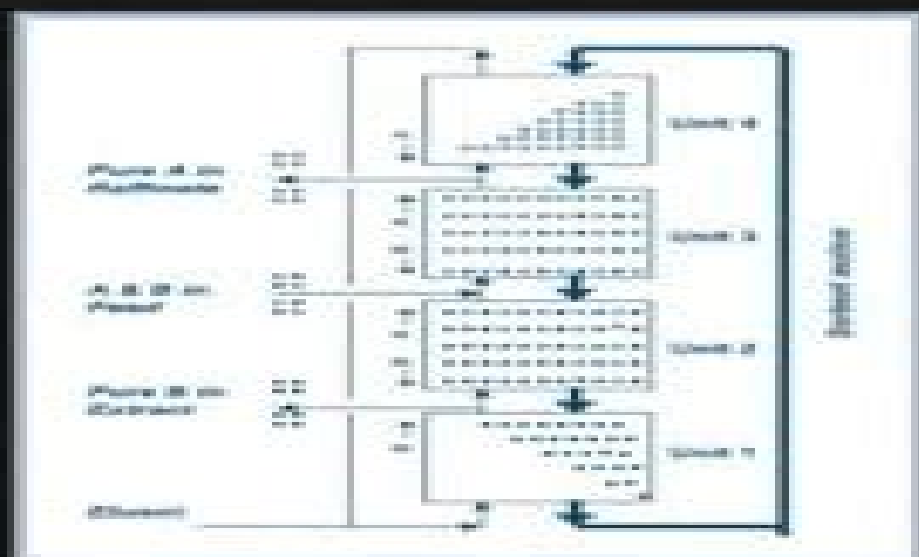


Scale-Up and Optimization in Preparative Chromatography

Principles and Biopharmaceutical Applications



edited by
Anurag S. Rathore
Ajoy Velayudhan

Scale Up And Optimization In Preparative Chromatography Principles And Biopharmaceutical Applications Chromatographic Science Series

Anthony R. Mire-Sluis



Scale Up And Optimization In Preparative Chromatography Principles And Biopharmaceutical Applications

Chromatographic Science Series:

Scale-Up and Optimization in Preparative Chromatography Anurag Rathore, Ajoy Velayudhan, 2002-09-26 Presenting guidelines to predict and improve separation system performance this book contains numerous case studies illustrating the practice of scale up principles in process development It offers solutions to limitations that occur in real world purification schemes methods to model optimize and characterize nonlinear separation processes data comparisons from all stages of production and industrial separation schemes for products such as synthetic molecules antibody fragments IgG growth factors and plasmid DNA The book covers external constraints separation economics correlations for transport and kinetic phenomena and the configuration and parameters of column design **Translational Medicine** Robert A.

Meyers, 2018-03-13 This reference work gives a complete overview of the different stages of drug development using a translational approach The book is structured in different parts following the different stages in drug development Almost half of the work is dedicated to core of drug discovery using a translational approach the identification of appropriate targets and screening methods for the identification of compounds interacting with these targets The rest of book covers the whole downstream pipeline after the identification of lead compounds such as bioavailability issues identification of appropriate drug delivery venues production and scaling issues and preclinical trials As has been the case with other works in the encyclopedia the book is made up of long comprehensive and authoritative chapters written by outstanding researchers in the field *Amino Acids, Peptides and Proteins in Organic Chemistry, Analysis and Function of Amino Acids and Peptides*, 2011-11-30 This is the last of five books in the Amino Acids Peptides and Proteins in Organic Synthesis series Closing a gap in the literature this is the only series to cover this important topic in organic and biochemistry Drawing upon the combined expertise of the international who s who in amino acid research these volumes represent a real benchmark for amino acid chemistry providing a comprehensive discussion of the occurrence uses and applications of amino acids and by extension their polymeric forms peptides and proteins The practical value of each volume is heightened by the inclusion of experimental procedures The 5 volumes cover the following topics Volume 1 Origins and Synthesis of Amino Acids Volume 2 Modified Amino Acids Organocatalysis and Enzymes Volume 3 Building Blocks Catalysis and Coupling Chemistry Volume 4 Protection Reactions Medicinal Chemistry Combinatorial Synthesis Volume 5 Analysis and Function of Amino Acids and Peptides Volume 5 of this series presents a wealth of methods to analyze amino acids and peptides Classical approaches are described such as X ray analysis chromatographic methods NMR AFM mass spectrometry and 2D gel electrophoresis as well as newer approaches including Surface Plasmon Resonance and array technologies Originally planned as a six volume series Amino Acids Peptides and Proteins in Organic Chemistry now completes with five volumes but remains comprehensive in both scope and coverage Further information about the 5 Volume Set and purchasing details can be viewed [here](#)

Comprehensive Natural Products III ,2020-07-22 Comprehensive Natural Products III Third Edition Seven Volume Set updates and complements the previous two editions including recent advances in cofactor chemistry structural diversity of natural products and secondary metabolites enzymes and enzyme mechanisms and new bioinformatics tools Natural products research is a dynamic discipline at the intersection of chemistry and biology concerned with isolation identification structure elucidation and chemical characteristics of naturally occurring compounds such as pheromones carbohydrates nucleic acids and enzymes This book reviews the accumulated efforts of chemical and biological research to understand living organisms and their distinctive effects on health and medicine and to stimulate new ideas among the established natural products community Provides readers with an in depth review of current natural products research and a critical insight into the future direction of the field Bridges the gap in knowledge by covering developments in the field since the second edition published in 2010 Split into 7 sections on key topics to allow students researchers and professionals to find relevant information quickly and easily Ensures that the knowledge within is easily understood by and applicable to a large audience

State of the Art Analytical Methods for the Characterization of Biological Products and Assessment of Comparability Anthony R. Mire-Sluis,2005 With the latest advances in analytical technologies most biological products can now be extensively characterized in terms of their identity heterogeneity and impurity profile The currently available analytical methods both physicochemical and biological can characterize the primary secondary and to some extent the higher order structure of proteins The sensitivity and selectivity of these methods allow for the identification and characterization not only of the desired protein component but also many product related substances and impurities as well as process related impurities present in the drug preparations Using an appropriate selection of analytical tools it may be possible to demonstrate physicochemical and functional comparability between protein products manufactured before and after a manufacturing change or during product development However the extent of demonstrable comparability depends on the tests used on the nature of the product and on the basic understanding of structure function relationships Assessment of immunogenicity is also a critical component of product characterization and is highly dependent on the types of assays used

Journal American Chemical Society,2003 **Handbook of Therapeutic Antibodies** Stefan Dübel,Janice M. Reichert,2014-08-04 Still the most comprehensive reference source on the development production and therapeutic application of antibodies this second edition is thoroughly updated and now has 30% more content Volume 1 covers selection and engineering strategies for new antibodies while the second volume presents novel therapeutic concepts and antibodies in clinical study as well as their potential Volumes 3 and 4 feature detailed and specific information about each antibody approved for therapeutic purposes including clinical data This unique handbook concludes with a compendium of marketed monoclonal antibodies and an extensive index Beyond providing current knowledge the authors discuss emerging technologies future developments and intellectual property issues such that this handbook meets the needs of academic

researchers decision makers in industry and healthcare professionals in the clinic **Biopharmaceutical Processing**
Gunter Jagschies,Eva Lindskog,Karol Lacki,Parrish M. Galliher,2018-01-18 Biopharmaceutical Processing Development Design and Implementation of Manufacturing Processes covers bioprocessing from cell line development to bulk drug substances The methods and strategies described are essential learning for every scientist engineer or manager in the biopharmaceutical and vaccines industry The integrity of the bioprocess ultimately determines the quality of the product in the biotherapeutics arena and this book covers every stage including all technologies related to downstream purification and upstream processing fields Economic considerations are included throughout with recommendations for lowering costs and improving efficiencies Designed for quick reference and easy accessibility of facts calculations and guidelines this book is an essential tool for industrial scientists and managers in the biopharmaceutical industry Offers a comprehensive go to reference for daily work decisions Covers both upstream and downstream processes Includes case studies that emphasize financial outcomes Presents summaries decision grids graphs and overviews for quick reference **Preparative**

Chromatography H. Schmidt-Traub,Michael Schulte,Andreas Seidel-Morgenstern,2020-02-27 The third edition of this popular work is revised to include the latest developments in this fast changing field Its interdisciplinary approach elegantly combines the chemistry and engineering to explore the fundamentals and optimization processes involved **Preparative Chromatography for Separation of Proteins** Arne Staby,Anurag S. Rathore,Satinder Ahuja,2017-02-02 Preparative Chromatography for Separation of Proteins addresses a wide range of modeling techniques strategies and case studies of industrial separation of proteins and peptides Covers broad aspects of preparative chromatography with a unique combination of academic and industrial perspectives Presents Combines modeling with compliance using of Quality by Design QbD approaches including modeling Features a variety of chromatographic case studies not readily accessible to the general public Represents an essential reference resource for academic industrial and pharmaceutical researchers

Preparative and Production Scale Chromatography G. Ganetsos,P.E. Barker,2019-11-11 Describes the latest developments in the scaling up and application of chromatographic operations and demonstrates that production scale chromatography is a powerful and invaluable separation process The book covers every important process design and reveals actual immediately applicable techniques and is designed to appeal to design chemical biochemical and research and development engineers process development managers bioprocess technologists analytical and clinical chemists and biochemists pharmacists and upper level undergraduate graduate and continuing education students in these disciplines

Preparative Scale Chromatography Eli Grushka,1988-10-28 Discusses a model for the propagation of a finite concentration zone in a chromatographic column for the case of a single component sample and explores operating conditions of ion exchange chromatography for the production of albumin from bovine serum and plasma Focus is on theoretical instrument *Protein Chromatography* Giorgio Carta,Alois Jungbauer,2020-02-21 An all in one practical guide

on how to efficiently use chromatographic separation methods Based on a training course that teaches the theoretical as well as practical aspects of protein bioseparation to bioprocess professionals this fully updated and revised new edition offers comprehensive coverage of continuous chromatography and provides readers with many relevant examples from the biopharmaceutical industry Divided into two large parts Protein Chromatography Process Development and Scale Up Second Edition presents all the necessary knowledge for effective process development in chromatographic bioseparation both on small and large scale The first part introduces chromatographic theory including process design principles to enable the reader to rationalize the set up of a bioseparation process The second part illustrates by way of case studies and sample protocols how the theory learned in the first part may be applied to real life problems Chapters look at Downstream Processing of Biotechnology Products Chromatography Media Laboratory and Process Columns and Equipment Adsorption Equilibrium Rate Processes and Dynamics of Chromatography Columns The book closes with chapters on Effects of Dispersion and Rate Processes on Column Performance Gradient Elution Chromatography and Chromatographic Column Design and Optimization Presents the most pertinent examples from the biopharmaceutical industry including monoclonal antibodies Provides an overview of the field along with design tools and examples illustrating the advantages of continuous processing in biopharmaceutical productions Focuses on process development and large scale bioseparation tasks making it an ideal guide for the professional bioengineer in the biotech and pharma industries Offers field tested information based on decades of training courses for biotech and chemical engineers in Europe and the U S Protein Chromatography Process Development and Scale Up Second Edition will appeal to biotechnologists analytical chemists chromatographers chemical engineers pharmaceutical industry biotechnological industry and biochemists **Preparative Chromatography H.**

Schmidt-Traub, Michael Schulte, Andreas Seidel-Morgenstern, 2012-09-27 Completely revised and substantially extended to reflect the developments in this fast changing field It retains the interdisciplinary approach that elegantly combines the chemistry and engineering involved to describe the conception and improvement of chromatographic processes It also covers recent advances in preparative chromatographic processes for the separation of smaller molecules using standard laboratory equipment as well as the detailed conception of industrial chemical plants The increase in biopharmaceutical substances is reflected by new and revised chapters on different modifications of continuous chromatography as well as ion exchange chromatography and other separation principles widely used in biochromatography Following an introductory section on the history of chromatography the current state of research and the design of chromatographic processes the book goes on to define the general terminology There then follow sections on stationary phases selection of chromatographic systems and process concepts A completely new chapter deals with engineering and operation of chromatographic equipment Final chapters on modeling and determination of model parameters as well as model based design optimization and control of preparative chromatographic processes allow for optimal selection of chromatographic processes Essential for chemists and

chemical engineers in the chemical pharmaceutical and food industries *Preparative Chromatography* H. Schmidt-Traub, 2006-03-06 This interdisciplinary approach combines the chemistry and engineering involved to describe the conception and improvement of chromatographic processes The book covers recent developments in preparative chromatographic processes for the separation of smaller molecules using standard laboratory equipment as well as the detailed conception of industrial chemical plants Following an introductory section on the history of chromatography the current state of research and the design of chromatographic processes the book goes on to define the general terminology There then follow sections on solid materials and packed columns process concepts Final chapters on modeling and determination of model parameters the design and optimization of preparative chromatographic processes and chromatographic reactors allow for the optimum selection of chromatographic systems Essential for chemists and engineers working in the chemicals and pharmaceutical industries as well as for food technologies due to the interdisciplinary nature of these processes **Preparative Layer Chromatography** Teresa Kowalska, Joseph Sherma, 2006-02-03 Preparative Layer Chromatography explains how this method is used for separating large quantities of mixtures containing a wide variety of important compounds It offers a broad review of preparative layer chromatography PLC applications and adaptable working procedures for microseparations involving organic inorganic and organometallic compound Fundamentals of Preparative and Nonlinear Chromatography Georges Guiochon, Dean G. Shirazi, Attila Felinger, 2006-03-21 The second edition of Fundamentals of Preparative and Nonlinear Chromatography is devoted to the fundamentals of a new process of purification or extraction of chemicals or proteins widely used in the pharmaceutical industry and in preparative chromatography This process permits the preparation of extremely pure compounds satisfying the requests of the US Food and Drug Administration The book describes the fundamentals of thermodynamics mass transfer kinetics and flow through porous media that are relevant to chromatography It presents the models used in chromatography and their solutions discusses the applications made describes the different processes used their numerous applications and the methods of optimization of the experimental conditions of this process *Optimization Studies in Preparative Chromatography of Biomolecules* Sundar Ramanan, 2000 Optimization of preparative nonlinear chromatography was carried out for the first time for a biomolecule mixture Conventional wisdom on optimization which roots from analytical chromatography dictates optimizing resolution in an analytical column and obtaining similar separation in a large column for isolation Such a method of optimization significantly under uses the capacity of the column and consumes large quantities of mobile phase Hence in preparative chromatography the objective function is productivity a measure of compromise between the amount of feed that can be loaded on to the column and time Here we report results from optimization studies carried out on a closely related binary peptide mixture on an analytical reversed phase column The goal is to optimize productivity under various chromatographic modes nonlinear isocratic elution gradient elution stepwise elution and displacement chromatography In each mode feed

mixtures at highest possible concentration limited by solubility for increasing feed volumes was used. Productivity was monitored for increasing feed volumes and loading was stopped as it went through a maximum. However, in some cases, solubility limitations from one of the feed components prevented further increase in loading. Even with this constraint, high productivities (5–10 g product/L stationary phase/h) were achieved. Separate experiments were carried out to measure the adsorption isotherms of these peptides over the range permitted by solubility. Separations under nonlinear chromatographic conditions were applied to isolate commercially significant two microcystins, microcystin LR and microcystin LA, from a cyanobacterial process waste. Milligram level loading of microcystins was obtained on a solid phase extraction cartridge packed with 0.5 g of C1 stationary phase. The separations were first carried out on an analytical column and then scaled up to a preparative column. We also report a simple and economical process to purify phycocyanins and allophycocyanins from a cyanobacterial process waste stream for two kinds of applications: food colorant and biomedical marker. A detailed design for the large scale production of biliproteins for both applications is also presented. Economic evaluation of the process resulted in comparable costs with the current market price for food grade product and substantially lower cost for the biomedical grade product.

Advances in Chromatography Nelu Grinberg, Eli Grushka, 2017-08-15 For more than five decades scientists and researchers have relied on the *Advances in Chromatography* series for the most up to date information on a wide range of developments in chromatographic methods and applications. For Volume 54 the series editors have invited established well known chemists to offer cutting edge reviews of chromatographic methods applied in the life sciences that emphasize the underlying principle of separation science. The clear presentation of topics and vivid illustrations for which this series has become known makes the material accessible and engaging to analytical, biochemical, organic, polymer and pharmaceutical chemists at all levels of technical skill.

Mathematical Modeling and Scale-Up of Liquid Chromatography Tingyue Gu, 2015-04-14 Tingyue Gu's second edition provides a comprehensive set of nonlinear multicomponent liquid chromatography (LC) models for various forms of LC such as adsorption, size exclusion, ion exchange, reversed phase, affinity, isocratic gradient elution and axial radial flow LC. Much has advanced since the first edition of this book and the author's software described here is now used for teaching and research in 32 different countries. This book comes together with a complete software package with graphical user interface for personal computers offered free for academic applications. Additionally, this book provides detailed methods for parameter estimation of mass transfer coefficients, bed voidage, particle porosity and isotherms. The author gives examples of how to use the software for predictions and scale up. In contrast to the first edition, authors do not need to deal with complicated math. Instead, they focus on how to obtain a few parameters for simulation and how to compare simulation results with experimental data. After reading the detailed descriptions in the book, a reader is able to use the simulation software to investigate chromatographic behavior without doing actual experiments. This book is aimed at readers who are interested in learning about LC behaviors and at those who want to scale up LC for

preparative and large scale applications Both academic personnel and industrial practitioners can benefit from the use of the book This new edition includes New models and software for pellicular cored beads in liquid chromatography Introduction of user friendly software with graphical user interface Detailed descriptions on how to use the software Step by step instructions on parameter estimation for the models New mass transfer correlations for parameter estimation Experimental methods for parameter estimation Several actual examples using the model for product development and scale up Updated literature review

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