

Streamline your USP <467> Residual Solvent Detection

Agilent Residual Solvent Analyzers



The manufacturing process of active pharmaceutical ingredients (APIs) may contribute to residual solvents remaining in the final pharmaceutical product. Producers need to monitor and control the levels of residual solvents for a number of reasons including safety, effect on crystalline form, solubility, bioavailability, and stability. All drug substances, excipients, and products must conform to strict regulatory limits.

Consistently analyze residual solvents immediately following installation

Agilent Residual Solvent Analyzers are based on the Agilent Intuvo 9000 GC system – and are factory pre-tested and preconfigured to deliver the results you need, *fast*, while saving you precious start-up time. What's more, their analytical precision exceeds USP method requirements for the three classes of residual solvents:

Class 1: Solvents to be avoided

- Known human carcinogens
- Strongly suspected human carcinogens
- Environmental hazards

Class 2: Solvents to be limited

- Nongenotoxic animal carcinogens, or possible agents that cause irreversible toxicity
- Solvents suspected of significant, but reversible, toxicity

Class 3: Solvents with low toxic potential

- No health-based exposure limits

The Analyzer's inert sample path and thermal zone stability—combined with the automation capabilities of the Agilent 7697A HeadspaceSampler—provide unsurpassed accuracy and repeatability.

Intuvo Residual Solvent Analyzers reflect innovative technology and a stringent quality control process

Systems include:

Factory

- System assembly, performance check, and leak testing
- Application, configuration, and Agilent J&W Ultra Inert columns
- Factory chemical performance verification with application-specific chemical checkout mix

Delivery

- DVD with method parameters and checkout data files for easy out-of-the-box operation
- Instrument and method operational manuals
- Information to help you reorder consumables easily

Installation

- Onsite installation by factory-certified support engineer
- Duplicate factory checkout with application-specific Class 2A checkout sample
- Optional application startup assistance



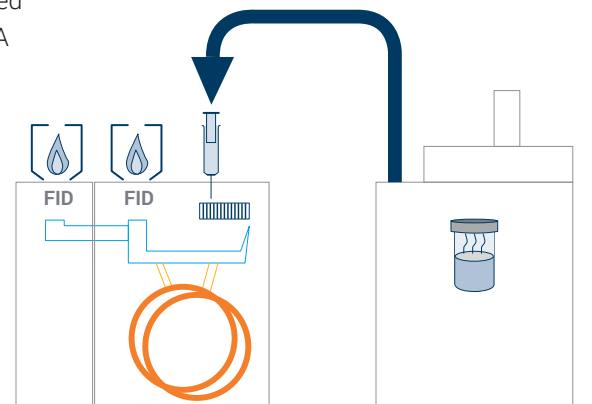
Facilitate your QA/QC with Agilent USP <467> Residual Solvent Analyzers

- Pre-configured to meet system suitability requirements for USP <467>, including column, consumables, calibration/checkout samples, and analytical method
- Chemically tested to ensure optimal analysis of Class 1 and Class 2A/B solvents
- With precise temperature and sampling control routines, the Agilent 7697A Headspace Sampler maximizes throughput and minimizes operator error
- Headspace thermal zone stability of ± 0.1 °C, inert flow path, and patented Capillary Flow Technology (CFT) provide excellent RSD for USP Class 1A and Class 2A/B solvents while minimizing carryover
- Begin system calibration and validation immediately following installation

Intuvo Dual-FID Residual Solvent Analyzers Easily quantitate OVI content

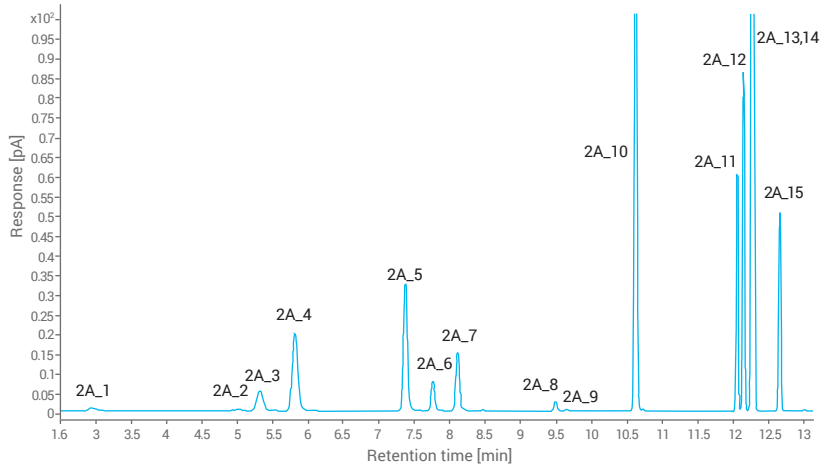
Intuvo Dual-FID Analyzers are ideal for identifying organic contaminants in active ingredients, formulations, and additives.

The dual-FID configuration uses dissimilar columns for additional confirmation within a single injection



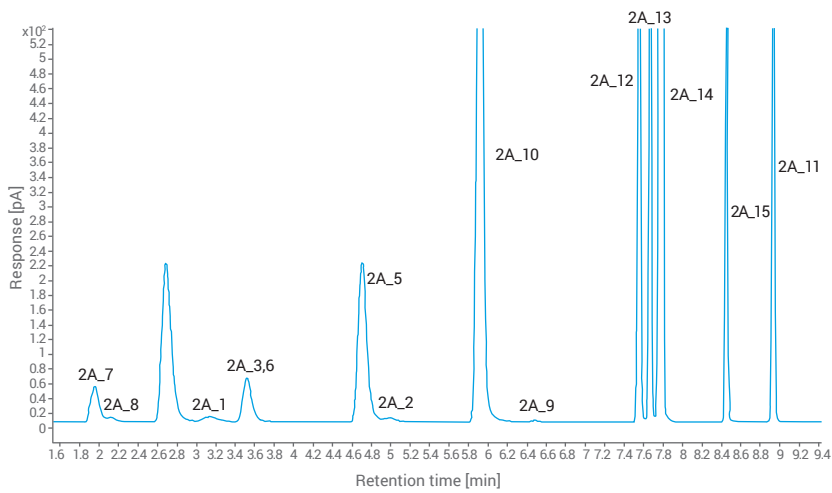
Intuvo 9000 GC

7697A Headspace Sampler



FID 1: Residual solvents Class 2A checkout mix and DB-624 Select UI column

| | Identity | USP limit (ppm) | RSD (%) |
|-----------------|--------------------------|-----------------|---------|
| Class 2A | | | |
| 1 | Methanol | 3,00 | 0.8 |
| 2 | Acetonitrile | 410 | 0.8 |
| 3 | Dichloromethane | 600 | 0.3 |
| 4 | trans-1,2-Dichloroethene | 1,870 | 0.8 |
| 5 | cis-1,2-Dichloroethene | 1,870 | 1.4 |
| 6 | Tetrahydrofuran | 720 | 1.1 |
| 7 | Cyclohexane | 3,880 | 1.4 |
| 8 | Methylcyclohexane | 1,180 | 1.5 |
| 9 | 1,4-Dioxane | 380 | 1.4 |
| 10 | Toluene | 890 | 1.7 |
| 11 | Chlorobenzene | 360 | 0.4 |
| 12 | Ethylbenzene | 2,170 | 0.6 |
| 13,14 | m-Xylene, p-Xylene | 2,170 | 2.2 |
| 15 | o-Xylene | 2,170 | 2.2 |



FID 2: Residual solvents Class 2A checkout mix and DB-WAX UI column

Agilent has the technology and experience to support your lab with fully customized solutions

Let Agilent help you meet your most challenging demands with specialized technologies that reduce your time from system arrival to final validation. With pre-configured hardware and method specific separation tools, your analysts can focus on calibration and validation per your laboratory's SOPs.

Beyond the box: A full portfolio of customized products, advice, and support

High-quality columns and supplies from the world GC leader

Agilent-engineered GC columns and supplies deliver what your pharmaceutical applications demand—including:

- Long-term reliability and robustness
- Trouble-free instrument operation
- Faster analysis *without* loss of resolution

Local, on-site assistance

From routine evaluation to critical assessments, Agilent makes it easier to find the answers you need to make smarter decisions about what comes next.

Best-in-class service and support

Whether you need support for a single instrument or a largescale, multi-vendor operation, Agilent service professionals can help solve problems quickly and increase your uptime, so you can focus on what you do best.

Custom GC and GC/MS configurations

Let Agilent customize a standard GC or GC/MS Analyzer with specialized columns, valves, tubing inlets, and other add-ons—including an extensive line of consumables and column modules.

Ordering information:

To order the Residual Solvent Analyzer (HSS/GC/FID/FID), specify: **Intuvo Option #601**

For more information about the Agilent Intuvo Residual Solvent Analyzers, visit

www.agilent.com/chem/intuvo-residual-solvent-analyzer

Contact your local Agilent representative or Agilent authorized distributor at

www.agilent.com/chem/contactus

Or call 800-227-9770 (in the U.S. or Canada)

Visit www.agilent.com/chem/USP467solutions for a description of available Analyzers and Application Kits

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