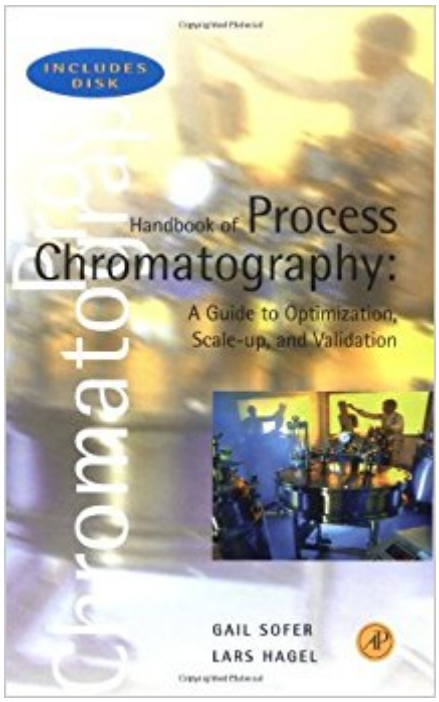
Handbook Of Process Chromatography: A Guide To Optimization, Scale Up, And Validation



Synopsis

This handbook is an excellent reference for graduates and researchers in biotechnology and practitioners in the pharmaceutical industry who wish to develop a commercial chromatographic purification process. The authors guide readers through each step of the development process, beginning with basic chromatography theory and practice and incorporating examples from companies with established processes and approved biotherapeutics. They also cover properties of biological molecules, and reveal pitfalls often encountered in the process. Design strategies are discussed in depth, considering common starting materials and their impact on purification design, scale-up concerns, and validation. The authors use their extensive consulting and teaching experience to present a practical approach to developing an optimal chromatographic process, scaling it up, and meeting requirements set forth by regulatory agencies. The included diskette contains modeling exercises providing valuable insights into the influence of chromatographic parameters on separation results and the impact of process design on production costs, making the Handbook an excellent hands-on teaching tool. Key Features* Considers the entire scope of process chromatography, including scale up, regulatory issues, equipment, evaluation studies, scheduling, and cost-effectiveness* Provides examples from companies with established processes and approved biotherapeutics* Includes an appendix which lists the most pertinent regulatory documents, allowing the user to gather necessary information to comply with global regulatory expectations for process chromatography* Contains a modeling program on the included disk

Book Information

Hardcover: 387 pages

Publisher: Academic Press; 1 edition (July 8, 1997)

Language: English

ISBN-10: 012654266X

ISBN-13: 978-0126542660

Product Dimensions: 9.4 x 6.2 x 1 inches

Shipping Weight: 1.2 pounds

Average Customer Review: 5.0 out of 5 stars 1 customer review

Best Sellers Rank: #3,472,666 in Books (See Top 100 in Books) #63 inÃ Â Books > Science & Math > Chemistry > Chromatography #1045 inÃ Â Books > Science & Math > Chemistry > Analytic #2256 inÃ Â Books > Textbooks > Engineering > Chemical Engineering

Customer Reviews

This Handbook offers a practical approach to developing an optimal chromatographic process, scaling it up, and adapting it to comply with requirements set by world-wide regulatory agencies.The reader is led through every stage of the development process using examples from companies with established processes and approved biotherapeutics. The aim is to help the reader to realize the scope of issues that must be evaluated and avoid common pitfalls. For the uninitiated, separate chapters also deal with basic chromatography theory and properties of biological molecules.The authors have used their extensive experience in teaching and consultancy to present a practical approach to the critical issue of validation. They have also compiled an appendix of the most pertinent regulatory documents. The accompanying disk contains modeling exercises providing valuable insight into the influence of chromatographic parameters on the separation result and the impact of process design on production costs.The holistic and practical approach of the Handbook make it an essential reference for graduates and researchers in biochemical engineering and biotechnology as well as practitioners in the pharmaceutical industry. The enclosed disk also makes the Handbook an excellent hands-on teaching tool.

Gail Sofer has been consulting with biotechnology and pharmaceutical companies for the past five years through the Fast Trak Validation(r) group of PharmaciaBiotech as the Director of International Validation Development. A series of publications on validation have provided guidance to many in this arena. She is active in organizations such as PDA and ASTM.Lars Hagel is a Ph.D. in analytical chemistry and also Associate Professor at the University of Uppsala. Dr. Hagel has held different management positions within the R&D department and is now a senior scientific consultant of Pharmacia Biotech. He is a member of the board for The Swedish Centre for Bioseparations, and he chairs the Centre for Bioprocess Technology. Dr. Hagel’s research has focused upon practical implications of chromatography theory and he has published a vast number of papers and chapters, with special reference to gel filtration.

Perfect for someone wanting to learn about IQ/OQ/PQ for chromatography. Easy to read. Good presentation. Useful examples. Software is great addition. Very practical approach. Plenty of useful up-to-date references. Great buy!

Handbook of Process Chromatography: A Guide to Optimization, Scale Up, and Validation Handbook of Process Chromatography, Second Edition: Development, Manufacturing, Validation and Economics CHROMATOGRAPHY OF ALKALOIDS, PART A, Volume 23A: THIN-LAYER

CHROMATOGRAPHY (Journal of Chromatography Library) Scale-Up and Optimization in Preparative Chromatography: Principles and Biopharmaceutical Applications (Chromatographic Science Series) Gas Chromatography and 2D-Gas Chromatography for Petroleum Industry: The Race for Selectivity ISO 11135:2014, Second Edition: Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices Pharmaceutical Process Validation, Second Edition (Drugs and the Pharmaceutical Sciences) Process Validation in Manufacturing of Biopharmaceuticals, Third Edition (Biotechnology and Bioprocessing) The Little Book on Digital Marketing SEO - Search Engine Optimization: Tips and tricks for keyword research in SEO or Search Engine Optimization Introduction to Linear Optimization (Athena Scientific Series in Optimization and Neural Computation, 6) Pyomo Ã¢â ¬â ¢ Optimization Modeling in Python (Springer Optimization and Its Applications) Engineering Design Optimization using Calculus Level Methods: A Casebook Approach: Math Modeling, Simulation, & Optimization Mathematical Modeling and Scale-Up of Liquid Chromatography: With Application Examples Instrument Engineers' Handbook, Vol. 2: Process Control and Optimization, 4th Edition Detailing Scale Model Aircraft (Scale Modeling Handbook) The Validation of Risk Models: A Handbook for Practitioners (Applied Quantitative Finance) L590 - Progressive Scale Studies - Scale Study and Practical Theory in Major and Minor Keys for the Young Violinist The Scale and Arpeggio Bible for Clarinet: (probably the only scale book you'll ever need) Pocket Neighborhoods: Creating Small-Scale Community in a Large-Scale World Walt Disney's Railroad Story: The Small-Scale Fascination That Led to a Full-Scale Kingdom