

Peak Tailing And Resolution

The critically acclaimed laboratory standard for more than forty years, Methods in Enzymology is one of the most highly respected publications in the field of biochemistry. Since 1955, each volume has been eagerly awaited, frequently consulted, and praised by researchers and reviewers alike. More than 260 volumes have been published (all of them still in print) and much of the material is relevant even today--truly an essential publication for researchers in all fields of life sciences. Liquid chromatography Electrophoresis Mass spectrometry

This text lists the necessary steps for meeting compliance requirements during the drug development process. It presents comprehensive approaches for validating analytical methods for pharmaceutical applications.

High pressure liquid chromatography--frequently called high performance liquid chromatography (HPLC or, LC) is the premier analytical technique in pharmaceutical analysis and is predominantly used in the pharmaceutical industry. Written by selected experts in their respective fields, the Handbook of Pharmaceutical Analysis by HPLC Volume 6, provides a complete yet concise reference guide for utilizing the versatility of HPLC in drug development and quality control. Highlighting novel approaches in HPLC and the latest developments in hyphenated techniques, the book captures the essence of major pharmaceutical applications (assays, stability testing, impurity testing, dissolution testing, cleaning validation, high-throughput screening). A complete reference guide to HPLC Describes best practices in HPLC and offers 'tricks of the trade' in HPLC operation and method development Reviews key HPLC pharmaceutical applications and highlights current trends in HPLC ancillary techniques, sample preparations, and data handling

Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmacists, QA officers, and public authorities.

High performance liquid chromatography (HPLC) has long been recognized as one of the most useful and

versatile analytical techniques. It has now progressed from being a highly expensive method of analysis to a routine technique with wide applications. Consequently there is a requirement in many chemistry and chemistry-related courses for students to acquire a detailed understanding of the principles and practice of HPLC. Written in a manner suitable for undergraduate students studying analytical chemistry and learning about chromatographic analytical techniques applied to pharmaceutical analysis, biochemistry and related disciplines, *High-performance Liquid Chromatography: Fundamental Principles and Practice* introduces the fundamentals of HPLC. Loosely structured in three parts, the text begins with a thorough introduction of the subject and then progresses through the essential knowledge of the instrumentation needed for HPLC. The final part covers with the applications of HPLC in real-world situations. Developed by a team of international experts from a wide cross-section of disciplines, the text is relevant to a wide range of courses.

The first edition of *Chromatography: Concepts and Contrasts*, published in 1988, was one of the first books to discuss all the different types of chromatography under one cover. The second edition continues with these principles but has been updated to include new chapters on sampling and sample preparation, capillary electrophoresis and capillary electrochromatography (CEC), chromatography with mass spec detection, and industrial and governmental practices in regulated industries. Covers extraction, solid phase extraction (SPE), and solid phase microextraction (SPME), and introduces mass spectrometry Updated with the latest techniques in chromatography Discusses both liquid chromatography (LC) and gas chromatography (GC)

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[Modern HPLC for Practicing Scientists](#)

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This book gives an overview of the numerical data analysis and signal treatment techniques that are used in chromatography and related separation techniques. Emphasis is given to the description of the symmetrical and asymmetrical chromatographic peak shape models. Both theoretical and empirical models are discussed. The fundamentals of data acquisition, types and effect of baseline noise, and methods of improving the signal-to-noise ratio (either in time or in frequency and wavelet domain) are thoroughly discussed. Resolution enhancement techniques, such as curve fitting, deconvolution by Fourier and wavelet

transforms, iterative deconvolution, Kalman filtering and multivariate methods of curve resolution are all discussed with several chromatographic examples. Quantitative analysis by peak area or peak height measurement, the precision and accuracy of the quantitation of stand-alone or overlapping and symmetrical or asymmetrical peaks are treated. In a separate chapter, guidelines are given for the use of transform techniques for the analysis of chromatograms. A statistical description of peak overlap is given in the final chapters. Since the concept of resolution has to be reconsidered when one separates complex mixtures, the problem of resolution and overlap is quantitatively discussed by means of statistical methods, and by using Fourier analysis of the complex chromatogram. Features of this book • The ultimate source of numerical techniques to enhance chromatographic data • Gives a detailed description of signal and resolution enhancement techniques in a manner applicable for enhancing not only chromatography, but also spectroscopic and other analytical signals • The first book with a thorough overview of the statistics of peak overlap. This is the first volume to encompass both the simple and more sophisticated methods for the numerical treatment of chromatograms. It is, therefore, the fundamental resource of numerical analysis methods for every analyst.

Uniquely integrates the theory and practice of key experimental techniques for bioscience undergraduates. Now includes drug discovery and clinical biochemistry.

Volumes in this widely revered series present comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. This organizational structure meets the needs of the pharmaceutical community and allows for the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series encompasses review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. Presents comprehensive reviews covering all aspects of drug development and formulation of drugs Profiles creatine monohydrate and fexofenadine hydrochloride, as well as five others Meets the information needs of the drug development community

The latest edition of the authoritative reference to HPLC High-performance liquid chromatography (HPLC) is today the leading technique for chemical analysis and related applications, with an ability to separate, analyze, and/or purify virtually any sample. Snyder and Kirkland's Introduction to Modern Liquid Chromatography has long represented the premier reference to HPLC. This Third Edition, with John Dolan as added coauthor, addresses important improvements in columns and equipment, as well as major advances in our understanding of HPLC separation, our ability to solve problems that were troublesome in the past, and the application of HPLC for new kinds of samples. This carefully considered Third Edition maintains the strengths of the previous edition while significantly modifying its organization in light of recent research and experience. The text begins by introducing the reader to HPLC, its use in relation to other modern separation techniques, and its history, then leads into such specific topics as: The basis of HPLC separation and the general effects of different experimental conditions Equipment and detection The column—the "heart" of the HPLC system Reversed-phase separation, normal-phase chromatography, gradient elution, two-dimensional separation, and other techniques Computer simulation, qualitative and quantitative analysis, and method validation

and quality control The separation of large molecules, including both biological and synthetic polymers Chiral separations, preparative separations, and sample preparation Systematic development of HPLC separations—new to this edition Troubleshooting tricks, techniques, and case studies for both equipment and chromatograms Designed to fulfill the needs of the full range of HPLC users, from novices to experts, Introduction to Modern Liquid Chromatography, Third Edition offers the most up-to-date, comprehensive, and accessible survey of HPLC methods and applications available.

Introduction to Statistical Analysis of Laboratory Data presents a detailed discussion of important statistical concepts and methods of data presentation and analysis Provides detailed discussions on statistical applications including a comprehensive package of statistical tools that are specific to the laboratory experiment process Introduces terminology used in many applications such as the interpretation of assay design and validation as well as “fit for purpose” procedures including real world examples Includes a rigorous review of statistical quality control procedures in laboratory methodologies and influences on capabilities Presents methodologies used in the areas such as method comparison procedures, limit and bias detection, outlier analysis and detecting sources of variation Analysis of robustness and ruggedness including multivariate influences on response are introduced to account for controllable/uncontrollable laboratory conditions

X-Ray fluorescence analysis is an established technique for non-destructive elemental materials analysis. This book gives a user-oriented practical guidance to the application of this method. The book gives a survey of the theoretical fundamentals, analytical instrumentation, software for data processing, various excitation regimes including grating incidents and microfocus measurements, quantitative analysis, applications in routine and micro analysis, mineralogy, biology, medicine, criminal investigations, archeology, metallurgy, abrasion, microelectronics, environmental air and water analysis. This book is the bible of X-Ray fluorescence analysis. It gives the basic knowledge on this technique, information on analytical equipment and guides the reader to the various applications. It appeals to researchers, analytically active engineers and advanced students.

[*Handbook of Pharmaceutical Analysis by HPLC*](#)

[*Report on the Results of the ICES/IOC/OSPARCOM Intercomparison Exercise on the Analysis of Chlorobiphenyl Congeners in Marine Media--step 1, and the Intercomparison Study of the Determination of CBs in Baltic Herring Oil*](#)

[*Developing Solid Oral Dosage Forms*](#)

[*Capillary Electrophoresis in Analytical Biotechnology*](#)

[*Pitfalls and Errors of HPLC in Pictures*](#)

[*Practical Skills in Forensic Science*](#)

[*Principles and Techniques of Biochemistry and Molecular Biology*](#)

[*Publications of the National Institute of Standards and Technology ... Catalog*](#)

[*Real Time Monitoring of the Suitability of High Resolution LC-MS Systems by Image Recognition Algorithm Using Peaks of Spiked-in Internal Standards*](#)

[*Quantitative Resolution of Fused Chromatographic Peaks in Gas Chromatography/Mass Spectrometry*](#)

Oligonucleotides represent one of the most significant pharmaceutical breakthroughs in

recent years, showing great promise as diagnostic and therapeutic agents for malignant tumors, cardiovascular disease, diabetes, viral infections, and many other degenerative disorders. The Handbook of Analysis of Oligonucleotides and Related Products is an essential reference manual on the practical application of modern and emerging analytical techniques for the analysis of this unique class of compounds. A strong collaboration among thirty leading analytical scientists from around the world, the book provides readers with a comprehensive overview of the most commonly used analytical techniques and their advantages and limitations in assuring the identity, purity, quality, and strength of an oligonucleotide intended for therapeutic use. Topics discussed include: Strategies for enzymatic or chemical degradation of chemically modified oligonucleotides toward mass spectrometric sequencing Purity analysis by chromatographic or electrophoretic methods, including RP-HPLC, AX-HPLC, HILIC, SEC, and CGE Characterization of sequence-related impurities in oligonucleotides by mass spectrometry and chromatography Structure elucidation by spectroscopic methods (IR, NMR, MS) as well as base composition and thermal melt analysis (T_m) Approaches for the accurate determination of molar extinction coefficient of oligonucleotides Accurate determination of assay values Assessment of the overall quality of oligonucleotides, including microbial analysis and determination of residual solvents and heavy metals Strategies for determining the chemical stability of oligonucleotides The use of hybridization techniques for supporting pharmacokinetics and drug metabolism studies in preclinical and clinical development Guidance for the presentation of relevant analytical information towards meeting current regulatory expectations for oligonucleotide therapeutics This resource provides a practical guide for applying state-of-the-art analytical techniques in research, development, and manufacturing settings.

This revision brings the reader completely up to date on the evolving methods associated with increasingly more complex sample types analyzed using high-performance liquid chromatography, or HPLC. The book also incorporates updated discussions of many of the fundamental components of HPLC systems and practical issues associated with the use of this analytical method. This edition includes new or expanded treatments of sample

preparation, computer assisted method development, as well as biochemical samples, and chiral separations.

Gradient elution demystified Of the various ways in which chromatography is applied today, few have been as misunderstood as the technique of gradient elution, which presents many challenges compared to isocratic separation. When properly explained, however, gradient elution can be less difficult to understand and much easier to use than often assumed. Written by two well-known authorities in liquid chromatography, High-Performance Gradient Elution: The Practical Application of the Linear-Solvent-Strength Model takes the mystery out of the practice of gradient elution and helps remove barriers to the practical application of this important separation technique. The book presents a systematic approach to the current understanding of gradient elution, describing theory, methodology, and applications across many of the fields that use liquid chromatography as a primary analytical tool. This up-to-date, practical, and comprehensive treatment of gradient elution:

- * Provides specific, step-by-step recommendations for developing a gradient separation for any sample
- * Describes the best approach for troubleshooting problems with gradient methods
- * Guides the reader on the equipment used for gradient elution
- * Lists which conditions should be varied first during method development, and explains how to interpret scouting gradients
- * Explains how to avoid problems in transferring gradient methods

With a focus on the use of linear solvent strength (LSS) theory for predicting gradient LC behavior and separations by reversed-phase HPLC, High-Performance Gradient Elution gives every chromatographer access to this useful tool.

"Volume 35 examines timely subjects such as performance requirements, detection modes, and ancillary techniques for optical detectors in capillary electrophoresis; and more." If you are studying forensic science, or a related course such as forensic chemistry or biology, then this book will be an indispensable companion throughout your entire degree programme. This 'one-stop' text will guide you through the wide range of practical, analytical and data handling skills that you will need during your studies. It will also give you a solid grounding in the wider transferable skills such as teamwork and study skills.

The application of high-resolution LC-MS experiments in drug discovery is very versatile due to high selectivity, sensitivity, and low sample volume requirements. A single HR LC-MS experiment is capable of quantitatively evaluating thousands of endogenous molecules as well as drug-derived metabolites. Advances in chromatographic separation, detector ruggedness and increased data acquisition rates enable the attainment of information-rich data sets which have shifted the bottleneck to data analysis. A primary concern of data analysis is the assessment of system suitability which reflects the quality of the collected signals. A common system suitability test evaluates the signals of characteristic peaks corresponding to a mixture of stable labeled internal standards spiked into a sample. These evaluations are driven by FDA guidelines and usually performed manually - an analyst examines the first and last injection as well as several randomly selected injections in between. A manual examination of each peak in a large study is not practical due to time and personnel constraints. Traditional statistics-based approaches to automation of system suitability testing require the calculation of averages of peak attributes such as area, symmetry, tailing factor, etc. Calculation of averaged peak attributes is sensitive to various factors including noise, system usage, and detector configuration and causes a lag in discovering abnormalities, finding them only when problems persist in a significant number of injections. This presentation discusses a novel approach to automation of data analysis which facilitates real-time signal processing during acquisition and utilizes a Convolutional Neural Network (CNN) model for peak image classification. Our approach uses images of characteristic peaks to detect abnormalities, bypassing the biases inherent in other methods of automatic monitoring. Automated data analysis algorithms gather the information relevant to mass spectroscopic characterization of molecules and report the quantitative composition of a biological sample while maintaining quality and time efficiency.

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[Handbook of Analysis of Oligonucleotides and Related Products](#)

[RNA Purification and Analysis](#)

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[Introduction to Modern Liquid Chromatography](#)

A comprehensive, practical approach to three powerful methods of polymer analysis and characterization This book serves as a complete compendium of three important methods widely used for the characterization of synthetic and natural polymers—light scattering, size exclusion chromatography (SEC), and asymmetric flow field flow fractionation (A4F). Featuring numerous up-to-date examples of experimental results obtained by light scattering, SEC, and A4F measurements, Light Scattering, Size Exclusion Chromatography and Asymmetric Flow Field Flow Fractionation takes an all-in-one approach to deliver a complete and thorough explanation of the principles, theories, and instrumentation needed to characterize polymers from the viewpoint of their molar mass distribution, size, branching, and aggregation. This comprehensive resource: Is the only book gathering light scattering, size exclusion chromatography, and asymmetric flow field flow fractionation into a single text Systematically compares results of size exclusion chromatography with results of asymmetric flow field flow fractionation, and how these two methods complement each other Provides in-depth guidelines for reproducible and correct determination of molar mass and molecular size of polymers using SEC or A4F coupled with a multi-angle light scattering detector Offers a detailed overview of the methodology, detection, and characterization of polymer branching Light Scattering, Size Exclusion Chromatography and Asymmetric Flow Field Flow Fractionation should be of great interest to all those engaged in the polymer analysis and characterization in industrial and university research, as well as in manufacturing quality control laboratories. Both beginners and experienced can confidently rely on this volume to confirm their own understanding or to help interpret their results.

Instrumental Liquid Chromatography

This new book on capillary electrophoresis (CE) is unique in its focus on biotechnology. It is devoted to proteins, peptides, and techniques especially useful in the area of recombinant DNA products. Emphasis is also placed on glycoproteins. Because of the growing role of the glycosylation process in CE, a comprehensive chapter on the subject acts as a book within a book. Although this well-known researcher in biotechnology presents a number of chapters extensively discussing theories, important practical aspects in the routine use of capillary electrophoresis are also covered.

The updated and much expanded 3e of the Handbook of Radioactivity Analysis is an authoritative reference providing the principles, practical techniques, and procedures for the accurate measurement of radioactivity from the very low levels encountered in the environment to higher levels measured in radioisotope research, clinical laboratories, biological sciences,

radionuclide standardization, nuclear medicine, nuclear power, and fuel cycle facilities and in the implementation of nuclear forensic analysis and nuclear safeguards. The book describes the basic principles of radiation detection and measurement and the preparation of samples from a wide variety of matrices, assists the investigator or technician in the selection and use of appropriate radiation detectors, and presents state-of-the-art methods of analysis. Fundamentals of radiation properties, radionuclide decay, the calculations involved, and methods of detection provide the basis for a thorough understanding of the analytical procedures. The Handbook of Radioactivity Analysis, 3e, is suitable as a teaching text for university and professional training courses. The only comprehensive reference that describes the principles of detection and practical applications of every type of radioactivity detector currently used. The new 3e is broader in scope, with revised and expanded chapters, new authors, and seven new chapters on Alpha Spectrometry, Radionuclide Standardization, Radioactive Aerosol Measurements, Environmental Radioactivity Monitoring, Marine Radioactivity Analysis, Nuclear Forensic Analysis and Analytical Techniques in Nuclear Safeguards Discusses in detail the principles, theory and practice applied to all types of radiation detection and measurement, making it useful for both teaching and research

Updated and revised throughout. Second Edition explores the chromatographic methods used for the measurement of drugs, impurities, and excipients in pharmaceutical preparations--such as tablets, ointments, and injectables. Contains a 148-page table listing the chromatographic data of over 1300 drugs and related substances--including sample matrix analyzed, sample handling procedures, column packings, mobile phase, mode of detection, and more.

This first book on the market covers the many new and important RNA species discovered over the past five years, explaining current methods for the enrichment, separation and purification of these novel RNAs. Building up from general principles of RNA biochemistry and biophysics, this book addresses the practical aspects relevant to the laboratory researcher throughout, while discussing the performance and potential problems of the methods discussed. An appendix contains a glossary with the important terms and techniques used in RNA analysis. By explaining the basic and working principles of the methods, the book allows biochemists and molecular biologists to gain much more expertise than by simply repeating a pre-formulated protocol, enabling them to select the procedure and materials best suited to the RNA analysis task at hand. As a result, they will be able to develop new protocols where needed and optimize and fine-tune the general purpose standard protocols that come with the purification equipment and instrumentation.

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Curve Resolution and the Generalized Inverse Method are used to calculate the molar compositions of mixture mass spectra acquired during coelution of unseparated GC peaks. Quantitative resolution of the GC signal, independent of peak shape, results. The effects of noise, peak separation, a drifting baseline and peak tailing are studied. No assumptions of peak shape or the presence of unique masses for the pure components are required.

The third edition of this popular problem-solving guide for this widely-used method includes eleven completely new examples and several updated ones, adding up to 100 contributions about pitfalls and errors in HPLC. Each example is presented on a double page with the text on the left-hand and a figure on the right-hand side, true to the motto 'a picture says more than a thousand words'. In addition, the author presents essential fundamentals as well as helpful strategies, such as equipment tests or quality assurance processes. New in this edition * Variability of the standard deviation * Influence of the acid type and concentration in the eluent * Water as an unintentional additive in the mobile phase * Inadequate purity of mobile phase water * Incomplete degassing * Inadequate stabilization of the extraction solvent * Tailing of phosphate compounds in the presence of steel * Different detection properties of diastereomers * Detector overload in ELSD * System suitability test * From repeatability to reproducibility A must-have resource for all users - showing how to use HPLC efficiently and obtain reliable results.

Principles and Practice of Bioanalysis provides a guide to the methods available and the techniques currently used in this field. It provides up to the minute information and guidance on the methods and strategy used in developing and running ultra-trace analyses for drugs, metabolites and other substances. The authors write in an informal and didactic style, offering a logical path through the problems of small molecule (bio)analysis and enables readers to choose appropriate methods of analysis for their needs. Principles and Practice of Bioanalysis provides an overview of analytical methods for analytical scientists within the pharmaceutical industry, research and development, the agrochemical industry, and scientists in the health service, biology and biochemistry. It also gives postgraduate students a useful reference for their research methods.

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst

interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

A comprehensive yet concise guide to Modern HPLC Written for practitioners by a practitioner, Modern HPLC for Practicing Scientists is a concise text which presents the most important High-Performance Liquid Chromatography (HPLC) fundamentals, applications, and developments. It describes basic theory and terminology for the novice, and reviews relevant concepts, best practices, and modern trends for the experienced practitioner. Moreover, the book serves well as an updated reference guide for busy laboratory analysts and researchers. Topics covered include: HPLC operation Method development

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Maintenance and troubleshooting Modern trends in HPLC such as quick-turnaround and "greener" methods Regulatory aspects While broad in scope, this book focuses particularly on reversed-phase HPLC, the most common separation mode, and on applications for the pharmaceutical industry, the largest user segment. Accessible to both novice and intermediate HPLC users, information is delivered in a straightforward manner illustrated with an abundance of diagrams, chromatograms, tables, and case studies, and supported with selected key references and Web resources. With intuitive explanations and clear figures, Modern HPLC for Practicing Scientists is an essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology.

Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, Second Edition illustrates how to develop high-quality, safe, and effective pharmaceutical products by discussing the latest techniques, tools, and scientific advances in preformulation investigation, formulation, process design, characterization, scale-up, and production operations. This book covers the essential principles of physical pharmacy, biopharmaceutics, and industrial pharmacy, and their application to the research and development process of oral dosage forms. Chapters have been added, combined, deleted, and completely revised as necessary to produce a comprehensive, well-organized, valuable reference for industry professionals and academics engaged in all aspects of the development process. New and important topics include spray drying, amorphous solid dispersion using hot-melt extrusion, modeling and simulation, bioequivalence of complex modified-released dosage forms, biowaivers, and much more. Written and edited by an international team of leading experts with experience and knowledge across industry, academia, and regulatory settings Includes new chapters covering the pharmaceutical applications of surface phenomenon, predictive biopharmaceutics and pharmacokinetics, the development of formulations for drug discovery support, and much more Presents new case studies throughout, and a section completely devoted to regulatory aspects, including global product regulation and international perspectives

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