

Each of the chapters, written by selected experts in their respective fields, is designed to provide the reader with an in-depth understanding of CE theory, hardware, methodologies, regulations, and applications. The text includes state-of-the-art information on CE analysis of

pharmaceuticals and provides the reader a clear and concise understanding of the following important topics:

- How to improve performance of CE methods
- How to develop and validate robust methods in CE
- How to increase precision in CE
- How to make CE method transfers more successful
- How to interpret ICH guidelines relating to CE
- How to perform IQ, OQ, PQ, and CE calibrations

Major applications covered include assays, impurity testing, high-throughput screening, chiral separation, pK_a determination, ion analysis, impurity profiling, orthogonal method, and characterization of proteins, peptides, and nucleotides. Furthermore, the latest developments in capillary electrochromatography (CEC), CE–MS, and coupling chip-based devices to MS are discussed at length.

We would like to thank all of the authors for their valuable efforts in making this book serve as a definitive reference source on CE for laboratory analysts, researchers, managers/executives in industry, academia, and government who are engaged in various phases of analytical research and development or in quality control.

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JULIE SCHAPPLER, JEAN-LUC VEUTHEY, AND SERGE RUDAZ

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I. INTRODUCTION

Electrophoresis is a separation technique that is based on the differential migration of charged compounds in a semi-conductive medium under the influence of an electric field. Its origin can be traced back to the 1880s; however, it got major recognition in 1937, when Arne

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