

Residual solvents determination in pharmaceutical products by GC-HS and GC-MS–SPME

Costin C. Camarasu ^{*}, Mária Mezei-Szűts, Gábor Bertók Varga

Gedeon Richter Ltd., Central Analytical Laboratory, Győmsző ut 19–21, Budapest H-1103, Hungary

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Abstract

Solid-phase microextraction (SPME) has been applied to the residual solvents determination in pharmaceutical products and was compared with the static headspace. Three fibers with different polymer films were compared and the polydimethylsiloxane/divinylbenzene coated fiber was found to be the most sensitive for the analyzed analytes. Between the investigated sample preparation techniques, gastight-SPME proved to be the most sensitive, with DL values ranging from 5 pg ml⁻¹ to 2 ng ml⁻¹. Headspace SPME is more precise, with RSD of peak areas values ranging from 2 to 3%. The headspace SPME method was successfully validated. The validation data are reported in the text. The most important difference between the two techniques is that the gastight SPME showed better behavior towards very volatile solvents. Compared with the static headspace technique, both SPME methods showed superior results, being compatible with the pharmaceutical samples. © 1998 Elsevier Science B.V. All rights reserved.

Keywords: Extraction methods; Solid phase microextraction; Residual solvent analysis; Headspace analysis

1. Introduction

The residual solvents determination in drug substances, excipients or drug products is known to be one of the most difficult and demanding analytical task in the pharmaceutical industry.

The practice shows that it is not a rare case when an on-going selectivity is quite hard to keep as unknown volatile components does appear in the chromatogram of the investigated pharmaceutical products. The identification of these un-

known components requires the selectivity and mass spectral capabilities of GC–MS. In order to reach the quantitation limits required by regulatory agencies [1], sample preparation methods should be used. The sample preparation method should be precise, simple, cheap and it should allow easy automation. The common extraction techniques for volatile organic compounds are compared in Table 1 from previous points of view.

In Table 1, we highlighted the headspace and SPME sample preparation methods as being the most suitable from all points of view for the determination of residual solvents in pharmaceutical products.

^{*} Corresponding author. Fax: +36-1-2605888; e-mail: costin@orthodox.com.

Residual Solvents Determination In Pharmaceutical Products

**Steen Hansen, Steen Honoré
Hansen, Stig Pedersen-Bjergaard, Knut
Rasmussen**

Residual Solvents Determination In Pharmaceutical Products:

Specification of Drug Substances and Products Christopher M. Riley, K. Lien Nguyen, 2024-09-22 Specification of Drug Substances and Drug Products is a fully comprehensive reference on Specification Setting for Pharmaceuticals There have been several recent developments in the ICH Guidelines which were not captured in previous editions notably the new guideline on Development of Analytical Procedure and the revisions to the validation guidelines and the specification guidelines This edition contains chapters discussing the unique requirements for the universal critical quality attributes as well as the specific tests required to characterize and control different types of products ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug antibody conjugates and mRNA based products This substantially expanded revision of the 2nd edition will serve as practical comprehensive reference for scientists managers educators and consultants involved in the development and regulation of pharmaceutical products Presents critical assessment potential impact and application of the recent revisions to ICH guidelines on method validation Q2 as well as the latest guideline on Analytical Method Development Q14 and the special regional requirements in non ICH regions Addresses comprehensive treatment of the development and validation of analytical methodologies used in the analysis control and specification of a variety of different types of dosage forms ranging from traditional oral solid dosage forms to proteins mRNA based drugs vaccines and gene therapy This book will also address drug device combination products such as digital drug delivery systems transdermal systems and inhalation products Presents detailed treatment of latest statistical approaches including new approaches to the treatment of validation data method specification setting and shelf life prediction based on stability data

ICH Quality Guidelines Andrew Teasdale, David Elder, Raymond W. Nims, 2017-09-29 Examining the implications and practical implementation of multi disciplinary International Conference on Harmonization ICH topics this book gives an integrated view of how the guidelines inform drug development strategic planning and decision making Addresses a consistent need for interpretation training and implementation examples of ICH guidelines via case studies Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines Uses case studies to help readers understand and apply ICH guidelines Provides valuable insights into guidelines development with chapters by authors involved in generating or with experience implementing the guidelines Includes coverage of stability testing analytical method validation impurities biotechnology drugs and products and good manufacturing practice GMP

Formulating Poorly Water Soluble Drugs Robert O. Williams III, Alan B. Watts, Dave A. Miller, 2016-12-16 The objective of this volume is to consolidate within a single text the most current knowledge practical methods and regulatory considerations pertaining to formulations development with poorly water soluble molecules A pharmaceutical scientist's approach toward solubility enhancement of a poorly water soluble molecule typically includes detailed characterization of the compound's physicochemical properties solid state modifications advanced

formulation design non conventional process technologies advanced analytical characterization and specialized product performance analysis techniques The scientist must also be aware of the unique regulatory considerations pertaining to the non conventional approaches often utilized for poorly water soluble drugs One faced with the challenge of developing a drug product from a poorly soluble compound must possess at minimum a working knowledge of each of the abovementioned facets and detailed knowledge of most In light of the magnitude of the growing solubility problem to drug development this is a significant burden especially when considering that knowledge in most of these areas is relatively new and continues to develop

Wide Spectra of Quality Control Isin Akyar, 2011-11-09 Quality control is a standard which certainly has become a style of living With the improvement of technology every day we meet new and complicated devices and methods in different fields Quality control explains the directed use of testing to measure the achievement of a specific standard It is the process procedures and authority used to accept or reject all components drug product containers closures in process materials packaging material labeling and drug products and the authority to review production records to assure that no errors have occurred The quality which is supposed to be achieved is not a concept which can be controlled by easy numerical or other means but it is the control over the intrinsic quality of a test facility and its studies The aim of this book is to share useful and practical knowledge about quality control in several fields with the people who want to improve their knowledge

Handbook of Solvents, Volume 2 George Wypych, 2024-02-11 This 4th edition of Handbook of Solvents Volume 2 contains the most comprehensive information ever published on solvents as well as an extensive analysis of the principles of solvent selection and use The book begins with a discussion of solvents used in over 30 industries which are the main consumers of solvents The analysis is conducted based on the available data and contains information on the types and frequently amounts of solvents used and potential problems and solutions Picking up where Handbook of Solvents Volume 1 leaves off Handbook of Solvents Volume 2 provides information on the methods of analysis of solvents and materials containing solvents with 2 sections containing standard and special methods of solvent analysis followed by a discussion of residual solvents left in the final products The environmental impact of solvents such as their fate and movement in the water soil and air fate based management of solvent containing wastes and ecotoxicological effects are discussed as are solvents impact on tropospheric air pollution The next 2 chapters are devoted to the toxicology of solvents and regulations aiming to keep solvent toxicity under control The analysis of the concentration of solvents in more than 15 industries specific issues related to the paint industry and characteristics of the environment in automotive collision repair shops are followed by a thorough discussion of regulations in the USA and Europe Following chapters show examples of solvent substitution by safer materials with an emphasis on supercritical solvents ionic liquids deep eutectic solvents and agriculture based products such as ethyl lactate Discussion of solvent recycling removal and degradation includes absorptive solvent recovery comparison of results of recovery and incineration and application of solar photocatalytic oxidation The book concludes with an evaluation

of methods of natural attenuation of various solvents in soils and modern methods of cleaning contaminated soils Assists in solvent selection by providing key information and insight on environmental and safety issues Provides essential best practice guidance for human health consideration Discusses the latest advances and trends in solvent technology including modern methods of cleaning contaminated soils selection of gloves suits and respirators Pharmaceutical Excipients Otilia M. Y. Koo,2016-10-03 This book provides an overview of excipients their functionalities in pharmaceutical dosage forms regulation and selection for pharmaceutical products formulation It includes development characterization methodology applications and up to date advances through the perspectives of excipients developers users and regulatory experts Covers the sources characterization and harmonization of excipients essential information for optimal excipients selection in pharmaceutical development Describes the physico chemical properties and biological effects of excipients Discusses chemical classes safety and toxicity and formulation Addresses recent efforts in the standardization and harmonization of excipients **Solvent**

Microextraction John M Kokosa, Andrzej Przyjazny, Michael Jeannot,2009-10-05 This book offers both a practical as well a theoretical approach to Solvent Microextraction SME and will help analytical chemists to evaluate SME for a given sample preparation Introductory chapters overview a comparison of SME with other sample preparation methods a summary of the technical aspects and a detailed theoretical treatment of SME The book then describes the practical aspects of the technique with detailed how to chapters devoted to the preparation and analysis of atmospheric solid and liquid environmental clinical and industrial samples This text will serve as both a handy laboratory desk reference and an indispensable instructional tool

Handbook of Solvents George Wypych,2001 A comprehensive extensive textual analysis of the principles of solvent selection and use the handbook is intended to help formulators select ideal solvents safety coordinators to protect workers and legislators and inspectors to define and implement technically correct public safeguards for use handling and disposal

Chromatographic Analysis of Pharmaceuticals John A. Adamovics,2017-09-29 Updated and revised throughout Second Edition explores the chromatographic methods used for the measurement of drugs impurities and excipients in pharmaceutical preparations such as tablets ointments and injectables Contains a 148 page table listing the chromatographic data of over 1300 drugs and related substances including sample matrix analyzed sample handling procedures column packings mobile phase mode of detection and more **Quality Control and Evaluation of Herbal Drugs** Pulok K.

Mukherjee,2019-05-30 Quality Control and Evaluation of Herbal Drugs brings together current thinking and practices for evaluation of natural products and traditional medicines The use of herbal medicine in therapeutics is on the rise in both developed and developing countries and this book facilitates the necessary development of quality standards for these medicines This book elucidates on various challenges and opportunities for quality evaluation of herbal drugs with several integrated approaches including metabolomics chemoprofiling marker analysis stability testing good practices for manufacturing clinical aspects Ethnopharmacology and Ethnomedicine inspired drug development Written by Prof Pulok K

Mukherjee a leader in this field the book highlights on various methods techniques and approaches for evaluating the purity quality safety and efficacy of herbal drugs Particular attention is paid to methods that assess these drugs activity the compounds responsible and their underlying mechanisms of action The book describes the quality control parameters followed in India and other countries including Japan China Bangladesh and other Asian countries as well as the regulatory profiles of the European Union and North America This book will be useful in bio prospecting of natural products and traditional medicine inspired drug discovery and development Provides new information on the research and development of natural remedies essential reading on the study and use of natural resources for preventative or healing purposes Brings together current thinking and practices in quality control and standardization of herbal drugs highlighting several integrated approaches for metabolomics chemo profiling and marker analysis Aids in developing knowledge of various techniques including macroscopy microscopy HPTLC HPLC LC MS MS GC MS etc with the development of integrated methods for evaluation of botanicals used in traditional medicine Assessment of herbal drugs through bio analytical techniques bioassay guided isolation enzyme inhibition pharmacological microbiological antiviral assays and safety related quality issues References global organizations such as the WHO USFDA CDSCO AYUSH TCM and others to serve as a comprehensive document for enforcement agencies NGOs and regulatory authorities

Introduction to Pharmaceutical Chemical Analysis Steen Hansen, Steen Honoré Hansen, Stig Pedersen-Bjergaard, Knut Rasmussen, 2011-12-12 This textbook is the first to present a systematic introduction to chemical analysis of pharmaceutical raw materials finished pharmaceutical products and of drugs in biological fluids which are carried out in pharmaceutical laboratories worldwide In addition this textbook teaches the fundamentals of all the major analytical techniques used in the pharmaceutical laboratory and teaches the international pharmacopoeias and guidelines of importance for the field It is primarily intended for the pharmacy student to teach the requirements in analytical chemistry for the 5 years pharmacy curriculum but the textbook is also intended for analytical chemists moving into the field of pharmaceutical analysis Addresses the basic concepts then establishes the foundations for the common analytical methods that are currently used in the quantitative and qualitative chemical analysis of pharmaceutical drugs Provides an understanding of common analytical techniques used in all areas of pharmaceutical development Suitable for a foundation course in chemical and pharmaceutical sciences Aimed at undergraduate students of degrees in Pharmaceutical Science Chemistry Analytical Science Chemistry Forensic analysis Includes many illustrative examples

Pharmaceutical Analysis for Small Molecules Behnam Davani, 2017-08-01 A comprehensive introduction for scientists engaged in new drug development analysis and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates especially chemistry analytical chemistry pharmacy and pharmaceutical majors into its ranks However because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult Designed to assist both recent graduates as well as

experienced chemists or scientists with limited regulatory compendial or pharmaceutical analysis background make that transition *Pharmaceutical Analysis for Small Molecules* is a concise yet comprehensive introduction to the drug development process and analysis of chemically synthesized small molecule drugs. It features contributions by distinguished experts in the field including editor and author Dr Behnam Davani, an analytical chemist with decades of technical management and teaching experience in compendial regulatory and industry. This book provides an introduction to pharmaceutical analysis for small molecules non biologics using commonly used techniques for drug characterization and performance tests. The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products. In addition, related required supporting studies including good laboratory documentation practices including analytical instrument qualification are highlighted in this book. Topics covered include Drug Approval Process and Regulatory Requirements, private standards, Pharmacopeias and Compendial Approval Process, public standards, Common methods in pharmaceutical analysis, typically compendial, Common Calculations for assays and impurities and other specific tests, Analytical Method Validation, Verification, Transfer, Specifications including how to handle out of specification (OOS) and out of trend (OOT) Impurities including organic, inorganic, residual solvents and elemental impurities, Good Documentation Practices for regulatory environment, Management of Analytical Laboratories, Analytical Instrument Qualifications including IQ, OQ, PQ and VQ. Due to global nature of pharmaceutical industry, other topics on both regulatory ICH and Compendial harmonization are also highlighted. *Pharmaceutical Analysis for Small Molecules* is a valuable working resource for scientists directly or indirectly involved with the drug development process including analytical chemists, pharmaceutical scientists, pharmacists and quality control, quality assurance professionals. It also is an excellent text reference for graduate students in analytical chemistry, pharmacy, pharmaceutical and regulatory sciences.

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

Handbook of Analytical Quality by Design
Sarwar Beg, Md Saquib Hasnain, Mahfoozur Rahman, Waleed H Almalki, 2021-01-09. *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 *Handbook of Pharmaceutical Manufacturing Formulations* Sarfaraz K. Niazi, 2016-04-19 While liquid drugs do not share the compression problems of solid dosage forms the filling problems of powder dosage forms or the consistency problems of semisolid dosage forms they do have their own set of considerations in the formulation and manufacturing stages Highlights from Liquid Products Volume Three include practical details into **Pharmaceutical Manufacturing Formulations** Dr. Priyanka Gupta Manglik, 2024-08-15 This book provides detailed insight into the various aspects of pharmaceutical manufacturing covering formulations process design technology and regulatory requirements essential for professionals in the pharma industry **High-Throughput Analysis in the Pharmaceutical Industry** Perry G. Wang, 2008-08-20 The introduction of combinatorial chemistry technology has increased the amount of compounds generated in a year from 50 to 2000 Conventional analytical approaches simply cannot keep up These circumstances have caused drug discovery to take on the shape of a bottleneck like traffic through a toll booth In order to break the bottleneck a corres **Cumulated Index Medicus**, 1970 **Preclinical Development Handbook** Shayne Cox Gad, 2008-03-11 A clear straightforward resource to guide you through preclinical drug development Following this book's step by step guidance you can successfully initiate and complete critical phases of preclinical drug development The book serves as a basic comprehensive reference to prioritizing and optimizing leads toxicity pharmacogenomics modeling and regulations This single definitive easy to use resource discusses all the issues that need consideration and provides detailed instructions for current methods and techniques Each chapter was written by one or more leading experts in the field These authors representing the many disciplines involved in preclinical toxicology screening and testing give you the tools needed to apply an effective multidisciplinary approach The editor with more than thirty years experience working with pharmaceutical and biotechnology companies carefully reviewed all the chapters to ensure that each one is thorough accurate and clear Among the key topics covered are In vitro mammalian cytogenetics tests Phototoxicity Carcinogenicity studies The pharmacogenomics of personalized medicine Bridging studies Toxicogenomics and toxicoproteomics Each chapter offers a full exploration of problems that may be encountered and their solutions The authors also set forth the limitations of various methods and techniques used in determining the safety and efficacy of a drug during the preclinical stage This is a hands on

guide for pharmaceutical scientists involved in preclinical testing enabling them to perform and document preclinical safety tests to meet all FDA requirements before clinical trials may begin *Drug Stability and Chemical Kinetics* Muhammad Sajid Hamid Akash, Kanwal Rehman, 2020-11-01 This book comprehensively reviews drug stability and chemical kinetics how external factors can influence the stability of drugs and the reaction rates that trigger these effects Explaining the important theoretical concepts of drug stability and chemical kinetics and providing numerous examples in the form of illustrations tables and calculations the book helps readers gain a better understanding of the rates of reactions order of reactions types of degradation and how to prevent it as well as types of stability studies It also offers insights into the importance of the rate at which the drug is degraded and or decomposed under various external and internal conditions including temperature pH humidity and light This book is intended for researchers PhD students and scientists working in the field of pharmacy pharmacology pharmaceutical chemistry medicinal chemistry and biopharmaceutics

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