Method Development And Validation For Particle Size And

We can say that the problems in method development and validation in HPLC are due to sample preparation, HPLC analysis conditions, standardization.During the preliminary method development stage, all individual components should be investigated before the final method optimization. This gives us a chance to critically evaluate the method performance in each component and streamline the final method optimization.

The coherent body of research described in the existing published work is concerned with new assay method development and validation using novel systematic approaches for pharmaceutical and diagnostic compounds. The first stage of the research was to study how analytical method development and validation are typically carried out at present and to formulate this into a simple step-by-step approach. Such a template and protocol was not only used as the foundation of this research programme but could also serve as a simple systematic guide for other practitioners and those new to the field. Furthermore, it was recognised that this protocol should satisfy the requirements of the most strategically important regulatory agencies. The second stage of this research involved evaluation and application of the above validation approach to new methods that were developed for a diverse range of analytes and samples. A new purity assay for 1,10-phenanthroline-5,6- dione and 4,7-phenanthroline-5,6-dione using high-performance liquid chromatography (HPLC) was developed and validated. Impurities in these compounds were identified by liquid chromatography-mass spectrometry (LCMS). Best practice in method development and validation is equally important in the analysis of both active components and excipients in formulated products. In the first case, a liquid chromatography assay method for determining the content of 2-(diethylamino)-N-(2,6-dimethylphenyl) acetamide in a gel formulation was developed and validated. In the second case, the individual contents of three phydroxy benzoic acid ester preservatives in a complex multi-component sample were determined following the development and validation of a liquid chromatography method. Finally, the validation approach was evaluated as applied to another analytical technique. Here, gas chromatography (GC) successfully used to develop a novel assay for p-cymene in tea tree oil formulations presented different analytical problems because of the very complex nature of this natural product. Stability study information to increase the shelf life of the product and validation data for the analytical method for p-cymene content was critically evaluated. iv In essence, the critical review of the requirements for method validation for various agencies and the subsequent preparation of guidelines on how to go about method validation have had a significant impact on how analytical practitioners worldwide go about method development and, more importantly, method validation. Further it was possible to apply these guidelines to conduct a series of effective, successful method validation for assays involving a range of typical pharmaceutical samples.

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.

Now days due to the new drug discovery and clinical development of effective antihypertensive drugs, so many newer classes of drugs are available to treat Hypertension. Telmisartan and Hydrochlorothiazide combination is newer which is used in the treatment of Hypertension. There is no official method is given for simultaneous estimation of Telmisartan with Hydrochlorothiazide in combined dosage forms. Literature survey reveals first-derivative, ratio derivative spectrophotometry, and TLC- densitometry and spectrofluorimetry methods for the simultaneous estimation of Telmisartan with Hydrochlorothiazide in combined dosage forms. Literature survey does not reveal any HPLC, Simultaneous equation, or Q- absorption ratio method for the simultaneous estimation of Telmisartan with Hydrochlorothiazide in combined dosage forms.

Hplc, Lc-Ms and Gc Method Development and Validation

Method Development and Validation for the Pharmaceutical Microbiologist

Guidance for the Validation of Analytical Methodology and Calibration of Equipment Used for Testing of Illicit Drugs in Seized Materials and Biological Specimens

Analytical Method Development and Validation of Stanazolol

A Sampling of Current Approaches

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

The pharmacy is a fastest growing filed among the different; with inclusion of wide variety of medicinal drugs daily into the market. The qualitative and quantitative analysis of the said drug is prime important as it directly deal with the quality product. The ICH mainly focused on the estimation and their validation which guides to pharmaceutical industry for maintaining the success. The said work will definitely guide to all pharma professional for the up gradation in knowledge and skill.

Nicorandil is Anti-anginal drug. There are several methods like HPLC, LC-MS, Ultraviolet Spectroscopy etc. are available for the estimation of Nicorandil in biological fluids and pharmaceutical dosage form.we could not trace Single HPLC Method with short Retention Time (RT). So to develop and validate a HPLC method for the estimation of Nicorandil in Pharmaceutical with the retention time around 5 min. HPLC method for estimation of Nicorandil in its dosage form was developed. The developed HPLC method was validated for specificity, linearity and range, accuracy, method and intermediate precision, robustness, system suitability and applied to pharmaceutical formulation and the %Assay of Nicorandil Tablets was found to be in the range of 98-102%. For developing HPLC technique for analysis of Nicorandil tablet. Numbers of trials were taken for selection of column, mobile phase. The developed method was validated as per ICH guideline. The advantages of chromatographic techniques were higher accuracy, small sample size and less consuming, however it requires costly HPLC grade solvents and availability of HPLC instrument. This method can be successfully applied for the estimation.

Analytical Method Development and ValidationCRC Press

Practical Approaches to Method Validation and Essential Instrument Qualification

Development and Validation of Analytical Methods

Evaluation and Application of Best Practice in Analytical Method Validation

Analytical Method Development And Validation For Assay Of Fampridine

This book seeks to introduce the reader to current methodologies in analytical calibration and validation. This collection of contributed research articles and reviews addresses current developments in the calibration of analytical methods and techniques and their subsequent validation. Section 1, "Introduction," contains the Introductory Chapter, a broad overview of analytical calibration and validation, and a brief synopsis of the following chapters. Section 2 "Calibration Approaches" presents five chapters covering calibration schemes for some modern analytical methods and techniques. The last chapter in this section provides a segue into Section 3, "Validation Approaches," which contains two chapters on validation procedures and parameters. This book is a valuable source of scientific information for anyone interested in analytical calibration and validation.

"A reversed-phase HPLC method was developed to separate a mixture of nine pharmaceutical active ingredients: Ciprofloxacin Hydrochloride, Gatifloxacin Hydrochloride, Levofloxacin Hemihydrate, Metoclopramide Hydrochloride, Pheniramine Maleate, Ropivacaine Hydrochloride, Theophylline Anhydrous, Thiocolchicoside, Trazodone Hydrochloride. These drugs are used as antibiotics and relievers and some are used to treat different kinds of diseases such as constant and recurrent migraines. Agilent 1100 series system with Diode Array Detector was used with Waters C8 (250 X 4.6mm, 5µm) column and mobile phase consisted of solvent A (25mM Potassium Phosphate Dibasic buffer at pH 7) and solvent B (8.4% Acetonitrile). DryLab® software with 3D modeling which involved gradient time, column temperature and different proportions of acetonitrile resulted in an optimum linear gradient of 8.4% organic solvent at zero time which slowly increased to 20.4% and 95% in 17.5 and 25 minute. Then, solvent Strength was controlled at 95% for 5 minute. Buffer was chosen at pH 7 with column temperature at 34oC, flow rate of 1.00 mL/min and detection wavelength at 220 nm. The developed method was validated in terms of robustness and considered robust."--

Describes analytical methods development, optimization and validation, and provides examples of successful methods development and validation in high-performance liquid chromatography (HPLC) areas. The text presents an overview of Food and Drug Administration (FDA)/International Conference on Harmonization (ICH) regulatory guidelines, compliance with validation requirements for regulatory agencies, and methods validation criteria stipulated by the US Pharmacopia, FDA and ICH.

Gemifloxacin, a flouroquinoline derivative has antibacterial activity. Ambroxol dibromoaminobenzyl derivatives have mucolytic activity.GEM and AMB are available in tablet dosage form (G-cin A, Lupin)for mucolytic action. The present work dealt with simultaneous estimation of GEM and AMB from bulk and tablet formulation by different UV spectrophotometric, RPHPLC and Dissolution techniques. Five UV methods were developed which are accurate, precise, rapid and economical for the estimation of GEM and AMB in Tablet dosage form. The developed HPLC method was validated in terms of accuracy, repeatability, and precision. A good linear relationship was observed for GEM An attempt has been made to carry out the dissolution study of the marketed formulation by applying four established UV-Visible Spectrophotometric methods for estimation of % release of the drug (GEM & AMB

A Commitment to Quality and Continuous Improvement

Recent Advances in Analytical Chemistry

UV,HPLC,Dissolution Methods

HPLC for Pharmaceutical Scientists

Analytical Method Validation and Instrument Performance Verification

Written for practitioners in both the drug and biotechnology industries, the Handbook of Analytical Validation carefully compiles current regulatory requirements on the validation of new or modified analytical methods. Shedding light on method validation from a practical standpoint, the handbook:Contains practical, up-to-date guidelines for analyti

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.

The coherent body of research described in published work is concerned with new assay method development and validation using novel systematic approaches for pharmaceutical and diagnostic compounds. The first stage of the research was to study how analytical method development and validation are typically carried out at present and to formulate this into a simple step-by-step approach. Such a template and protocol was not only used as the foundation of this research programme but could also serve as a simple systematic guide for other practitioners and those new to the field. Furthermore, it was recognised that this protocol should satisfy the requirements of the most strategically important regulatory agencies. The second stage of this research involved evaluation and application of the above validation approach to new methods that were developed for a diverse range of analytes using HPLC, LC-MS and GC. In essence, the critical review of the requirements for method validation for various agencies and the subsequent preparation of guidelines on how to go about method validation have had a significant impact on analytical practitioners worldwide.

Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those regulatory bodies. This book provides a thorough explanation of both the fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation. It teaches the proper procedures for using the tools and analysis methods in a regulated lab setting. Readers will learn the appropriate procedures for calibration of laboratory instrumentation and validation of analytical methods of analysis. These procedures must be executed properly in all regulated laboratories, including pharmaceutical and biopharmaceutical laboratories, clinical testing laboratories (hospitals, medical offices) and in food and cosmetic testing laboratories.

Handbook for Analytical Scientists

Of Lafutidine and Domperidone

Method Development and Validation for Determination of Aluminum by Reversed Phase Liquid Chromatography

Calibration and Validation of Analytical Methods

A Thesis Presented to the Faculty of the Department of Chemistry, Northeastern Illinois University in Partial Fulfillment of the Requirements for the Degree Master of Science in Chemistry

This handbook is concerned with new chromatographic method development and validation using novel systematic approaches for pharmaceutical compounds. The first stage of the research was to study how method development and validation are typically carried out at present and to formulate this into a simple step-by-step approach. Such a template and protocol was not only used as the foundation of this research programme but could also serve as a simple systematic guide for other practitioners in the pharmaceutical industry. Furthermore, it was recognised that this protocol should satisfy the requirements of the major regulatory agencies. The second stage of this research involved evaluation and application of the above validation approach to new methods that were developed for a diverse range of analytes using HPLC, LC-MS and GC. In essence, the critical review of the requirements for method validation for various agencies and the subsequent preparation of single guidelines on how to go about method validation have had a significant impact on analytical practitioners worldwide.

This book focuses on recent and future trends in analytical methods and provides an overview of analytical chemistry. As a comprehensive analytical chemistry book, it takes a broad view of the subject and integrates a wide variety of approaches. The book provides separation approaches and method validation, as well as recent developments and applications in analytical chemistry. It is written primarily for researchers in the fields of analytical chemistry, environmental chemistry, and applied chemistry. The aim of the book is to explain the subject, clarify important studies, and compare and develop new and groundbreaking applications. Written by leading experts in their respective areas, the book is highly recommended for professionals interested in analytical chemistry because it provides specific and comprehensive examples.

The aim was to develop and validate high performance liquid chromatography assay for rapid determination of Fampridine which should offer simplicity, reproducibility, selectivity, sensitivity, and accuracy of the assay method which should be suitable for routine analysis. Developed method has been successfully applied for the analysis of tablets and can be used for the routine analysis of formulations containing above drug without any alteration in the assay. The superiority of the method is common chromatographic conditions adopted for formulation. The simplicity, specificity, selectivity, rapidity and reproducibility of the proposed method completely fulfill the objective of the research work.

Handbook of Analytical Quality by Design addresses the steps involved in analytical method development and validation in an effort to avoid quality crises in later stages. The AQbD approach significantly enhances method performance and robustness which are crucial during inter-laboratory studies and also affect the analytical lifecycle of the developed method. Sections cover sample preparation problems and the usefulness of the QbD concept involving Quality Risk Management (QRM), Design of Experiments (DoE) and Multivariate (MVT) Statistical Approaches to solve by optimizing the developed method, along with validation for different techniques like HPLC, UPLC, UFLC, LC-MS and electrophoresis. This will be an ideal resource for graduate students and professionals working in the pharmaceutical industry, analytical chemistry, regulatory agencies, and those in related academic fields. Concise language for easy understanding of the novel and holistic concept Covers key aspects of analytical development and validation Provides a robust, flexible, operable range for an analytical method with greater excellence and regulatory compliance

Method Validation in Pharmaceutical Analysis

Practical HPLC Method Development

Guideline for Submitting Samples and Analytical Data for Methods Validation

Analytical Method Development and Validation of Nicorandil by HPLC

Problems in Method Development and Validation in HPLC

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, pharmaceutists, QA officers, and public authorities.

Ion mobility spectrometry (IMS) instrumentation has been identified as a suitable technology for the detection and reporting of drug product and detergent residues from pharmaceutical manufacturing equipment. Ion mobility is not a new technology, but is entering the field of cleaning validation because of tightened requirements from the US Food and Drug Administration (FDA). The purpose of this thesis is to outline a practical implementation of the analytical technique, Ion Mobility Spectrometry in a cleaning validation program. Ion Mobility Spectrometry (IMS) is fast and specific for the analysis of small organic molecules and has been gaining popularity in the pharmaceutical industry. The challenge in the implementation of any new analytical technique in a pharmaceutical laboratory is establishing suitable methodology and this thesis will outline the steps taken for developing and validating a method for detection of the antihistamine drug Loratadine. The author will also provide a detailed introduction to the requirements of equipment qualification, cleaning validation and analytical method validation programs in the pharmaceutical industry.

We determine Lafutidine and Domperidone simultaneously by simple, rapid, accurate and precise UV-Spectroscopic methods, HPLC, and HPTLC. First Order Derivative method was based on the fact that LAF and DOM showed one zero crossing points 286.60 nm and 273.20 nm respectively. The estimation of both drugs by these two wavelength. Area under Curve Method was done by taking area under the curve in the range of 273 5nm and 287.2 5nm was selected for the analysis for LAF and DOM. The absorptivity values calculated. The calibration curve was plotted regression equation was calculated. HPLC method carried out by using Purospher(r) RP C18 (25 cm x 4.6 mm i.d., 5 m) with mobile phase used as a combination of Methanol: Water (with TFA) pH 4.8 = 65:35. The detection was carried out at 280 nm and at flow rate of 1.0 ml/min. HPTLC method was carried out by using Precoated silica gel G60F254 Aluminum sheet, 10 x 10cm and thickness of layer 0.2mm with mobile phase used as a combination of Ethyl Acetate: Ethyl Methyl Ketone: Ammonia (3:7:0.2 v/v/v).The detection was carried out at 280 nm.The proposed methods were successfully applied for the analysis of pharmaceutical formulation

Giving a brief account of methods of estimation of Drugs, followed by brief account of HPLC method, instrumentation, performance calculations and information related to proposed method. Another part of work is method validation which includes introduction, steps in validation, validation report and validation parameters for chromatographic methods. RP-HPLC method for the quantitative estimation of Antiviral drug. These methods are validated in terms of sensitivity, accuracy and precision and can be used for the routine determination of Antiviral drug, in bulk drug and Pharmaceutical formulations.

Practical Hplc and Lc-Ms Method Development and Validation

Specification of Drug Substances and Products

Equipment Qualification of Ion Mobility Spectrometry and Method Development and Validation for Pharmaceutical Equipment Cleaning Validation

Simultaneous Estimation, Method Validation, ICH

Handbook of Analytical Validation

The validation of analytical methods and the calibration of equipment are important aspects of quality assurance in the laboratory. This manual deals with both of these within the context of testing of illicit drugs in seized materials and biological specimens. It provides an introduction and practical guidance to national authorities and analysts in the implementation of method validation and verification, and also in the calibration/performance verification of laboratory instrumentation and equipment within their existing internal quality assurance programmes. The procedures described represent a synthesis of the experience of scientists from several reputable laboratories around the world.

Stanazolol is a steroidal class drug. Stanazolol is a synthetic anabolic steroid with therapeutic uses in treating c1-inhibitor deficient hereditary Angioedema. Our main objective is to Development and Validation of Simple UV-Spectroscopic Method for stanazolol in bulk and Pharmaceutical dosage Form and development and Validation of RP-HPLC methods for estimation of Stanazolol in Bulk and Pharmaceutical dosage Form. Comparison of Developed and Validated RP-HPLC Method against the developed and Validated Simple Uv-Spectrophotometric Method. development of force degradation method for detection of possible impurity of Stanazolol in API and pharmaceutical dosage form.

Analytical method development and validation play a major role in the discovery, development and manufacturing of pharmaceuticals. The official test method that results from these processes is used by quality control laboratories to ensure the identity, purity, potency and performance of drug product quality, essential for drug safety and efficiency. Method development is a formalized process by which a set of separation criteria are determined with a defined set of parameters such that the same separation profile is achieved. The process of method development can be quantitative or qualitative.

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.

Analytical Method Development & Validation

Method Development and Validation for the Determination of 1-Methyl-2-Pyrrolidone (NMP) in the Pharmaceutical Suspension D10010 Using High Performance Liquid Chromatography

HPLC Method Development and Validation in Pharmaceutical Analysis

Analytical Method Development and Validation of Antiviral Drug

Method Development and Validation for Voglibose by Uplc-Elsd

Specification of Drug Substances and Products: Development and Validation of Analytical Methods, Second Edition, presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development, validation of analytical methods, and their application in practice. This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition, including method development and validation in the clinical phase, method transfer, process analytical technology, analytical life cycle management, special challenges with generic drugs, genotoxic impurities, topical products, nasal sprays and inhalation products, and biotechnology products. The book's authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines, and/or subject-matter experts in the industry, academia and in government laboratories. Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject-matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis, control and specification of new drug substances and products Covers the latest statistical approaches (including analytical quality by design) in the development of specifications, method validation and shelf-life prediction

This book details: 1. Development and validation of a HPTLC-densitometric method for concurrent estimation of metformin hydrochloride, pioglitazone hydrochloride and gliclazide in combined dosage form. 2. Development and validation of a HPTLC method for simultaneous estimation of moxifloxacin hydrochloride and dexamethasone sodium phosphate in combined pharmaceutical dosage form. 3. Development and validation of a RP-HPLC method for simultaneous estimation of ciprofloxacin hydrochloride and dexamethasone in combined dosage form, which is a better alternative to existing ones. The developed analytical methods are simple, selective, accurate, robust, and precise with shorter analysis time for the analysis of drug/s in combined pharmaceutical dosage forms. All the developed HPTLC and HPLC methods have been validated as per ICH Q2 (R1) guideline. Developed analytical methods could boost analytical researchers to work more efficiently in the field of analytical method development and validation of Pharmaceutical dosage forms.

The coherent body of research described in this book is concerned with new HPLC method development and validation using novel systematic approaches for pharmaceutical and diagnostic compounds. The first stage of the research was to study how analytical method development and validation are typically carried out at present and to formulate this into a simple step-by-step approach. Such a template and protocol was not only used as the foundation of this research programme but could also serve as a simple systematic guide for other practitioners and those new to the field. Furthermore, it was recognised that this protocol should satisfy the requirements of the most strategically important regulatory agencies. The second stage of this research involved evaluation and application of the above validation approach to new methods that were developed for a diverse range of analytes using HPLC and LC-MS. In essence, the critical review of the requirements for method validation for various agencies and the subsequent preparation of guidelines on how to go about method validation have had a significant impact on analytical practitioners worldwide.

Practical approaches to ensure that analytical methods and instruments meet GMP standards and requirements Complementing the authors' first book, Analytical Method Validation and Instrument Performance Verification, this new volume provides coverage of more advanced topics, focusing on additional and supplemental methods, instruments, and electronic systems that are used in pharmaceutical, biopharmaceutical, and clinical testing. Readers will gain new and valuable insights that enable them to avoid common pitfalls in order to seamlessly conduct analytical method validation as well as instrument operation qualification and performance verification. Part 1, Method Validation, begins with an overview of the book's risk-based approach to phase appropriate validation and instrument qualification; it then focuses on the strategies and requirements for early phase drug development, including validation of specific techniques and functions such as process analytical technology, cleaning validation, and validation of laboratory information management systems Part 2, Instrument Performance Verification, explores the underlying principles and techniques for verifying instrument performance—coverage includes analytical instruments that are increasingly important to the pharmaceutical industry, such as NIR spectrometers and particle size analyzers—and offers readers a variety of alternative approaches for the successful verification of instrument performance based on the needs of their labs At the end of each chapter, the authors examine important practical problems and share their solutions. All the methods covered in this book follow Good Analytical Practices (GAP) to ensure that reliable data are generated in compliance with current Good Manufacturing Practices (cGMP). Analysts, scientists, engineers, technologists, and technical managers should turn to this book to ensure that analytical methods and instruments are accurate and meet GMP standards and requirements.

Development And Validation Of Chromatographic Methods For Simultaneous Quantification Of Drugs In Bulk And In Their Formulations: HPLC And HPTLC Techniques

Handbook of Analytical Quality by Design

Stability-indicating Method Development and Validation for the Determination of Ranolazine in Pharmaceutical Drug Product Using Reversed-phase Liquid Chromatography

Analytical Method Development and Validation by Uv and Hplc Techniques

Analytical Method Development and Validation

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.

HPLC Method Development for Pharmaceuticals

Method Development and Validation for Separation of Nine Pharmaceutical Active Ingredients Using Reversed-phase Liquid Chromatography and DryLab® Modeling Software

Analytical Method Development and Validation with Respect to ICH

Analytical Method Development and Validation for the Determination of Telmisarta

A Guide to Best Practice