

An
Introduction to
HPLC
for
Pharmaceutical
Analysis

OONA MCPOLIN



An Introduction To Hplc For Pharmaceutical Analysis

Oona Mcpolin

Marcel A. Müller



An Introduction To Hplc For Pharmaceutical Analysis Oona Mcpolin:

An Introduction to HPLC for Pharmaceutical Analysis Oona McPolin, 2009-03-01 If you are new to HPLC this book provides an invaluable guide to how HPLC is actually used when analysing pharmaceuticals. It is full of practical advice on the operation of HPLC systems combined with the necessary theoretical knowledge to ensure understanding of the technique. Key features include: A thorough discussion of the stationary phase enabling the reader to make sense of the many parameters used to describe a HPLC column. Practical advice and helpful hints for the preparation and use of mobile phase. A complete overview of each of the different components which together make up a HPLC system. A description of the contents of a typical HPLC analytical method and how to interpret these. A step by step guide on how to follow a method and set up a HPLC analysis. A discussion of system suitability criteria and how to interpret the values obtained during an analysis. Explanation of the common methods of calibration and quantification used for pharmaceutical analysis. Validation of Analytical Methods for Pharmaceutical Analysis Oona McPolin, 2009-05-01 This book provides a comprehensive guide on validating analytical methods. Key features: Full review of the available regulatory guidelines on validation and in particular ICH Sections of the guideline Q2 R1 have been reproduced in this book with the kind permission of the ICH Secretariat. Thorough discussion of each of the validation characteristics: Specificity, Linearity, Range, Accuracy, Precision, Detection Limit, Quantitation Limit, Robustness, System Suitability, plus practical tips on how they may be studied. What to include in a validation protocol with advice on the experimental procedure to follow and selection of appropriate acceptance criteria. How to interpret and calculate the results of a validation study including the use of suitable statistical calculations. A fully explained case study demonstrating how to plan a validation study, what to include in the protocol, experiments to perform, setting acceptance criteria, interpretation of the results and reporting the study. 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. Introduction to Pharmaceutical Chemical Analysis Steen Honoré Hansen, Stig Pedersen-Bjergaard, Knut Rasmussen, 2011-10-18 This textbook is the first to present a systematic introduction to chemical analysis of pharmaceutical

raw materials finished pharmaceutical products and of drugs in biological fluids which are carried out in pharmaceutical laboratories worldwide In addition this textbook teaches the fundamentals of all the major analytical techniques used in the pharmaceutical laboratory and teaches the international pharmacopoeias and guidelines of importance for the field It is primarily intended for the pharmacy student to teach the requirements in analytical chemistry for the 5 years pharmacy curriculum but the textbook is also intended for analytical chemists moving into the field of pharmaceutical analysis Addresses the basic concepts then establishes the foundations for the common analytical methods that are currently used in the quantitative and qualitative chemical analysis of pharmaceutical drugs Provides an understanding of common analytical techniques used in all areas of pharmaceutical development Suitable for a foundation course in chemical and pharmaceutical sciences Aimed at undergraduate students of degrees in Pharmaceutical Science Chemistry Analytical Science Chemistry Forensic analysis Includes many illustrative examples Pharmaceutical Analysis for Small Molecules Behnam Davani, 2017-08-14 A comprehensive introduction for scientists engaged in new drug development analysis and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates especially chemistry analytical chemistry pharmacy and pharmaceutical majors into its ranks However because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult Designed to assist both recent graduates as well as experienced chemists or scientists with limited regulatory compendial or pharmaceutical analysis background make that transition Pharmaceutical Analysis for Small Molecules is a concise yet comprehensive introduction to the drug development process and analysis of chemically synthesized small molecule drugs It features contributions by distinguished experts in the field including editor and author Dr Behnam Davani an analytical chemist with decades of technical management and teaching experience in compendial regulatory and industry This book provides an introduction to pharmaceutical analysis for small molecules non biologics using commonly used techniques for drug characterization and performance tests The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products In addition related required supporting studies including good laboratory documentation practices including analytical instrument qualification are highlighted in this book Topics covered include Drug Approval Process and Regulatory Requirements private standards Pharmacopoeias and Compendial Approval Process public standards Common methods in pharmaceutical analysis typically compendial Common Calculations for assays and impurities and other specific tests Analytical Method Validation Verification Transfer Specifications including how to handle out of specification OOS and out of trend OOT Impurities including organic inorganic residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ OQ PQ and VQ Due to global nature of pharmaceutical industry other topics on both regulatory ICH and Compendial harmonization are also

highlighted Pharmaceutical Analysis for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process including analytical chemists pharmaceutical scientists pharmacists and quality control quality assurance professionals It also is an excellent text reference for graduate students in analytical chemistry pharmacy pharmaceutical and regulatory sciences

HPLC in the Pharmaceutical Industry Godwin W. Fong, 2022-01-26 A practical guide for chemists in the pharmaceutical industry to making automated analyses of drugs that will meet the standards of regulatory agencies Reviews the standard techniques of high performance liquid chromatography specialized detection methods automation in pharmaceutical analysis analyses of pharmaceuticals helping readers meet rigorous regulatory agency standards for acceptable test results Written by leading experts in the field this text describes current liquid chromatographic techniques in pharmaceutical analysis discusses highly sensitive detailed detection of drugs considers automation in pharmaceutical analysis examines new molecular entities and optical isomers and more

HPLC for Pharmaceutical Scientists Yuri V. Kazakevich, Rosario LoBrutto, 2006-12-13 HPLC for Pharmaceutical Scientists is an excellent book for both novice and experienced pharmaceutical chemists who regularly use HPLC as an analytical tool to solve challenging problems in the pharmaceutical industry It provides a unified approach to HPLC with an equal and balanced treatment of the theory and practice of HPLC in the pharmaceutical industry In depth discussion of retention processes modern HPLC separation theory properties of stationary phases and columns are well blended with the practical aspects of fast and effective method development and method validation Practical and pragmatic approaches and actual examples of effective development of selective and rugged HPLC methods from a physico chemical point of view are provided This book elucidates the role of HPLC throughout the entire drug development process from drug candidate inception to marketed drug product and gives detailed specifics of HPLC application in each stage of drug development The latest advancements and trends in hyphenated and specialized HPLC techniques LC MS LC NMR Preparative HPLC High temperature HPLC high pressure liquid chromatography are also discussed

HPLC in Pharmaceutical Analysis Gabór Szepesi, 1990

Introduction to Pharmaceutical Analytical Chemistry Stig Pedersen-Bjergaard, Bente Gammelgaard, Trine G. Halvorsen, 2019-02-11 The definitive textbook on the chemical analysis of pharmaceutical drugs fully revised and updated Introduction to Pharmaceutical Analytical Chemistry enables students to gain fundamental knowledge of the vital concepts techniques and applications of the chemical analysis of pharmaceutical ingredients final pharmaceutical products and drug substances in biological fluids A unique emphasis on pharmaceutical laboratory practices such as sample preparation and separation techniques provides an efficient and practical educational framework for undergraduate studies in areas such as pharmaceutical sciences analytical chemistry and forensic analysis Suitable for foundational courses this essential undergraduate text introduces the common analytical methods used in quantitative and qualitative chemical analysis of pharmaceuticals This extensively revised second edition includes a new chapter on chemical analysis of biopharmaceuticals

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HPLC Methods for Pharmaceutical Analysis George Lunn, Norman R. Schmuff, 1997 Full text included in Knovel Library within the subject area of Chemistry and Chemical Engineering **Method Validation in Pharmaceutical Analysis** Joachim Ermer, Phil W. Nethercote, 2014-11-10 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 HPLC Methods for Pharmaceutical Analysis George Lunn, Norman R. Schmuff, 1997 Full text included in Knovel Library within the subject area of Chemistry and Chemical Engineering **HPLC Methods for Clinical Pharmaceutical Analysis** Hermann Mascher, 2012-02-13 Filling a gap in the literature for a hands on guide focusing on everyday laboratory challenges this English edition has been expanded and revised using the feedback received on the successful German precursor Throughout the book Professor Mascher draws on his 30 years of experience and provides abundant practical advice troubleshooting and other hints highlighted in boxes as well as a broad selection of walkthrough case studies Based on a course taught by the author the first part of the book intuitively explains all steps of routine bioanalysis and explains how to set up a robust inexpensive and efficient method for a given substance In the second part he includes 20 worked example cases that highlight common challenges and how to overcome them With its appendix

containing tried and tested analytical methods for 100 clinically relevant substances from the author's own laboratory complete with spectral and MS data as well as literature references and basic pharmacokinetic information this is a life long companion for everyone working in clinical pharmaceutical and biochemical analysis Comments to the German book The book comes to life through its examples showing not only what did work in the author's laboratory but also what didn't ChemieReport Indispensable for novices while even old hands will be able to expand their knowledge A collection of analytical data for ca 100 substances completes the book's offering leaving almost nothing to be desired pharmind

HPLC in Pharmaceutical Analysis: Practical applications Gábor Szepesi, 1990 *HPLC Methods for Pharmaceutical Analysis* George Lunn, 2000-06-06 HPLC and CE Methods for Pharmaceutical Analysis The complete up to date library at the click of a mouse This invaluable database gives you fast easy access to more than 13 000 abstracts from the current literature on HPLC and capillary electrophoresis CE Incorporating the four volume HPLC Methods for Pharmaceutical Analysis plus the newly introduced Capillary Electrophoresis for Pharmaceutical Analysis this CD ROM features an extensive library of methods used in the analysis of most pharmaceutical compounds It lists available HPLC techniques for more than 1 300 compounds and CE methods for more than 700 compounds with a number of techniques described for each compound Detailed precise information lets you replicate methods without having to refer to the original publications as well as customize methods for very specific needs You can instantly locate basic compound information molecular weight and formula CAS number and Merck index number plus experimental conditions for each method Complex and substructure searching capabilities let you search the entire database by compound matrix HPLC variables and author saving you countless hours of online or library research Minimum system requirements IBM compatible PC 486 Win95 or higher CD ROM drive 8MB RAM XXXMB free hard disk space Visit us on the Internet www.wiley.com

HPLC Methods for Recently Approved Pharmaceuticals George Lunn, 2005-04-22 An indispensable resource for busy researchers Your time is valuable too valuable to spend hunting through the technical literature in search of the right HPLC assay techniques for your projects With HPLC Methods for Recently Approved Pharmaceuticals you'll quickly identify and replicate the ideal procedures for your project needs without having to refer to original source publications More of your time can then be spent in the lab not the library Covering the relevant world literature through 2003 this book picks up where Dr Lunn's acclaimed HPLC Methods for Pharmaceutical Analysis left off It arms you with established HPLC assay techniques for hundreds of newly approved drugs as well as drugs for which assay methods were only recently developed Combining detailed descriptions of procedures with specially annotated references this practical handbook gives you HPLC methods for 390 commonly prescribed pharmaceutical compounds Various procedures for each drug listed together making it easy to mix and match for customized approaches Methods for drugs in biological fluids and for bulk and formulated drugs Chemical structures molecular weights and formulas and CAS Registry Numbers Cross references to The Merck Index Retention times of other drugs that can be

assayed using the same methods **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

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 **HPLC and UHPLC for Practicing Scientists**

Michael W. Dong, 2019-07-10 A concise yet comprehensive reference guide on HPLC UHPLC that focuses on its fundamentals latest developments and best practices in the pharmaceutical and biotechnology industries Written for practitioners by an expert practitioner this new edition of HPLC and UHPLC for Practicing Scientists adds numerous updates to its coverage of high performance liquid chromatography including comprehensive information on UHPLC ultra high pressure liquid chromatography and the continuing migration of HPLC to UHPLC the modern standard platform In addition to introducing readers to HPLC's fundamentals applications and developments the book describes basic theory and terminology for the novice and reviews relevant concepts best practices and modern trends for the experienced practitioner HPLC and UHPLC for Practicing Scientists Second Edition offers three new chapters One is a standalone chapter on UHPLC covering concepts benefits practices and potential issues Another examines liquid chromatography mass spectrometry LC MS The third reviews the analysis of recombinant biologics particularly monoclonal antibodies mAbs used as therapeutics While all chapters are revised in the new edition five chapters are essentially rewritten HPLC columns instrumentation pharmaceutical analysis method development and regulatory aspects The book also includes problem and answer sections at the end of each chapter Overviews fundamentals of HPLC to UHPLC including theories columns and instruments with an abundance of tables figures and key references Features brand new chapters on UHPLC LC MS and analysis of recombinant biologics Presents updated

information on the best practices in method development validation operation troubleshooting and maintaining regulatory compliance for both HPLC and UHPLC Contains major revisions to all chapters of the first edition and substantial rewrites of chapters on HPLC columns instrumentation pharmaceutical analysis method development and regulatory aspects Includes end of chapter quizzes as assessment and learning aids Offers a reference guide to graduate students and practicing scientists in pharmaceutical biotechnology and other industries Filled with intuitive explanations case studies and clear figures HPLC and UHPLC for Practicing Scientists Second Edition is an essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology It will be a great benefit to every busy laboratory analyst and researcher

High Performance Liquid Chromatography W.J. Lough, I.W. Wainer, 1995-09-30 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

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