

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

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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.

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Residual Solvents Determination In Pharmaceutical Products

RD Boyd

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Table of Contents Residual Solvents Determination In Pharmaceutical Products

1. Understanding the eBook Residual Solvents Determination In Pharmaceutical Products
 - The Rise of Digital Reading Residual Solvents Determination In Pharmaceutical Products
 - Advantages of eBooks Over Traditional Books
2. Identifying Residual Solvents Determination In Pharmaceutical Products
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Residual Solvents Determination In Pharmaceutical Products
 - User-Friendly Interface
4. Exploring eBook Recommendations from Residual Solvents Determination In Pharmaceutical Products
 - Personalized Recommendations
 - Residual Solvents Determination In Pharmaceutical Products User Reviews and Ratings

- Residual Solvents Determination In Pharmaceutical Products and Bestseller Lists
- 5. Accessing Residual Solvents Determination In Pharmaceutical Products Free and Paid eBooks
 - Residual Solvents Determination In Pharmaceutical Products Public Domain eBooks
 - Residual Solvents Determination In Pharmaceutical Products eBook Subscription Services
 - Residual Solvents Determination In Pharmaceutical Products Budget-Friendly Options
- 6. Navigating Residual Solvents Determination In Pharmaceutical Products eBook Formats
 - ePub, PDF, MOBI, and More
 - Residual Solvents Determination In Pharmaceutical Products Compatibility with Devices
 - Residual Solvents Determination In Pharmaceutical Products Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Residual Solvents Determination In Pharmaceutical Products
 - Highlighting and Note-Taking Residual Solvents Determination In Pharmaceutical Products
 - Interactive Elements Residual Solvents Determination In Pharmaceutical Products
- 8. Staying Engaged with Residual Solvents Determination In Pharmaceutical Products
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Residual Solvents Determination In Pharmaceutical Products
- 9. Balancing eBooks and Physical Books Residual Solvents Determination In Pharmaceutical Products
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Residual Solvents Determination In Pharmaceutical Products
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Residual Solvents Determination In Pharmaceutical Products
 - Setting Reading Goals Residual Solvents Determination In Pharmaceutical Products
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Residual Solvents Determination In Pharmaceutical Products
 - Fact-Checking eBook Content of Residual Solvents Determination In Pharmaceutical Products
 - Distinguishing Credible Sources

13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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