[Book] Stability Indicating Hplc Methods For Drug Analysis

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Stability-indicating HPLC Methods for Drug Analysis
- Quanyun A. Xu - 2008
Stability-Indicating HPLC Methods for Drug Analysis compiles summaries of stability-indicating HPLC analytical methods that have appeared in the published literature. A first stop for pharmaceutical scientists, analytical chemists, and librarians in the quest for information about the stability of drugs. Co-published by the American Pharmaceutical Association and the Pharmaceutical Press, a
pharmaceutical scientists, Pharmaceutical Society of Great Britain.

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**Development of Novel Stability Indicating Methods Using Liquid Chromatography** - Mukesh Maithani - 2019-08-07
Reversed-phase high-performance liquid chromatography (RP-HPLC) has become the most widely used method for ensuring accuracy, specificity and reproducibility for the quantification of drugs, while avoiding interference from any of the excipients that are normally present in pharmaceutical dosage forms. This book presents a simple methodology for developing stability-indicating methods and offers a ‘how-to guide’ to creating novel stability-indicating methods using liquid chromatography. It provides the detailed information needed to devise a stability-indicating method for drug substances and drug products that comply with international regulatory guidelines. As such, it is a must-read for anyone engaged in analytical and bioanalytical chemistry: professionals at reference, test, and control laboratories; students and academics at research laboratories, and scientists working for chemical, pharmaceutical, and biotechnology companies.
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**HPLC for Pharmaceutical Scientists** - Yuri V. Kazakevich - 2007-02-16

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...
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Modern HPLC for Practicing Scientists - Michael W. Dong - 2016-04-06
A comprehensive yet concise guide to Modern HPLC Written for practitioners by a practitioner, Modern HPLC for Practicing Scientists is a concise text which presents the most important High-Performance Liquid Chromatography (HPLC) fundamentals, applications, and developments. It describes basic theory and terminology for the novice, and reviews relevant concepts, best practices, and modern trends for the experienced practitioner. Moreover, the book serves well as an updated reference guide for busy laboratory 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.

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operation Method
devolution 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
cered-phase HPLC, the
most common separation
mode, and on applications for
the pharmaceutical industry,

Accessible to both novice and
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diagrams, chromatograms,
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Practical HPLC Method
Development - Lloyd R.
Snyder - 2012-12-03
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**HPLC and UHPLC for Practicing Scientists** - Michael W. Dong - 2019-07-23

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 transition 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 at 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
 Scientists, Second Edition is 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.

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Presents updated information on the best practices in method development, validation, operation, troubleshooting, and maintaining regulatory compliance for both HPLC and UHPLC.

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Development and Validation of a Stability-indicating RP-HPLC Method for Simultaneous Determination of Dapagliflozin and Saxagliptin in Fixed-dose Combination - - 2018

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High-Performance Gradient Elution - Lloyd R. Snyder - 2007-01-09
Gradient elution demystified Of the various ways in which chromatography is applied today, few have been as misunderstood as the technique of gradient elution, which presents many challenges compared to isocratic separation. When gradient elution can be less difficult to understand and much easier to use than often assumed. Written by two well-known authorities in liquid chromatography, High-Performance Gradient Elution: The Practical Application of the Linear-Solvent-Strength Model takes the mystery out of the practice of gradient elution and helps remove barriers to the practical application of this important separation technique. The book presents a systematic approach to the current understanding of gradient elution, describing theory, methodology, and applications across many of the fields that use liquid chromatography as a primary analytical tool. This up-to-date, practical, and comprehensive treatment of gradient elution: * Provides specific, step-by-step recommendations for developing a gradient separation for any sample * Describes the best approach for troubleshooting problems with gradient methods * Guides the reader on the
chromatography, High-
elution * Lists which
conditions should be varied
first during method
development, and explains
how to interpret scouting
gradients * Explains how to
avoid problems in transferring
gradient methods With a
focus on the use of linear
solvent strength (LSS) theory
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behavior and separations by
reversed-phase HPLC, High-
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High-Performance
Gradient Elution - Lloyd R.
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Gradient elution demystified
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Guides the reader on the
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Method Validation in Pharmaceutical Analysis - Joachim Ermer - 2006-03-06
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 avoid problems in transferring gradient methods With a focus on the use of linear solvent strength (LSS) theory for predicting gradient LC behavior and separations by reversed-phase HPLC, High-Performance Gradient Elution gives every chromatographer access to this useful tool.

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Analysis by HPLC Volume 6, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmacists, QA officers, and public authorities.

Handbook of Pharmaceutical Analysis by HPLC - Satinder Ahuja - 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 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.

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19. Congresso nazionale: Terapie adiuvanti e neoadiuvanti in chirurgia oncologica - - 1995

Pharmaceutical Stress Testing - Steven W. Baertschi - 2005-06-24
The first book devoted to the topic, this reference discusses the predictive power and limitations of current stress testing strategies and emphasizes the critical role of stress testing in the determination of the stability characteristics of pharmaceuticals-offering an extensive compilation of drug degradation studies from real-world examples in the literature.
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**UV-Spectrophotometric and Stability Indicating RP-HPLC Methods for the Determination of the Hepatitis C Virus Inhibitor Sofosbuvir in Tablet Dosage Form - - 2018**

**Analytical Chemistry - Abhay Nanda Srivastva - 2021-09-08**
Analytical insight of materials provides a lucid pathway for further opportunities in the development of high-potential modified materials. The analytical assessment also enhances the probability of finding suitable materials for various applications. This book presents the latest advancements and applications of analytical chemistry in a systematic manner. It is an anthology of scientific findings and views of researchers from various research centers across the globe on emerging topics of instrumentation, energy, environment, biotechnology, and synthetic enhancement analysis techniques related to analytical chemistry. The volume contains twelve chapters containing discussion, analogies, and graphics for a better understanding of the presented concepts.

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**Stability and Applications of Coordination Compounds** - Abhay Nanda Srivastva - 2020-07-08
In the current era of incessant developing needs for the betterment and ease in living style for humans, technology is seeking upgraded, well structured materials for utilization in various fields of human-wellness such as medication, energy, environment protection and the same direction, chemists are doing very well at synthesizing compounds and materials from different groups of chemicals. Among them, coordination compounds also play a key role in serving humanity as these compounds have a wide range of applications in health care from antimicrobial to anticancer, bioengineering, bio-mimetic models, catalysis, photosensitized materials etc. Along with development of stable coordination compounds, their extensive structural studies are also in the main line of work for researchers. Twenty-nine authors from different countries have contributed their scientific views and work in magnifying the importance and scope of coordination compounds in the present book entitled “Stability and Applications of Coordination Compounds”. I hope that the book will achieve its target of supplementing the community of researchers and readers working in the field of coordination chemistry.
countries have contributed to the advancement of Coordination Compounds - Abhay Nanda Srivastva - 2020-07-08

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Identification and Determination of Impurities in Drugs - S. Görög - 2000-05-19

Impurity profiling is the common name of a group of analytical activities, the aim of which is the detection, identification/structure elucidation and quantitative determination of organic and inorganic impurities, as well as residual solvents in bulk drugs and pharmaceutical formulations. Since this is the best way to characterise the quality and stability of bulk drugs and pharmaceutical formulations, this is the core activity in modern drug analysis. Due to the very rapid development of the analytical
special problems of this purpose and the similarly rapid increase of the demands as regards the purity of drugs it is an important task to give a summary of the problems and the various possibilities offered by modern analytical chemistry for their solution. That is the aim of this book. The book is methodology-oriented. In the first chapter some important aspects of the background of impurity-related analytical studies (toxicological, pharmacopoeial aspects, the characterisation of the sources of impurities and the role of impurity profiling in various fields of drug research, production and therapeutic use) are summarised. Chapter two deals with related organic impurities, the strategies for impurity profiling, the use of chromatographic and related separation methods, spectroscopic, and hyphenated techniques. The subject of the third chapter is the identification and determination of residual solvents. The determination of inorganic impurities is discussed in chapter four. The degradation products as impurities are dealt with in chapter five. A separate chapter has been compiled to deal with one of the most up-to-date problems in contemporary pharmaceutical analysis, the estimation of enantiomeric purity of chiral drugs. Chapter seven is devoted to various approaches to solve the problem of polymorphic modifications as impurities. Since in the broader sense of the word the microbiological purity of drugs and drug products also belongs to this circle, the most important information from this field is summarised in chapter eight. After the mainly methodology-oriented chapters, the final one concentrates on four groups of drugs (peptides, biotechnological products, antibiotics and steroids) in order to demonstrate the use of the methods described earlier.

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Benzodiazepines II - Harald Schütz

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**Stability Indicating Method of Diclofenac Sodium by Hplc** - Divya Yadav - 2012-04

The present book contains the simple, fast and precise stability indicating method for the extended release formulation of Diclofenac sodium using high pressure liquid chromatography (HPLC). It contains the fundamental concepts to the analytical chemistry along with the in depth knowledge of HPLC. The objective of this book was to provide the basic
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**Practical HPLC Methodology and Applications** - Brian A. Bidlingmeyer - 1993-05-06
Of related interest. Trace and Ultratrace Analysis by HPLC Satinder Ahuja Written by a leading scientist in the field, this monograph provides the first definitive and technically up-to-date treatment of the theory, equipment, and most powerful reliable analytical technique. Coverage includes an encyclopedic compendium of common substances that require trace and ultratrace analysis, and features clear discussion of such important topics as considerations for HPLC equipment, sensitive detectors, sample preparation, method development, selectivity and computer-based optimizations, optimizing detectability, and much more. 1991 (0 471-51419-5) 432 pp.

**High Performance Liquid Chromatography in Biotechnology** Edited by William S. Hancock Analytical chemists, biochemists, and chemical engineers will find this up-to-date guide to HPLC's recent developments essential for enhancing on-the-job technical expertise. Extensive coverage includes the broad applications of HPLC, ranging from major chromatographic techniques (including reversed phase, ion exchange, affinity and hydrophobic interaction chromatography) to specific
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Unified Separation Science J. Calvin Giddings This advanced text/monograph brings together for the first time the variety of techniques used for chemical separations by outlining their common underlying mechanisms. The mass transport phenomena underlying all separation processes are developed in a simple physical-mathematical form, facilitating analysis of alternative separation techniques and the factors integral to separation power.

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**Handbook of Isolation and Characterization of Impurities in Pharmaceuticals** - Satinder Ahuja - 2003-06-26
The United States Food and Drug Administration (FDA) and other regulatory bodies around the world require that impurities in drug substance and drug product levels recommended by the International Conference on Harmonisation (ICH) be isolated and characterized. Identifying process-related impurities and degradation products also helps us to understand the production of impurities and assists in defining degradation mechanisms. When this process is performed at an early stage, there is ample time to address various aspects of drug development to prevent or control the production of impurities and degradation products well before the regulatory filing and thus assure production of a high-quality drug product.
This book, therefore, has been designed to meet the need for a reference text on the complex process of isolation and characterization of process-related (synthesis and formulation) impurities and degradation products to meet critical regulatory requirements. Its objective is to provide guidance on isolating and characterizing impurities of pharmaceuticals such as drug candidates, drug substances, and drug products. The book outlines impurity identification processes and will be a key resource document for impurity analysis, isolation/synthesis, and characterization. It provides valuable information on isolation and characterization of impurities. It gives a regulatory perspective on the subject. It describes various considerations involved in meeting regulatory requirements. It discusses various sources of impurities and degradation products.

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**HPLC Method Development for Pharmaceuticals**

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that addresses these unique 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.

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Methods for Stability Testing of Pharmaceuticals

Discusses how HPLC is used in each phase of pharmaceutical development and how methods are developed to support activities in each phase.

Methods for Stability Testing of Pharmaceuticals
- Sanjay Bajaj - 2019-06-08
This detailed volume collects numerous methods and protocols related to different aspects of stability programs that are followed in pharmaceutical development laboratories. Implementation of a successful stability program, vital in preventing product failures and recalls, requires critical and logical thinking that goes beyond the regular documented protocols and methods, so the experiences of the book’s internationally-based expert contributors fill the chapters with practical guidance. As a volume in the Methods in Pharmacology and Toxicology series, this book presents the kind of real-world advice that is essential for advancing laboratory research.

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**Chiral Liquid Chromatography** - w Lough - 2012-12-06
While working as a chromatographer in the pharmaceutical industry, it became apparent to the editor that there was a pressing need for a comprehensive reference text for analysts working on the resolution of enantiomers by liquid chromatography (LC). This need arises from the fact that, whereas previously it was very difficult to determine enantiomers by direct means, there is now a wide choice of direct LC methods. At the same time, regulatory authorities have been changing their attitudes towards the administration of pharmaceuticals as racemates, partly because it is now possible to study the individual enantiomers. Clearly this abundance of new rationalized. More importantly, the chiral LC systems which are commercially available or readily accessible to the practising chromatographer needed to be reviewed and, to a much greater extent than in existing reviews or books, discussed in terms of their practical application. Accordingly this book is very much orientated towards the practical aspects of these commercially available and readily accessible chiral LC systems. To this end, it is written for practising chromatographers by a team of practising, experienced chromatographers who have spent many years tackling the problems presented by resolving enantiomers by LC. The practical aspects of common chiral LC systems cannot be fully understood if discussed in isolation.

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**Investigation of Ethosuximide Stability Under Certain ICH-recommended Stress Conditions Using a Validated Stability-indicating HPLC Method** - 2018

**Guideline for Submitting Samples and Analytical**
Although the official compendia define a drug substance as to identity, purity, strength, and quality, they normally do not provide other physical or chemical data, nor do they list methods of synthesis or pathways of physical or biological degradation and metabolism. Such information is scattered throughout the scientific literature and the files of pharmaceutical laboratories. Edited by the Associate Director of Analytical Research and Development for the American Association of Pharmaceutical Scientists, Analytical Profiles of Drug Substances and Excipients brings this information together into one source. The scope of the series has recently been expanded to include profiles of excipient materials.
method development, sample preparation, and industrial applications.

**High Performance Liquid Chromatography Method Development for the PheroidTM.** - Elaine Van den Berg - 2010


**Biochemical Analysis Tools**
- Oana-Maria Boldura -
2020-06-24

This book explores the role of nucleic acid analysis and the advances it has led to in the field of life sciences. The first section is a collection of chapters covering experimental methods used in molecular biology, the techniques adjacent to these methods, and the steps of analysis before and after obtaining raw DNA data. The second section deals with the principles of chromatography, method development, sample preparation, and industrial applications.

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conditions for photostability

**HPLC Method For Combined Dosage Form** - Imran Chaki - 2016-07-12

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**Drugs** - Angelo Albini - 2007-10-31
Since Pasteur in 1846, scientists have been aware that many drugs are photoreactive, but until recently research in this area had been somewhat limited. However, since the introduction of acutely sensitive analytical methods, the realisation of the need to identify the photochemical properties of a potential drug as early in its development as possible and the increased attention to the phototoxic effect of drugs, more details are becoming available. Drugs: Photochemistry and Photostability presents the basic elements of the science, and serves as an excellent introduction to this emerging field of photochemistry. Detailed experimental studies are given, along with a discussion of the recently implemented ICH Guidelines for drug photostability. With contributions from international experts in the field and including a comprehensive literature review, this book provides all the up-to-date information needed by researchers in many fields, especially medicinal and pharmaceutical chemistry.

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**Quality Management and Quality Control** - Paulo Pereira (mikrobiolog.) - 2019

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**Green Analytical Chemistry** - Justyna Płotka-Wasylka - 2019-08-02

The book explains the principles and fundamentals of Green Analytical Chemistry and highlights the current developments and future potential of the analytical green chemistry-oriented applications of various solutions. The book consists of sixteen chapters, including the history and milestones of GAC; issues related to teaching of green analytical chemistry and greening the university laboratories; evaluation of impact of analytical activities on the environmental and human health, direct techniques of detection, identification and determination of trace constituents; new achievements in the field of extraction of trace analytes from samples characterized by complex composition of the matrix; “green” nature of the derivatization process in analytical chemistry; passive techniques of sampling of analytes; green sorption materials used in analytical procedures; new types of solvents in the field of analytical chemistry. In addition green chromatography and related techniques, fast tests for
of Green Analytical Chemistry spectrum of pollutants in the different types of the medium, remote monitoring of environmental pollutants, qualitative and comparative evaluation, quantitative assessment, and future trends and perspectives are discussed. This book appeals to a wide readership of the academic and industrial researchers. In addition, it can be used in the classroom for undergraduate and graduate Ph.D. students focusing on elaboration of new analytical procedures for organic and inorganic compounds determination in different kinds of samples characterized by complex matrices composition. Jacek Namieśnik was a Professor at the Department of Analytical Chemistry, Gdańsk University of Technology, Poland. Justyna Płotka-Wasylka is a teacher and researcher at the same department.

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RP-HPLC Method Development & Validation for Pregabalin & Aceclofenac - Suvarna Ningal - 2021-09-06

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