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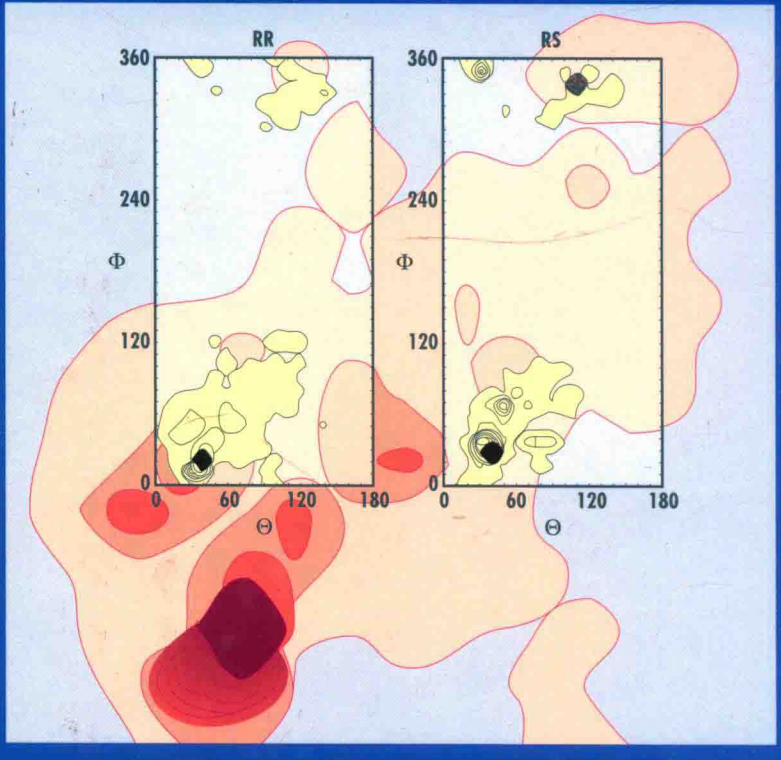
Chiral Separation Techniques

A Practical Approach

Edited by G. Subramanian



Second, completely revised and updated edition

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Preface

During the past two decades there has been intense interest in the development and application of chiral chromatographic methods, particularly in the pharmaceutical industries. This is driven both by desire to develop and exploit "good science" and by the increasing pressure by regulatory authorities over the past ten years against the marketing of racemic mixtures. The regulation of chiral drug provides a good demonstration of the mutual relationship between progress in scientific methodology and regulatory guidelines. It has also provided a common platform in establishing good understanding between international regulatory authorities and pharamceutical industries, leading to a consensus in recognition of the global nature of pharmaceutical development. This has provided a great challenge for the industries to seek techniques that are efficient, economical and easy to apply, in the manufacture of enantiopure products.

The versatility of chiral stationary phases and its effecitve application in both analytical and large-scale enantioseparation has been discussed in the earlier book '*A Practical Approach to Chiral Separation by Liquid Chromatography*' (Ed. G. Subramanian, VCH 1994). This book aims to bring to the forefront the current development and sucessful application chiral separation techniques, thereby providing an insight to researchers, analytical and industrial chemists, allowing a choice of methodology from the entire spectrum of available techniques.

I am indebted to the leading international group of contributors, who have agreed to share their knowlegde and experience. Each chapter represents an overview of its chosen topic. Chapter 1 provider an overview of techniques in preparative chiral separation, while Chapter 2 provides an account on method development and optimisation of enantiomer separation using macrocyclic glycopeptide chiral stationary phase. Combinatorial approach and chirabase applications are discussed in Chapters 3 and 4. Chapter 5 details the development of membranes for chiral separation, while Chapter 6 gives an overview of implanting techniques for enantiopurification. Non chromatographic solid-phase purification of enantiomers is explained in Chapter 7, and Chapter 8 discusses modeling and simulation of SMB and its application in enantioseparation. A perspective on cGMP compliance for preparative chiral chromatography in discussed Chapter 9, and Chapter 10 provides an account of electrophoretically driven preparative chiral separation and sub- and supercritical fluid

chromatography for enentioseparation is explained in Chapter 11. An insight into International Regulation of chiral drugs is provided in Chapter 12.

It is hoped that the book will be of value to chemists and chemical engineers who are engaged in the manufacture of enantiopure products, and that they will sucessfully apply some of the techniques described. In this way, an avenue will be provided for further progess to be made in this important field.

I wish to express my sincere thanks to Steffen Pauly and his colleagues for their enthusiasm and understanding in the production this book.

Canterbury, Kent, UK
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