Introduction

Analysis of residual solvent is a critical application in the pharmaceutical industry. The choice of solvent during manufacturing can improve yield or affect chemical properties of the product synthesized. However, solvents do not enhance the product’s efficacy, and must be removed as completely as possible to meet product specification and good manufacturing practices. Therefore, testing for residual solvents during production or purification processes is a necessary aspect of manufacturing.

USP 467 specifies a single column analysis with a secondary analysis in the case of detection above concentration limits. With the Agilent 7697A Headspace Sampler and an Agilent Intuvo 9000 GC configured with an inlet splitter, both analyses can be performed with a single system configured with dual columns and dual detectors.

The Agilent Intuvo 9000 GC Analyzer for Residual Solvents adds to the Intuvo ease-of-use innovations by improving the application development process with proven Agilent-developed methods shipped with results from the factory.

Technology overview

• Application-specific factory solutions for using the Intuvo 9000 GC, 7697A Headspace Sampler, and Agilent Ultra Inert columns
• Analyzers are factory-configured, and tested with complete flow path, method files, and factory test results
• Agilent factory test results are duplicated upon installation

The Intuvo 9000 GC can be configured with an inlet splitter to allow dual column/dual detection analysis. By using the Agilent Ultra Inert columns, analytes can be quantified and accurately identified by retention time.

For more information, visit:
www.agilent.com

Agilent Technologies
Instrumentation

- Agilent 7697A Headspace Sampler
- Agilent Intuvo 9000 GC with inlet splitter and dual FIDs
- Agilent Ultra Inert capillary columns for Intuvo: DB-Select 624 UI (123-0334UI-INT) and DB-WAX UI (123-7032UI-INT)
- Tested at Agilent factory, and after installation, with Agilent USP 467 Residual Solvents Mixture (5190-0492)

Results and Discussion

The Intuvo Residual Solvent Analyzer, featuring the 7697A Headspace Sampler and Agilent Ultra Inert columns, combines user-friendly operation and a small footprint.

A proven hardware and application solution saves method development time resulting in faster, trusted results.

Residual Solvents Mixture (5190-0492) on Agilent Ultra Inert capillary columns:

1. Methanol
2. Acetonitrile
3. Methylene chloride
4. trans-1,2-dichloroethene
5. cis-1,2-dichloroethene
6. Tetrahydrofuran
7. Cyclohexane
8. Methylcyclohexane
9. 1,4-dioxane
10. Toluene
11. Chlorobenzene
12. Ethylbenzene
13. m-xylene
14. p-xylene
15. o-xylene

Reference