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Development and Validation of a Reverse-phase HPLC Method for the Assay of Hydrocodone Bitartrate, Chlorpheniramine Maleate, Methylparaben and Propylparaben in Extended-release Oral Suspension - Riemon Anwiya - 2018

"Hydrocodone Bitartrate and Chlorpheniramine Maleate Oral Solution, is a commonly available drug product used to relieve cough and symptoms associated with upper respiratory allergies or the common cold. It consists of two main Active Pharmaceutical Ingredients (API’s), Hydrocodone Bitartrate and Chlorpheniramine Maleate. It also contains Methylparaben and Propylparaben which, serve as preservatives and provide anti-fungal capabilities. The purpose of this project was to develop an efficient reverse-phase assay method using HPLC that is stability indicating, robust, rugged, precise, linear, accurate and capable of being replicated in different laboratories. In order for a method to be considered effective and be utilized to test and release products, it must be validated according to the ICH Guideline Q2(R1). The validation parameters evaluated were: system suitability, specificity, forced degradation, linearity, accuracy/recovery, precision, ruggedness/intermediate precision, filter study, solution stability and robustness. The method was developed and validated for a concentration range of 60-180 ppm for Hydrocodone Bitartrate, 48-144 ppm for Chlorpheniramine Maleate, 45-135 ppm for Methylparaben and 9-27 ppm for Propylparaben (50% to 150% of the specification). Specificity of the method was also established and forced degradation was performed. The method was found to be specific, stability indicating, precise, accurate and robust. However, during the robustness portion of the validation, the method was found to be sensitive to the reduction of organic solvent in mobile phase A composition. In addition, working standards and sample solutions were deemed stable up to 4 days, while the stock standard solutions are stable up to 33 days when stored at room temperature."

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How to Use Reverse-Phase HPLC - G. Szepesi - 1992-03-18

This important contribution to the scientific community explains various aspects of reverse-phase separations. How to Use Reverse-Phase HPLC surveys the basics of liquid chromatography and summarizes the theoretical aspects of reverse-phase HPLC. Chapters also discuss: the influence of stationary and mobile phases on the efficiency and selectivity of the separations; the use of conventionally used and special reverse phase packings as well as that of masking agents added in the mobile phase; the evaluation of column performance in reverse phase chromatography; the applicability of special methods and techniques in RP-HPLC; the most important practical aspects of phase system optimization; and HPLC method validation summarizing the practical approaches recommended for the design and performance of validation experiments.

Development And Validation Of Chromatographic Methods For Simultaneous Quantification Of Drugs In Bulk And In Their Formulations: HPLC And HPTLC Techniques - Satish Y. Gabhe - 2014-08

This book details: 1. Development and validation of a HPTLC-densitometric method for concurrent estimation of metformin hydrochloride, pioglitazone hydrochloride and glitazide 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.

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Bendamustine Hydrochloride Using Reversed-phase Liquid Chromatography - Moizuddin Mohammed - 2016

"Bendamustine Hydrochloride is an anticancer drug classified under alkylating agents. In this research work the reverse-phase HPLC method has been developed. The main focus was to develop a method for routine analysis within a short span of time, with accurate and precise results. The column used was C18 (4.6 x 250 mm, 5μm) and pH 7 maintain at ambient temperature. The flow rate was 1.0mL/min, injection volume 15μL and wavelength was 330nm. The developed method was validated for System Suitability, Specificity, Solution Stability, Robustness, Accuracy, Precision, Linearity, Limit of Detection (LOD) and Limit of Quantitation (LOQ)."--


"Telaprevir is a protease inhibitor that acts on the serine protease and disrupts processing of viral proteins and arrangement of a viral replication complex in reverse transcription of viral RNA to DNA inside the host cell. A reversed-phase HPLC method has been developed and validated for the determination of Telaprevir in raw material and to for the determination of impurities and degradants that may arise in the sample. The separation was achieved on Phenomenex fusion synerge C18 column using mobile phase consisting of 6% methanol and 40% phosphate buffer of pH 2.9, the flow rate was 1 mL/min, injection volume was 20μL, and the wavelength was set at 237nm. The retention time for Telaprevir was about 7 minutes. This developed method was validated and has met the ICH acceptance criteria for all the parameters including system suitability, specificity, solution stability, linearity, robustness, precision, accuracy, limit of detection and limit of quantitation."--


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HPLC Method for Determination of APIs in pharmaceutical formulation - Parmal Chatrabhuji - 2014

"Dolutegravir is an antiretroviral drug, which inhibits the enzyme integrase, this enzyme is responsible for the reverse transcription of viral DNA into RNA. A reversed-phase HPLC method has been developed and validated for the determination of Dolutegravir in raw material and to for the determination of impurities and degradants that may arise in the sample. The separation was achieved on Phenomenex fusion synerge C18 column using mobile phase consisting of 65% potassium phosphate dibasic buffer (pH 7) and 35% Acetonitrile (100% ACN), a very good separation achieved. The flow rate was 1.0 mL/min, injection volume was 20μL, and the detection was accomplished at 267 nm. The retention time for Dolutegravir was about 7 minutes. This developed method was validated and has met the ICH acceptance criteria for all the parameters including system suitability, specificity, solution stability, linearity, robustness, precision, accuracy, limit of detection and limit of quantitation."--


"Hepatitis C is a liver sickness caused by hepatitis C virus (HCV), which can be both acute and chronic in condition. Telaprevir is a Hepatitis C drug which acts as protease inhibitor that objectives the viral HCV NS3-4A serine protease and disrupts processing of viral proteins and arrangement of a viral replication complex in Hepatitis C disease. A reversed-phase HPLC method was developed and validated for the determination of Telaprevir in raw material and to determine impurities and degradants that may developed in the tested samples. Using Waters C18 column (4.6 x 250 mm, 5μm) and mobile phase consisting of 65% potassium phosphate dibasic buffer (pH 7) and 35% acetonitrile (100% ACN), a very good separation achieved. The flow rate was 1.0 mL/min, injection volume 20μL, and detection was accomplished at 267 nm. The retention time for Telaprevir was 13 minutes. The developed method was validated and met all the acceptance criteria for validation parameters-system suitability, specificity, solution stability, robustness, linearity, accuracy, precision, limit of detection (LOD), and limit of quantitation (LOQ). The LOD was determined to be 0.1 ppb and LOQ was found to be 0.5 ppb."--


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Selection of the HPLC Method in Chemical Analysis - Serban C. Moldoveanu - 2016-11-01

Selection of the HPLC Method in Chemical Analysis serves as a practical guide to users of high-performance liquid chromatography and provides criteria for method selection, development, and validation. High-performance liquid chromatography (HPLC) is the most common analytical technique currently practiced in chemistry. However, the process of finding the appropriate information for a particular analytical project requires significant effort and pre-existent knowledge in the field. Further, sorting through the wealth of published data and literature takes both time and effort away from the critical aspects of HPLC method selection. For the first time, a systematic approach for sorting through the available information and reviewing critically the up-to-date progress in HPLC for selecting a specific analysis is available in a single book.

Selection of the HPLC Method in Chemical Analysis is an inclusive go-to reference for HPLC method selection, development, and validation. The book provides criteria for HPLC method selection, development, and validation. For the first time, a systematic approach for sorting through the available information and reviewing critically the up-to-date progress in HPLC for selecting a specific analysis is available in a single book. The book addresses the various aspects of practice and instrumentation needed to obtain reliable HPLC analysis results. Researchers to the best choice of an HPLC method from the overabundance of information existent in the field.

Analysis of analytical data and comparing it with the database of the HPLC method results in the best choice of an HPLC method from the overabundance of information existent in the field.

Food Analysis by HPLC - Leo M.L. Nollet - 2012-11-16

For food scientists, high-performance liquid chromatography (HPLC) is a powerful tool for product composition testing and assessing product quality. Since the last edition of this volume was published, great strides have been made in HPLC analysis techniques with particular attention given to miniaturization, automation, and green chemistry. The book provides a validated, up-to-date, and comprehensive guide for food scientists working in the following fields: food analysis, and food safety.

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Evidence-Based Validation of Herbal Medicine - Pulok K. Mukherjee - 2015-02-17

Evidence-Based Validation of Herbal Medicines brings together current thinking and practice in the areas of characterization and validation of natural products. This book reviews all aspects of evaluation and development of medicines from plant sources, including their cultivation, collection, phytochemical and phyto-pharmacological evaluation, and therapeutic potential. Emphasis is placed on describing the full range of evidence-based analytical and bio-analytical techniques used to characterize natural products, including –omic technologies, phyto-chemical analysis, hyphenated techniques, and many more. Includes state-of-the-art methods for detecting, isolating, and performing structure elucidation by degradation and spectrosopic techniques Covers biosynthesis, synthesis, and biological activity related to natural products Consolidates information to save time and money in research Increases confidence levels in quality and validity of natural products


"Adefovir dipivoxil, is an orally administered acyclic nucleotide analog reverse transcriptase inhibitor used for the treatment of hepatitis B. It is an anti viral drug with a chemical name of (1(5'-O-[[2-(6-amino-9H-purin-9-yl)ethoxy][methyl]2,2-dimethylpropanoyloxy][methoxy]phosphoryl)oxy)methyl2,2-dimethylpropanoate. A stability indicating reversed phase high performance liquid chromatography has been developed and validated for determination of adefovir dipivoxil in raw material. Agilent 1100 series high performance liquid chromatography system was used for method development studies. The separation was performed on phenomenex nucleosil C18, 250 x 4.0 mm column with the flow rate of 1 ml/min at room temperature. Isocratic elution was carried out with mobile phase consisting of solvent A (25 mM monobasic Potassium dihydrogen Phospahte, pH 2.5) and solvent B (35%ACN). The U/V detection wavelength is 260 nm. The stability study of adefovir dipivoxil was carried out by forced degradations using Hydrochloric acid, sodium hydroxide, 0.3% hydrogen peroxide, UV light and heat. The correlation coefficient was 0.9996. The percentage recovery of the method was 99-100%. The RSD for precision was 1.60 (n=6). The developed method is specific, linear, precise, accurate and robust based on validation results according to ICH guidelines."


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Using Reversed-phase HPLC - Mario Flores - 2004

Method Development and Validation for the Determination of Methyl Anthranilate and Padimate O Using Reversed-phase HPLC - Mario Flores - 2004

Method Development, Degradation Studies and Validation of Bupropion Hydrochloride Using Reversed Phase High Performance Liquid Chromatography - Sandra Neri - 2016

"Bupropion HCl, or 2-(t-butylamino)-1-(3-chlorophenyl)propan-1-one hydrochloride is an aminoketone primarily used for depression and smoking cessation. It is the most widely used anti-depressant in the United States and Canada. A simple, robust, and accurate RP-HPLC method was developed and validated for the determination and stability of Bupropion HCl raw material. A Waters Bondapak C18 column (300 x 3.9 mm, 10μ) was used in isocratic mode with a mobile phase composition of 25 mM Triethylamine/25 mM dibasic potassium phosphate (pH 7): acetonitrile/water (45:55 v/v), flow rate at 1 ml/min, and UV detection at 247 nm. The method resulted in average retention time of 8.2 minutes and good linearity in the concentration range 100-2,000 ppm with a correlation coefficient of 0.995. The chemical stability was also determined by subjecting Bupropion HCl to forced degradation conditions and then validated according to ICH guidelines to establish that the newly developed method is suitable for its intended purpose."

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Method Development and Validation for Determination of Aluminum by Reversed Phase Liquid Chromatography - Yosuke Sato - 2003

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Taxaceae and Cephalotaxaceae - Da-Cheng Hao - 2021-01-05

Taxaceae and Cephalotaxaceae: Biodiversity, Chemodiversity, and Pharmacotherapy accounts for the biodiversity and chemodiversity of these medicinal plants, examining and synthesizing existing research into their biology, chemistry and pharmacotherapy. The title examines how pharmacophylogeny allows sustainable conservation and exploitation, presents how these plants work from the chemical level upward, and examines associated microe compounds. Chapters present a summary of biological and biochemical research of Taxaceae plants, progress in mining their chemodiversity, mining pharmacotherapy utility from their chemodiversity and biodiversity, drug metabolism and pharmacokinetic diversity of their medicinal compounds, mining pharmacotherapy utility from associated microes, and more. Sections cover the biodiversity, chemodiversity and pharmacotherapy of Cephalotaxus medicinal plants, Amentotaxus, Pseudotaxus and Torreya medicinal plants. The book envisages that multiple omics platforms and advanced systems biology will allow further exploration of Taxaceae and Cephalotaxaceae, thus streamlining the future drug supply chain. Covers the biodiversity and chemodiversity of Taxaceae/Cephalotaxaceae medicinal plants Considers how a pharmacophylogeny framework can benefit conservation and sustainable exploitation of these plants Presents how Taxaceae/Cephalotaxaceae work from the chemical level upward"
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. Contributions from leading authorities informs and updates on all the latest developments in the field.

Profiles of Drug Substances, Excipients and Related Methodology

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. Contributions from leading authorities informs and updates on all the latest developments in the field.

Method Validation for Ofloxacin by Using Reversed-phase High Performance Liquid Chromatography (HPLC)

This method validation for Ofloxacin by using reversed-phase high performance liquid chromatography (HPLC) was developed to separate a mixture of eight pharmaceutical active ingredients: Theophylline, Lidocaine, Pheniramine, Ondanstron HCI, Triprolidine, Chloridiazepoxide and Doxepin HCI. 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 C18 (250 X 4.6mm, 5 μm) column and mobile phase consisted of solvent A (25mM Sodium acetate buffer at pH4) and solvent B (17% Acetonitrile). DryLab® software with 3D modeling which involved gradient time, column temperature and different proportions of acetonitrile resulted in an optimum linear gradient of 17% organic solvent at zero time which slowly increased to 35% in 22 minutes. Solvent Strength was controlled at 50% for 3 minutes and decreased to 17% in 3 seconds. Buffer was chosen at pH4 with column temperature at 53°C, flow rate of 1.00 mL/min and detection wavelength at 270 nm. The developed method was validated in terms of robustness and considered robust.**

Method Development and Validation for Separation of Eight Pharmaceutical Raw Materials Using Reversed-phase Liquid Chromatography and Drylab® Simulation

This method development and validation for separation of eight pharmaceutical raw materials using reversed-phase liquid chromatography and drylab® simulation was developed to separate a mixture of eight pharmaceutical active ingredients: Theophylline, Lidocaine, Pheniramine, Ondanstron HCI, Triprolidine, Chloridiazepoxide and Doxepin HCI. 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 C18 (250 X 4.6mm, 5 μm) column and mobile phase consisted of solvent A (25mM Sodium acetate buffer at pH4) and solvent B (17% Acetonitrile). DryLab® software with 3D modeling which involved gradient time, column temperature and different proportions of acetonitrile resulted in an optimum linear gradient of 17% organic solvent at zero time which slowly increased to 35% in 22 minutes. Solvent Strength was controlled at 50% for 3 minutes and decreased to 17% in 3 seconds. Buffer was chosen at pH4 with column temperature at 53°C, flow rate of 1.00 mL/min and detection wavelength at 270 nm. The developed method was validated in terms of robustness and considered robust.**

Proven and validated reverse-phase hplc method for the...
Method Development and Validation for Separation of Nine Pharmaceutical Active Ingredients Using Reversed-phase Liquid Chromatography and DryLab® Modeling Software - Lena Ghadimipour - 2018

A reversed-phase HPLC method was developed to separate a mixture of nine pharmaceutical active ingredients: Ciprofloxacin Hydrochloride, Gatifloxacin Hydrochloride, Levofloxacin Hemihydrate, Metoprolol Tartrate, Phenergan 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 7.0) 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 34°C, 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.--

Method Development and Validation for Separation of Nine Pharmaceutical Active Ingredients Using Reversed-phase Liquid Chromatography and DryLab® Modeling Software - Lena Ghadimipour - 2018

Method Development and Validation for Separation of Nine Pharmaceutical Active Ingredients Using Reversed-phase Liquid Chromatography and DryLab® Modeling Software - Lena Ghadimipour - 2018

Pharmaceutical Dosage Forms - Larry L. Augsburger - 2017-10-30

Pharmaceutical Dosage Forms: Capsules covers the development, composition, and manufacture of capsules. Despite the important role that capsules play in drug delivery and product development, few comprehensive texts on the science and technology of capsules have been available for the research and academic environments. This text addresses this gap, discussing how capsules provide unique capabilities and options for dosage form design and formulation.


Issues in Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology. The editors have built Issues in Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology: 2011 Edition on the vast information databases of ScholarlyEditions™. You can expect the information about Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Issues in Analysis, Measurement, Monitoring, Imaging, and Remote Sensing Technology: 2011 Edition has been produced by the world’s leading scientists, engineers, analysts, research institutions, and companies. All of the content is peer-reviewed, sourced, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.


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Method Validation for Predisolone by Using Reversed-phase High Performance Liquid Chromatography - Mann Yee Chow - 2006

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Modern HPLC for Practicing Scientists - Michael W. Dong - 2006-05-19

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 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 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 usersegment. Accessible to both novice and intermediate HPLC users, information is delivered in a straightforward manner illustrated with an abundance of diagrams, chromatograms, tables, and casestudies, and supported with selected key references and Webresources. 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 versatileanalytical technology.

Modern HPLC for Practicing Scientists - Michael W. Dong - 2006-05-19

A comprehensive yet concise guide to Modern HPLC Written for practitioners by a practitioner, Modern HPLC
Profiles of Drug Substances, Excipients, and Related Methodology - Harry G. Brittain - 2020-03-10

Chemistry, Biology and Potential Applications of Honeybee Plant-Derived Products - Susana M. Cardoso - 2016-06-06

Protein Sequencing Protocols - Bryan John Smith - 2002

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition - Anurag S. Rathore - 2012-05-09

Protein Sequencing Protocols - Bryan Smith - 2002

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Process Validation in Manufacturing of Biopharmaceuticals, Third Edition - Anurag S. Rathore - 2012-05-09

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Chemistry, Biology and Potential Applications of Honeybee Plant-Derived Products - Susana M. Cardoso - 2016-06-06

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RP-HPLC Method for the Determination of Anti-Anginal Drugs - S.Hasan Amrohi - 2013

Profiles of Drug Substances, Excipients, and Related Methodology, Volume 45, presents comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. The series encompasses review articles, with this release focusing on Azilsartan Medoxomil, Pirloxiam, Carbetapentane Citrate, Emtricitabine, Ertolotinib, Isotretinoin and Meloxicam. Contains contributions from leading authorities. Consolidates and updates on all the latest developments in the field of drug substances, excipients and methodologies.

Chemistry, Biology and Potential Applications of Honeybee Plant-Derived Products, Second Edition, provides for both novice and expert investigators alike a ready source of easy-to-follow protocols that simplify choosing the most appropriate method for protein sequence determination.

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Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.

RP-HPLC Method for the Determination of Anti-Anginal Drugs - S.Hasan Amrohi - 2013

A simple, specific, accurate and precise stability indicating reverse phase high performance liquid chromatographic (RP-HPLC) method has been developed for the simultaneous estimation of Aspirin and Isosorbide 5-mononitrate in bulk drug and its pharmaceutical dosage form. A chromatographic separation was achieved with reverse phase phenomex(r) Luna 5u C18 (2) 100A (250 x 4.60 mm) column in an isocratic mode at ambient temperature. The mobile phase consisting of water: methanol: acetonitrile (55:28:17% v/v/v) at a flow rate of 1 ml/min. The eluents were monitored at 217 nm. The retention times of Aspirin and Isosorbide 5-mononitrate were found to be 2.05 0.06 min and 4.27 0.016 min respectively. The regression analysis revealed linear regression with correlation coefficients of 1.00 and 0.99 respectively for Aspirin and Isosorbide 5-mononitrate respectively. The method was validated in terms of linearity, accuracy, precision, limit of detection (LOD), limit of quantification (LOQ) in accordance with ICH guide line. The results of the study showed that the developed method is simple, precise and accurate, and therefore suitable for routine analysis of these drugs in pharmaceutical dosage for...
"A reversed-phase HPLC method was developed to separate a mixture of eight pharmaceutical drug substances at ambient temperature. The mobile phase consisting of water: methanol: acetonitrile (55:28:17% v/v/v) at a flow rate of 1 ml/min. The eluents were monitored at 217 nm. The retention times of Aspirin and Isosorbide 5-mononitrate were found to be 2.05 0.056 min and 4.27 0.016 min respectively. The regression analysis revealed linearity in the concentration range of 1-10 ug/ml and 1-10 ug/ml for Aspirin and Isosorbide 5-mononitrate respectively. The method was validated in terms of linearity, accuracy, precision, limit of detection (LOD), limit of quantification (LOQ) in accordance with ICH guide lines. The results of the study showed that the developed method is simple, precise and accurate, and therefore suitable for routine analysis of these drugs in pharmaceutical dosage form.

Handbook of Analytical Validation - Michael E. Swartz - 2012-04-24
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

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which included Lidocaine, Meclizine, Ciprofloxacin HCl, Ropivacain HCl, Adifivre dipiroxil, Doxpin HCl, Thiocolchicoside and Trazodone HCl. These drugs are used a local anesthetic, an antihistamine, antimicrobial agent, for to treat Chronic Hepatitis B infection, depression, anxiety, insomnia, and for muscle relaxation. Agilent 1260 infinity HPLC system with Diode Array Detector was used with Waters C18 (250 x 4.6mm, 5 µm) column with mobile phase as solvent A which is 25mM Potassium Phosphate Monobasic buffer with pH 2.5 and solvent B which is 20% methanol and 80% acetonitrile mixture. DryLab® software with 3D modeling involving gradient time, column temperature and proportion of methanol to acetonitrile simulated optimum segmented gradient of 12% organic solvent at time zero which gradually increased to 18% in 11 minutes and then sharply increased to 90% in 9 minutes. Solvent strength remained at 90% for 3 minutes and was sharply reduced to 12% in 30 seconds. The method was developed under the following chromatographic conditions: buffer pH at 2.5, column temperature at 56 oC, flow rate of 1.00 ml/min and detection wavelength at 235 nm. For validation of developed method robustness was studied and developed method considered as robust.

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Validation in Chemical Measurement - Paul De Biévre - 2005-01-12
The validation of analytical methods is based on the characterisation of a measurement procedure (selectivity, sensitivity, repeatability, reproducibility). This volume collects 31 outstanding papers on the topic, mostly published in the period 2000-2003 in the journal "Accreditation and Quality Assurance". They provide the latest understanding, and possibly the rationale why it is important to integrate the concept of validation into the standard procedures of every analytical laboratory. In addition, this anthology considers the benefits to both: the analytical laboratory and the user of the measurement results.

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Hplc Method for Detection of Ingredients of Cough and Cold Preparations - Rahul Sahu - 2012-04
The purpose of this book is to provide guidance for the development of an analytical method on HPLC for the analysis of active pharmaceutical ingredients of pharmaceutical formulation. Topics included are basic method development and its application to ICH guidelines. This manual will only cover the use of reverse phase liquid chromatography. HPLC assays are used to demonstrate control of the process, to track and minimize impurities, and to maximize the yield and purity of the isolated product. Characterized working standards are utilized for quantification. In this thesis work has been carried out for the determination of Guaiifenesin and Pseudoephedrine hydrochloride in cold and cough preparations.
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