

# QUALITY CONTROL IN PHARMACEUTICAL ANALYSIS

SEPARATION METHODS

EDITED BY  
Z. DEVL

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# Quality Control In Pharmaceutical Analysis Separation Methods

**Dr. MOHD JUNAID ,Dr. Pawan Singh  
,Dr. Manoj Shrawan Charde ,Dr. Prithu  
Pathak ,Prof. Sushil K. Kashaw**

## **Quality Control In Pharmaceutical Analysis Separation Methods:**

**Quality Control in Pharmaceutical Analysis** Z. Deyl, Zdeněk Deyl, 1997 It is difficult if not impossible to visualize pharmaceutical industry processes without appropriate analytical control of which chromatographic and more recently capillary electromigration techniques constitute a considerable proportion Problems such as deciding which separation technique will be the best whether a chromatographic or an electrokinetically driven method is preferred calibration procedures and method validation identification of impurities by on line hyphenation with techniques based on physicochemical principles other than chromatography and electrophoresis and assaying of basic physicochemical properties are all to be solved by the analytical chemist Unintended errors can occur quite frequently This volume covers all the above outlined areas emphasizing those which the authors know from pharmaceutical research to cause problems in practice The basic guidelines have been summarized along with the necessary theoretical background to help analysts select and apply modern chromatographic and electrokinetic methods of analysis in drug production and quality control and help them solve their particular problems      Pharmaceutical Analysis David C Lee, Michael L. Webb, 2009-02-12 The use of analytical sciences in the discovery development and manufacture of pharmaceuticals is wide ranging From the analysis of minute amounts of complex biological materials to the quality control of the final dosage form the use of analytical technology covers an immense range of techniques and disciplines This book concentrates on the analytical aspects of drug development and manufacture focusing on the analysis of the active ingredient or drug substance It provides those joining the industry or other areas of pharmaceutical research with a source of reference to a broad range of techniques and their applications allowing them to choose the most appropriate analytical technique for a particular purpose The volume is directed at analytical chemists industrial pharmacists organic chemists pharmaceutical chemists and biochemists      *Chiral Separation Methods for Pharmaceutical and Biotechnological Products* Satinder Ahuja, 2011-03-31 Discusses chiral separations and offers guidance for selecting the optimum method for desired results Chiral separations represent the most intriguing and by some measures most difficult separations of chemical compounds This book provides researchers and students an understanding of chiral separations and offers a convenient route to selecting the best separation method saving considerable time and cost in product development Considering chiral separations in the biotechnological and pharmaceutical industries as well as for food applications Dr Ahuja provides insights into a broad range of topics Opening with a broad overview of chiral separations regulatory considerations in drug product development and basic issues in method development the book Covers a variety of modern methods such as gas chromatography high performance liquid chromatography supercritical fluid chromatography and capillary electrophoresis Deals with the impact of chirality on the biological activity of small and large molecules Provides detailed information on useful chiral stationary phases CSPs for HPLC Includes handy information on selection of an appropriate CSP including mechanistic studies Offers strategies for fast method development with HPLC SFC and CE

Discusses preparatory methods utilized in the pharmaceutical industry With in depth discussions of the current state of the field as well as suggestions to assist future developments **Chiral Separation Methods for Pharmaceutical and Biotechnological Products** is an essential text for laboratory investigators managers and regulators who are involved in chiral separations in the pharmaceutical industry as well as students preparing for careers in these fields **Capillary**

**Electromigration Separation Methods** Colin F. Poole, 2018-04-13 **Capillary Electromigration Separation Methods** is a thorough encompassing reference that not only defines the concept of contemporary practice but also demonstrates its implementation in laboratory science Chapters are authored by recognized experts in the field ensuring that the content reflects the latest developments in research Thorough comprehensive coverage makes this the ideal reference for project planning and extensive selected referencing facilitates identification of key information The book defines the concept of contemporary practice in capillary electromigration separation methods also discussing its applications in small mass ions stereoisomers and proteins Edited and authored by world leading capillary electrophoresis experts Presents comprehensive coverage on the subject Includes extensive referencing that facilitates the identification of key research developments Provides more than 50 figures and tables that aid in the retention of key concepts **Handbook of Modern**

**Pharmaceutical Analysis** Satinder Ahuja, Stephen Scypinski, 2001-08-02 This book describes the role modern pharmaceutical analysis plays in the development of new drugs Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug Coverage includes state of the art topics such as analytics for combinatorial chemistry and high throughput screening formulation development stability studies international regulatory aspects and documentation and future technologies that are likely to impact the field Emphasis is placed on current easy to follow methods that readers can apply in their laboratories No book has effectively replaced the very popular text **Pharmaceutical Analysis** that was edited in the 1960s by Tak Higuchi This book will fill that gap with an up to date treatment that is both handy and authoritative **Method Validation in Pharmaceutical Analysis** Joachim

Ermer, Phil W. Nethercote, 2014-08-27 This second edition of a global bestseller has been completely redesigned and extensively rewritten to take into account the new Quality by Design QbD and lifecycle concepts in pharmaceutical manufacturing As in the first edition the fundamental requirements for analytical method validation are covered but the second edition describes how these are applied systematically throughout the entire analytical lifecycle QbD principles require adoption of a systematic approach to development and validation that begin with predefined objectives For analytical methods these predefined objectives are established as an Analytical Target Profile ATP The book chapters are aligned with recently introduced standards and guidelines for manufacturing processes validation and follow the three stages of the analytical lifecycle Method Design Method Performance Qualification and Continued Method Performance Verification Case studies and examples from the pharmaceutical industry illustrate the concepts and guidelines presented and the standards

and regulations from the US FDA European EMA and global ICH regulatory authorities are considered throughout The undisputed gold standard in the field

**Capillary Electrophoresis Methods for Pharmaceutical Analysis** Satinder Ahuja, Mohamed Elias Jimidar, 2011-08-09 Capillary electrophoresis CE is a powerful analytical technique that is widely used in research and development and in quality control of pharmaceuticals Many reports of highly efficient separations and methods have been published over the past 15 years CE offers several advantages over high pressure or high performance liquid chromatography HPLC These include simplicity rapid analysis automation ruggedness different mechanisms for selectivity and low cost Moreover EC requires smaller sample size and yet offers higher efficiency and thus greater resolution power over HPLC These characteristics are very attractive in research and development even more so in pharmaceutical quality control QC and stability monitoring SM studies This book will provide busy pharmaceutical scientists a complete yet concise reference guide for utilizing the versatility of CE in new drug development and quality control Provides current status and future developments in CE analysis of pharmaceuticals Explains how to develop and validate methods Includes major pharmaceutical applications including assays and impurity testing

Handbook of Pharmaceutical Analysis by HPLC Satinder Ahuja, Michael Dong, 2005-02-09 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

*Chiral Separations and Stereochemical Elucidation* Quezia Bezerra Cass, Maria Elizabeth Tiritan, João Marcos Batista Junior, Juliana Cristina Barreiro, 2023-04-04 An expert resource for chemists using stereochemical analysis methods In *Chiral Separations and Stereochemical Elucidation* Fundamentals Methods and Applications a team of distinguished researchers delivers a robust and authoritative discussion of the theoretical fundamentals of chiral separation the most commonly used chiral selectors and stereochemical elucidation methods The book offers expert discussions of a variety of chiral separation methods by gas chromatography GC supercritical fluid chromatography SFC capillary electrophoresis CE and liquid chromatography LC The authors also describe several methods for stereochemical elucidation including X ray crystallography nuclear magnetic resonance spectroscopy and chiroptical methods The explored material is ideal for practicing chemists seeking a resource to help them guide method development and optimization or to explain quality control

complements during target compound production Readers will also find A thorough introduction to the most important advances and applications in LC GC CE SFC and preparative chromatography Comprehensive explorations of the role of 2D LC for chiral separation methods development and applications Practical discussions of the design mechanisms and applications of the most commonly used chiral selectors Fulsome treatments of the theoretical backgrounds advantages limitations and applications of stereochemical elucidation methods Perfect for academic and industrial chemists specially in organic analytical chemistry and pharmaceutical analysis Chiral Separations and Stereochemical Elucidation Fundamentals Methods and Applications will also benefit biochemists environmental analysts forensic and medicinal chemists as well as natural product chemists and those involved with stereochemistry or structural elucidation

**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES** Mrs. Mitali Yogesh Patil, Mr. Biprojit Paul, Mr. Mohit Chadha, Dr. Saroj Kumar Raul, In the dynamic realm of pharmaceutical sciences this project explores Modern Pharmaceutical Analytical Techniques delving into cutting edge methodologies crucial for ensuring the quality and efficacy of drugs From spectroscopy to advanced technologies like metabolomics each chapter demystifies the application and significance of these techniques Bridging academia and industry this work aims to be a practical guide underlining the realworld implications of these tools Gratitude is extended to mentors colleagues and institutions as this concise exploration seeks to serve students researchers and professionals navigating the ever evolving landscape of pharmaceutical analysis

**HPLC Method Development for Pharmaceuticals** Satinder Ahuja, Henrik Rasmussen, 2011-09-21 High pressure or high performance liquid chromatography HPLC is the method of choice for checking purity of new drug candidates monitoring changes during scale up or revision of synthetic procedures evaluating new formulations and running control assurance of the final drug product HPLC Method Development for Pharmaceuticals provides an extensive overview of modern HPLC method development that addresses these unique concerns Includes a review and update of the current state of the art and science of HPLC including theory modes of HPLC column chemistry retention mechanisms chiral separations modern instrumentation including ultrahigh pressure systems and sample preparation Emphasis has been placed on implementation in a pharmaceutical setting and on providing a practical perspective HPLC Method Development for Pharmaceuticals is intended to be particularly useful for both novice and experienced HPLC method development chemists in the pharmaceutical industry and for managers who are seeking to update their knowledge Covers the requirements for HPLC in a pharmaceutical setting including strategies for software and hardware validation to allow for use in a regulated laboratory Provides an overview of the pharmaceutical development process clinical phases chemical and pharmaceutical development activities Discusses how HPLC is used in each phase of pharmaceutical development and how methods are developed to support activities in each phase

**Capillary Electrophoresis - Mass Spectrometry (CE-MS)** Gerhardus de Jong, 2016-06-16 This monograph offers the reader a complete overview on both principles and applications of CE MS Starting with an introductory chapter on detection in CE

also related and more specialized techniques such as electrophoretic and chromatographic preconcentration are discussed. A special emphasis is put on CE-MS interfaces which are described in detail. In a separate chapter attention is paid to sheath liquid interfacing. The developments and possibilities of microchip CE-MS are also described. Applications to all relevant areas are discussed in distinct chapters each written by experts in the respective fields. Besides applications in pharmaceutical analysis and bioanalysis, recent implementations in food science, forensic analysis, analysis of intact proteins, metabolomics and proteomics are highlighted. MS is a perfectly appropriate detection system for CE as efficient separation is coupled to sensitive and selective detection. Moreover, MS can provide structure information on the separated compounds. CE-MS has now been developed into a strong hyphenated system complementary to LC-MS. This monograph is a unique source of knowledge for everyone dealing with and interested in CE-MS.

**Separation Methods in Drug Synthesis and Purification** Klara Valko, 2000-10-13 Separation Methods in Drug Synthesis and Purification **Modern Pharmaceutical**

**Analytical Techniques** Prof. (Dr.) Amit Upadhyay, Dr. Piyush Yadav, 2025-08-13 M Pharm First Semester According to the syllabus based on Pharmacy Council of India PHARMACEUTICAL ENGINEERING Dr Reshu Tiwari, Dr Shechinah Felice

Choragudi, Dr. Pankaj Mohan Pimpalshende, Mrs. P. Parameswari, Dr. Stuti Pandey, **Particle Separation Techniques**, 2022-07-22 Particle Separation Techniques Fundamentals Instrumentation and Selected Applications presents the latest research in the field of particle separation methods. This edited book, authored by subject specialists, is logically organized in sections grouping the separation techniques according to their preparative or analytical purposes and the particle type. Along with the traditional and classical separation methods suitable for micron particles, an update survey of techniques appropriate for nanoparticle characterization is presented. This book fills the gap in the literature of particle suspension analysis of a synthetic but comprehensive manual helping the reader to identify and apply selected techniques. It provides an overview of the techniques available to a reader who is not an expert on particle separation yet about to enter the field, design an experiment or buy an instrument for his/her new lab. Presents a resource that is ideal for anyone preparing samples across a variety of fields including pharmaceuticals, food science, pollution analysis and control, agricultural products and more. Includes real case examples discussed by leading experts in the field. Provides chapters that contain a unique common table that summarizes points of strength and the weaknesses of each technique. **Aseptic Pharmaceutical**

**Manufacturing II** Michael J. Groves, Ram Murty, 1995-05-31 Aseptic Pharmaceutical Manufacturing II explores the sophisticated technology developments and applications that allow aseptic processing to approach the sterility levels achieved with terminal sterilization. Written by experts in sterile manufacturing, this book covers aseptic technology developments and applications and makes a valuable contribution to understanding the issues involved in aseptic manufacture. Topics include the processing of biopharmaceuticals, lyophilization, personnel training, radiopharmaceuticals, hydrogen peroxide vapor sterilization, regulatory requirements, validation and quality systems. **The Analytical Chemistry**

**Laboratory Companion** Michael D. Holloway, 2025-07-15 The Analytical Chemistry Laboratory Companion is essential for both students and professionals as it provides quick clear explanations on critical topics in analytical chemistry equipping you with the statistical tools necessary to ensure accurate and reliable data interpretation The Analytical Chemistry Laboratory Companion serves as a reference guide for students and professionals alike who need quick explanations on specific topics laboratory operations the structure of designing experiments and the use of statistics to gain increased accuracy precision repeatability and reproducibility of data This volume will also provide in depth and advanced studies and build the necessary background knowledge for success in the field This companion provides a concise examination of the various analytical tools used for chemistry and defines basic analytical instrument principles techniques and applications in addition to exploring statistical tools useful in data interpretation test result reporting and common root causes for faulty data with suggested remedies The introduction provides a concise guide on foundational topics such as developing standard operating procedures laboratory safety instrumental analytical methods and common statistical tools useful for data interpretation This companion covers both wet chemical and instrumental analysis including their principles applications and pitfalls The Analytical Chemistry Laboratory Companion is a must have comprehensive guide in the field of analytical chemistry

**TEXT BOOK OF MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES** Dr. MOHD JUNAID ,Dr. Pawan Singh ,Dr. Manoj Shrawan Charde ,Dr. Prithu Pathak ,Prof. Sushil K. Kashaw, 2025-01-07 The Textbook of Modern Pharmaceutical Analytical Techniques is a comprehensive resource designed for students researchers and professionals in pharmaceutical sciences It provides an in depth exploration of advanced analytical methodologies critical to drug development quality control and research

- 1 UV Visible Spectroscopy Covers fundamental principles laws instrumentation solvent effects and versatile applications in pharmaceutical analysis
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- 3 Spectrofluorimetry Discusses fluorescence theory factors affecting emission quenching phenomena and applications
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- 5 NMR Spectroscopy Delves into chemical shifts spin spin coupling relaxation processes and FT NMR advancements
- 6 Mass Spectroscopy Focuses on ionization techniques mass fragmentation rules isotopic analysis and applications
- 7 Chromatography Techniques Comprehensive coverage from paper to advanced HPLC and affinity chromatography emphasizing resolution and practical applications
- 8 Electrophoresis Explores diverse techniques their instrumentation and roles in pharmaceutical separation processes
- 9 X ray Crystallography Examines diffraction methods Bragg s law and their importance in structural determination of compounds
- 10 Immunological Assays Details RIA ELISA and bioluminescence techniques pivotal in drug and disease research

The textbook emphasizes both theoretical foundations and practical applications bridging the gap between academic learning and industrial practice Rich in diagrams examples and technical insights it s an essential guide for mastering modern analytical techniques

**Animal Cell**



**Biotechnology** Hansjörg Hauser,Roland Wagner,2014-11-10 This book introduces fundamental principles and practical application of techniques used in the scalable production of biopharmaceuticals with animal cell cultures A broad spectrum of subjects relevant to biologics production and manufacturing are reviewed including the generation of robust cell lines a survey of functional genomics for a better understanding of cell lines and processes as well as advances in regulatory compliant upstream and downstream development The book is an essential reference for all those interested in translational animal cell based pharmaceutical biotechnology

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