

Residual Solvent Analysis

Implementing USP <467>

- Satisfy USP <467> requirements—detailed procedures inside.
- Improve system suitability pass rates with an optimized system.
- Easy technical tips ensure successful implementation.

The RESTEK logo features the word "RESTEK" in a bold, white, sans-serif font. Above the letter "E", there is a white graphic element consisting of two curved lines that suggest a stylized arch or a chromatogram peak.

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Achieving USP <467> Compliance— Your Guide to Successfully Implementing the Revised Method

Overview of Method

The United States Pharmacopeia (USP) general chapter <467> Residual Solvents is a widely used compendial method for identifying and quantifying residual solvents when no information is available on what solvents are likely to be present. In an attempt to harmonize with the International Conference on Harmonization (ICH) guidelines, the USP proposed a more comprehensive method in USP 30/NF 25. This revision significantly increases the number of residual solvents to be routinely tested and includes three distinct procedures.¹

The revised USP <467> method consists of a static headspace extraction coupled with a gas chromatographic separation and flame ionization detection. In this guide, we demonstrate the USP <467> application using two different types of headspace autosamplers. Procedure A was performed using a pressured loop autosampler and transfer line. Procedure B was performed using a heated syringe injection. Either system can be used to meet method requirements.

USP <467> is divided into two separate sections based upon sample solubility: water-soluble and water-insoluble articles. The methodology for both types of articles is similar, but the diluent used in both standard and sample preparations differs based upon the solubility of the test article. The test method consists of three procedures (A, B, and C), that are designed to identify, confirm, and then quantify residual solvents in drug substances and products (Figure 1).

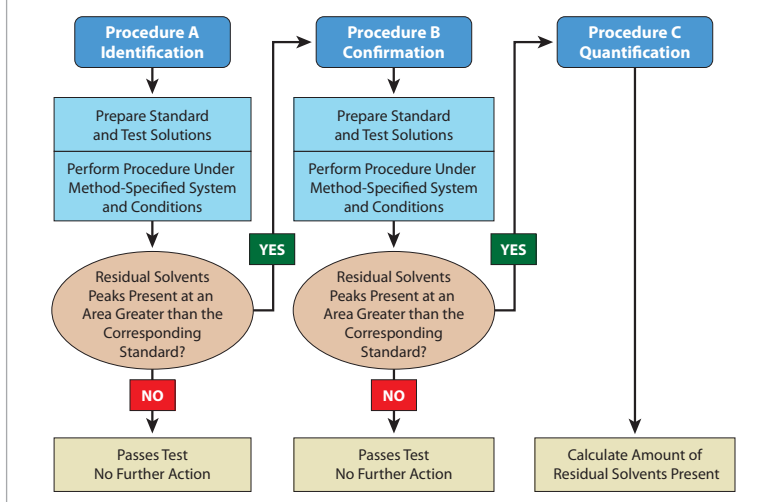
Analytical Reference Materials

The ICH guideline classifies residual solvents by class according to toxicity. Class 1 compounds are carcinogenic and pose a risk to both the consumer and the environment. The use of these solvents must be avoided or tightly controlled. Class 2 compounds are nongenotoxic animal carcinogens and their concentration should be limited. Both Class 1 and 2 compounds require chromatographic determination and are separated into 3 test mixes: Class 1 Mixture, Class 2 Mixture A, and Class 2 Mixture B. Class 3 compounds have low toxic potential. Concentration levels of up to 0.5% are acceptable and, therefore, they can be assayed by nonspecific techniques, such as weight loss on drying. Class 2 Mixture C is not used in the current USP <467> and contains solvents that are not readily detectable by headspace analysis. These solvents should be assayed by other appropriately validated procedures.

Procedure A - Identification

Procedure A is the first step in the identification process and is performed on a 6% cyanopropylphenyl-94% dimethyl polysiloxane (G43) column to determine if any residual solvents are present in the sample at detectable levels. First, Class 1 standard and system suitability solutions and Class 2 Mix A standard solutions are assayed under the method-specified operating conditions to establish system suitability. In the Class 1 system suitability solution, all peaks must have a signal-to-noise ratio not less than 3, and the 1,1,1-trichloroethane response must be greater than 5. Also, the resolution of acetonitrile and dichloromethane must be not less than 1 in the Class 2 Mixture A solution. When system suitability has been achieved, the test solutions are assayed along with the Class 1 and Class 2 Mixtures A and B standard solutions. If a peak is determined in the sample that matches a retention time and has a greater response than that of a corresponding reference material, then Procedure B is performed for verification of the analyte. In the second supplement of USP 30/NF 25, an exemption was made for 1,1,1-trichloroethane, where a response greater than 150 times the peak response denotes an amount above the percent daily exposure limit. Figures 2 through 4 illustrate the analysis of Class 1, Class 2 Mixture A, and Class 2 Mixture B residual solvent mixes by Procedure A.

Figure 1 Analytical flow chart for residual solvent testing under the revised USP <467> method.



¹ This number of analytes to be tested represents the sum of Class 1 and 2 residual solvents that can be effectively assayed using HS/GC. The actual number of analytes may be more if xylenes, ethyl benzene and *cis/trans* 1,2 dichloroethylene are differentiated, or if circumstances require the quantification of specific Class 3 residual solvents.

Technical Opportunities

Expand your knowledge and improve your results with Restek.

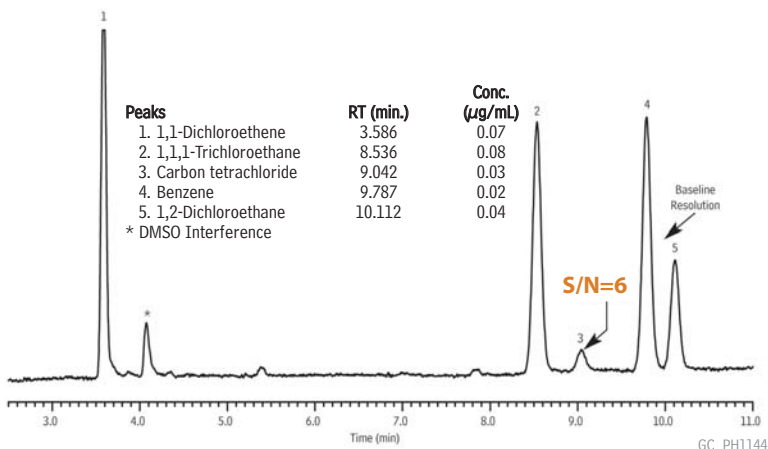
- Download our free *Technical Guide for Static Headspace Analysis*. (cat.# 59895A)
- View a free webinar.
- Contact us for on-site residual solvent training.

www.restek.com/usp467

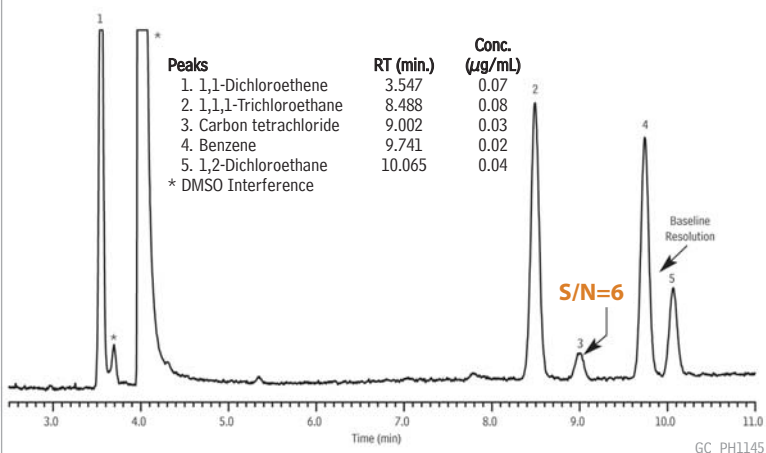


Figure 2 USP residual solvent Class 1 standard solution on an Rxi®-624Sil MS (G43) column.

A: Water-Soluble Articles



B: Water-Insoluble Articles



i tech tip

Increase the signal-to-noise ratio for carbon tetrachloride by using an appropriate data acquisition rate. 5–10 Hz is sufficient for peak widths of 0.1 minutes or above.

Column Rxi®-624Sil MS, 30 m, 0.32 mm ID, 1.80 µm (cat.# 13870)
Sample Residual Solvents - Class 1 (cat.# 36279)
Diluent: Chromatogram A: water
 Chromatogram B: DMSO
Injection headspace-loop split (split ratio 5:1)
 1mm Split (cat.# 20972)
Liner:
Headspace-Loop
 Inj. Port Temp.: 140 °C
 Instrument: Tekmar HT3
 Inj. Time: 1 min.
 Transfer Line Temp.: 110 °C
 Valve Oven Temp.: 110 °C
 Sample Temp.: 80 °C
 Sample Equil. Time: 60 min.
 Vial Pressure: 10 psi
 Pressurize Time: 0.5 min.
 Pressure
 Equilibration Time: 0.05 min.
 Loop Pressure: 5 psi
 Loop Fill Time: 0.1 min.
Oven
 Oven Temp: 40 °C (hold 20 min.) to 240 °C at 10 °C/min. (hold 20 min.)
Carrier Gas
 Linear Velocity: He, constant flow
 35 cm/sec.
 Dead Time: 1.45 min. @ 40 °C
Detector
 Data Rate: 5 Hz
 FID @ 250 °C
Instrument
 Agilent/HP6890 GC
Acknowledgement
 Teledyne Tekmar

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DMSO, when used in water-insoluble articles, can cause peak interferences and carryover. Contaminants can be removed by baking out the sample path at high temperatures between sample batches. Alternatively, DMF or DMI can be used if interferences are present.

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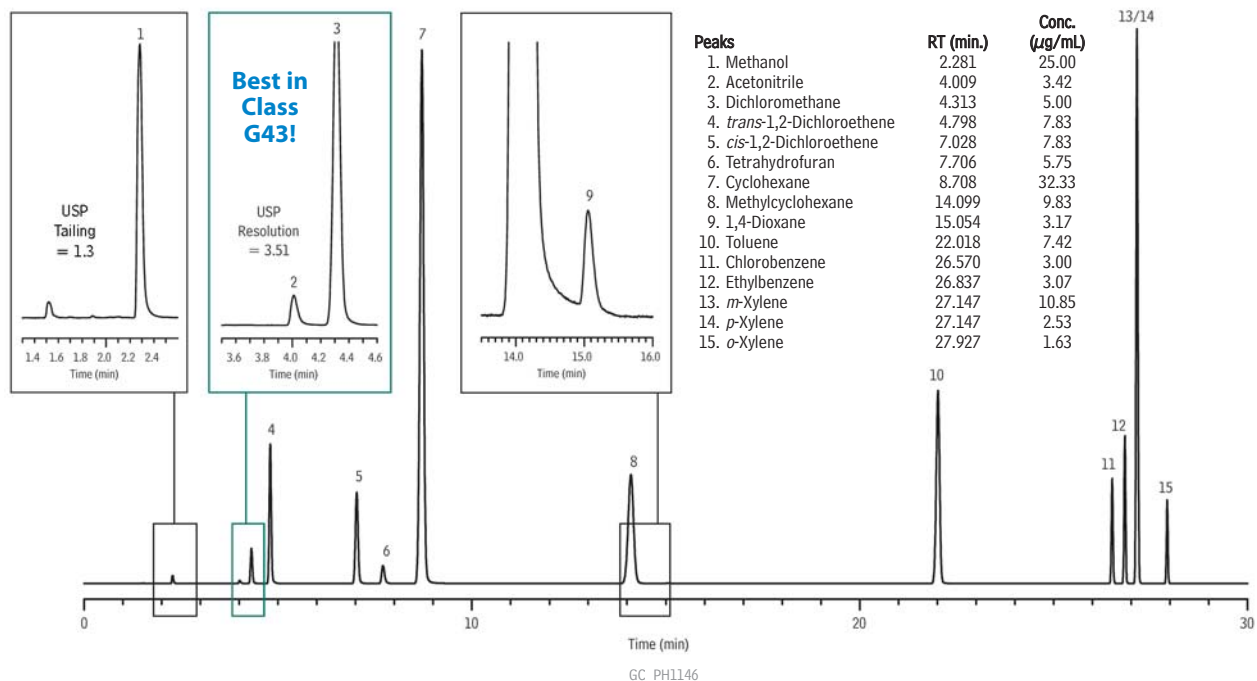
Download your free copy of our Technical Guide for Static Headspace Analysis from www.restek.com/usp467

lit. cat.# 59895A



Figure 3 USP residual solvent Class 2 Mixture A standard solution on an Rxi®-624Sil MS (G43) column.

A: Water-Soluble Articles



B: Water-Insoluble Articles

See Figure 2 for Conditions.
Best in Class G43!

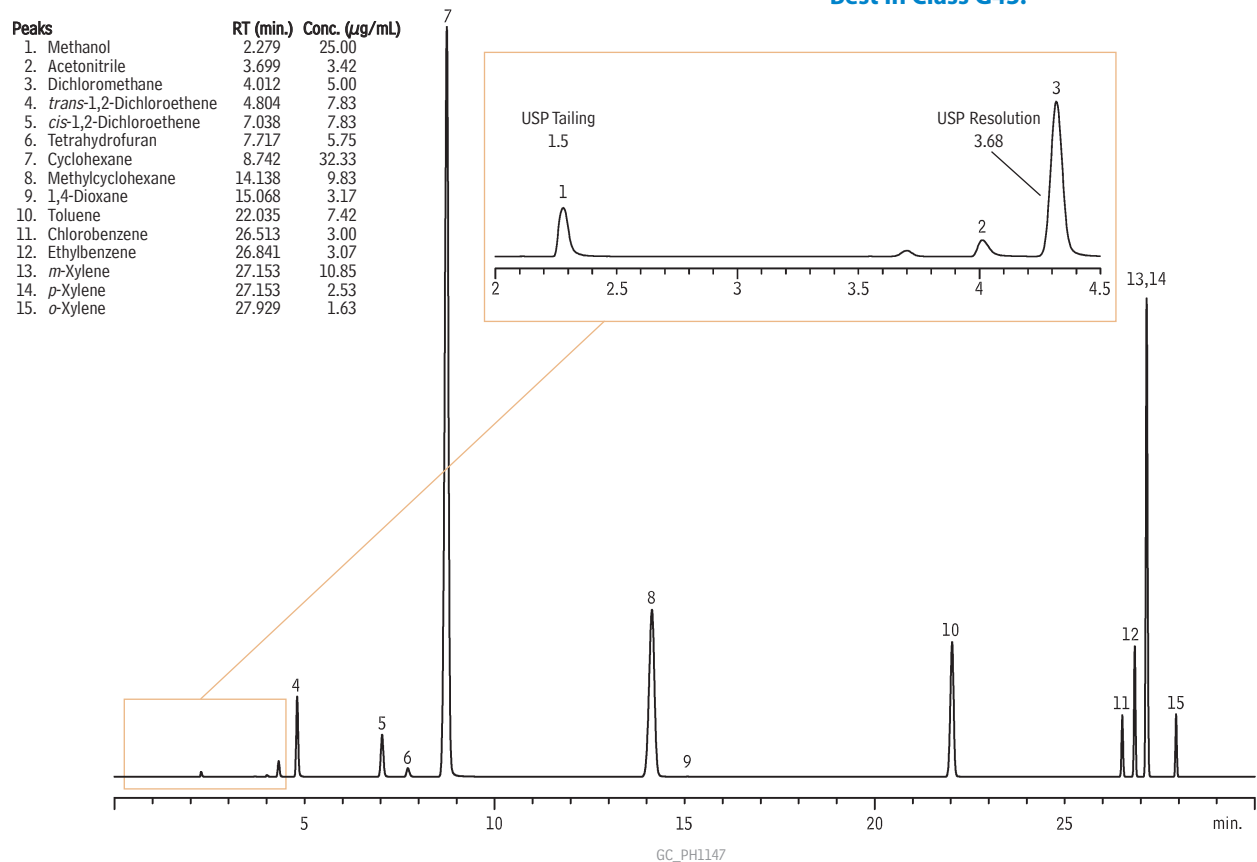
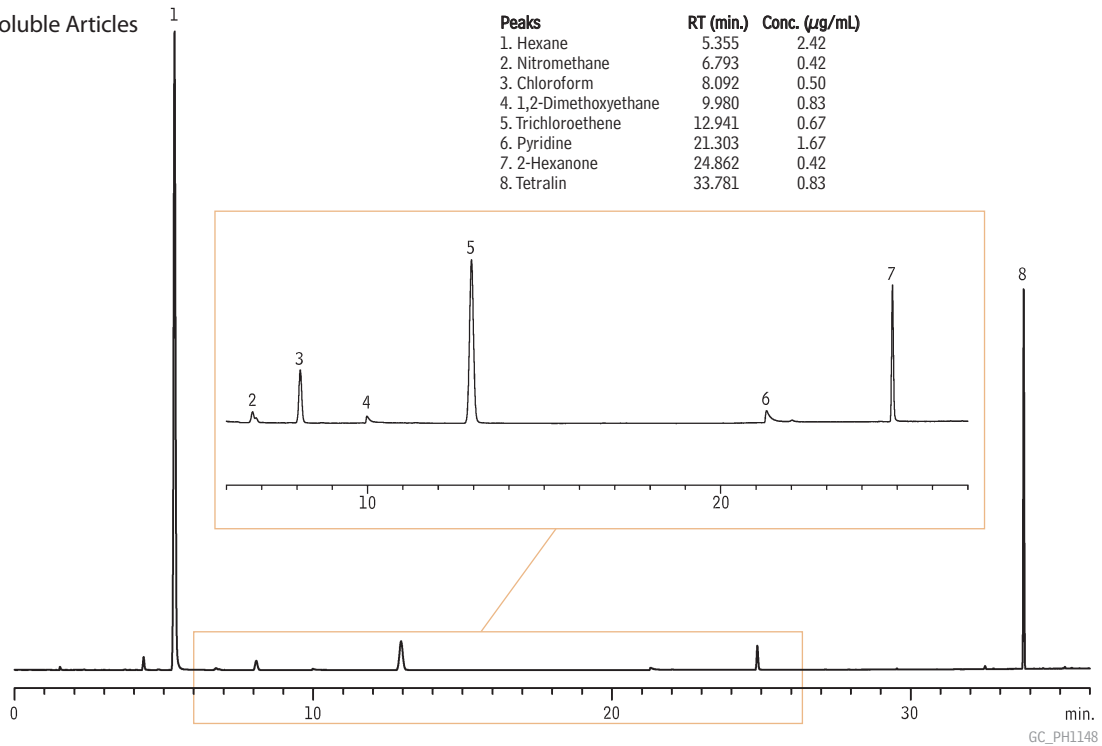


Figure 4 USP residual solvent Class 2 Mixture B standard solution on an Rxi®-624Sil MS (G43) column.

A: Water-Soluble Articles



B: Water-Insoluble Articles

See Figure 2 for Conditions.

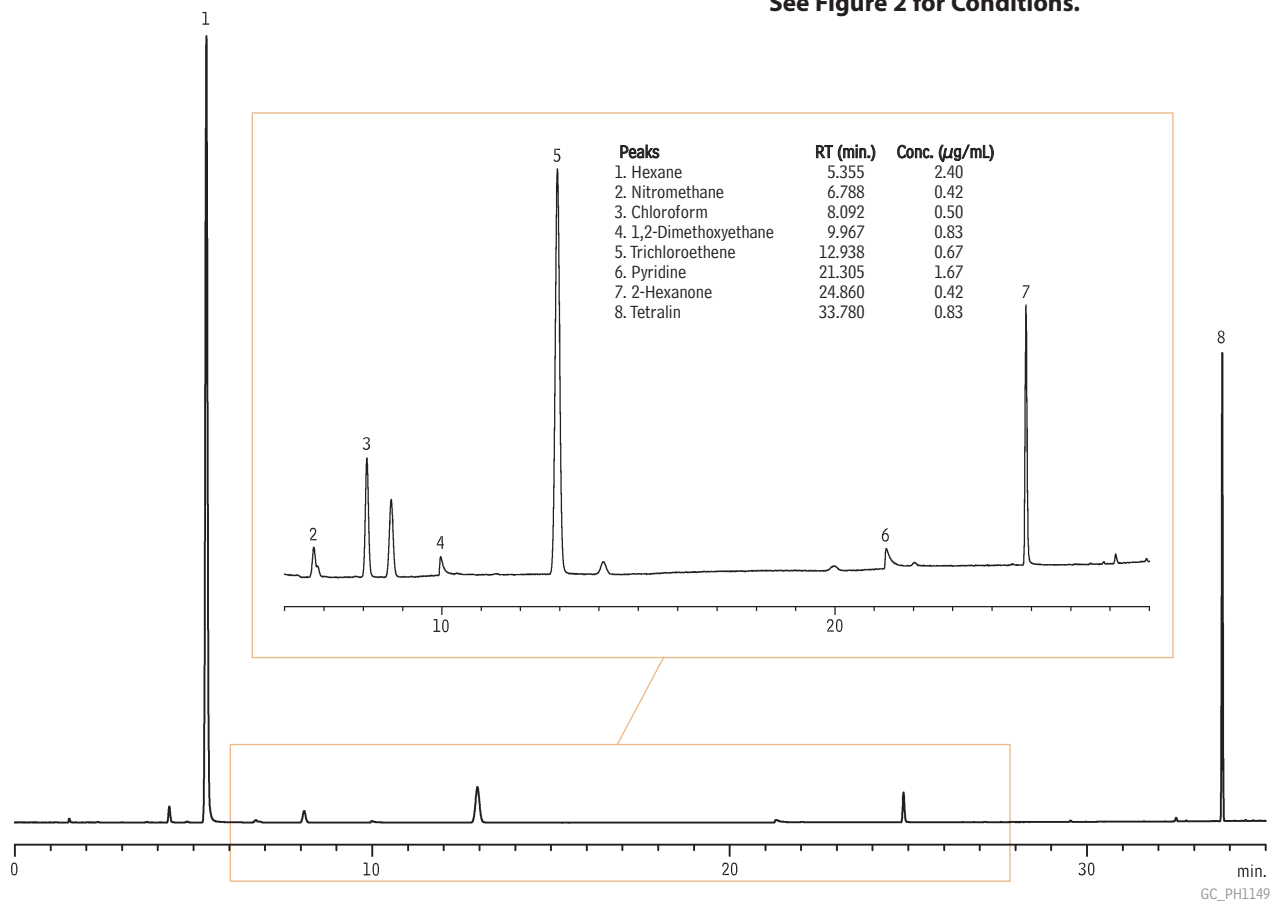
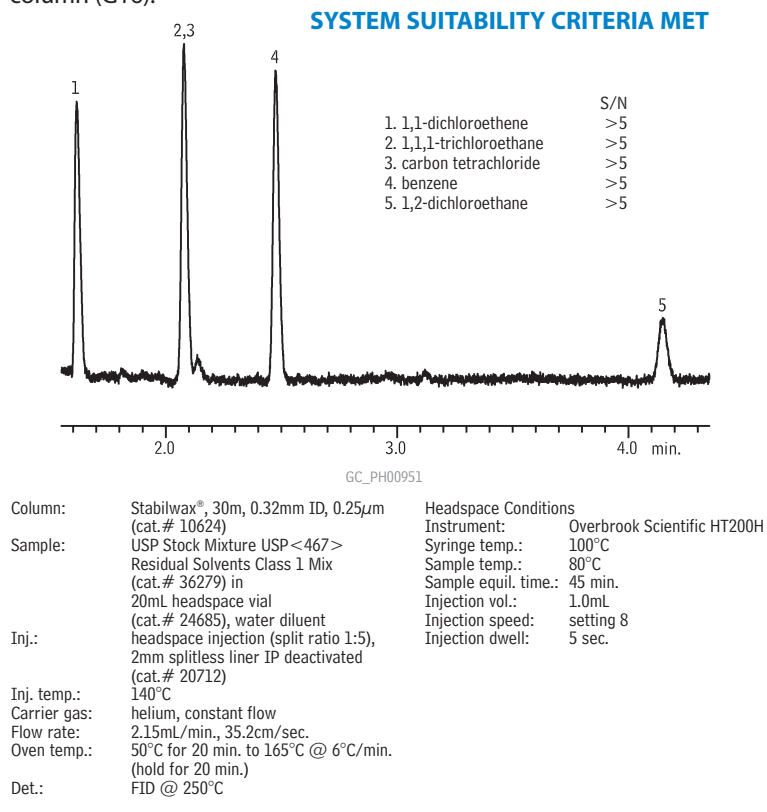


Figure 5 USP residual solvent Class 1 standard solution on a Stabilwax® column (G16).



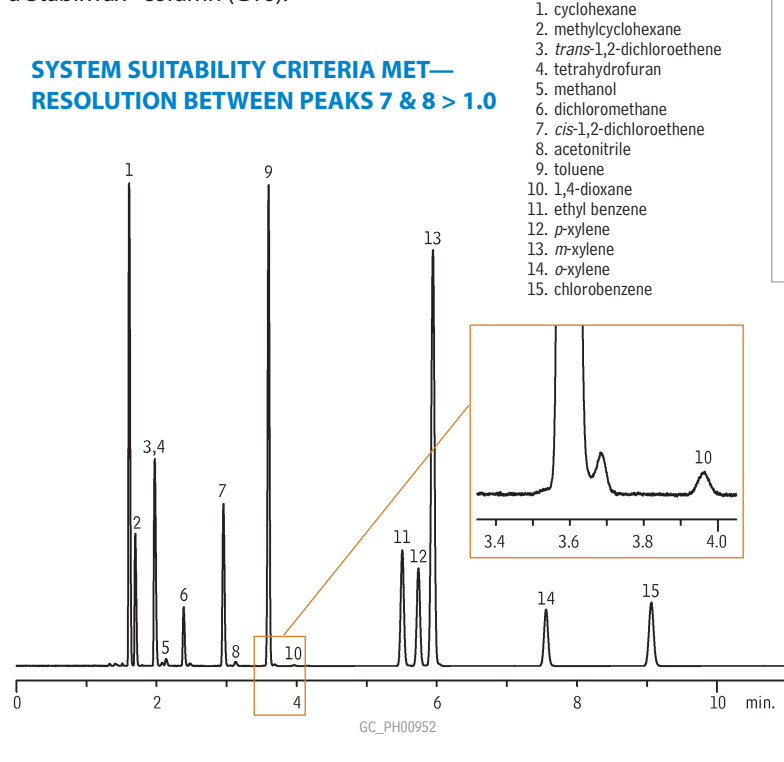
Procedure B - Confirmation

Once a residual solvent is identified and found to be above the percent daily exposure limit, Procedure B is performed to confirm analyte identity. A G16 capillary column is used here as a confirmation column, because it yields an alternate selectivity compared to a G43 column. The same standard and system suitability preparations are used in Procedures A and B. The system suitability requirements differ here in that the Class 1 standard solution must have a benzene response greater than 5 and the resolution of acetonitrile and *cis*-dichloroethene must not be less than 1 in the Class 2 Mixture A solution, a change from the original version. If the analyte identified in Procedure A again matches the retention time and exceeds the peak response of the reference materials (with the same exception to 1,1,1-trichloroethane), the analyst must quantify the analyte using Procedure C. Figures 5 through 7 illustrate the analysis of Class 1, Class 2 Mixture A, and Class 2 Mixture B residual solvent mixes on a Stabilwax® column. Again, the system suitability requirements were easily met.

Procedure C - Quantification

Once a residual solvent has been identified and verified, Procedure C is used to quantify the analyte by analyzing the sample against compound-specific reference materials. Individual standards are prepared by diluting the analyte in solution to a concentration of 1/20 of the concentration limit given under concentration limit Table 1 or 2 of the method. Following the procedure and instrument conditions in either Procedure A or B (whichever provides the most definitive results), a quantifiable result is produced. For water-insoluble articles, the same procedure is followed, except dimethylformamide or dimethylsulfoxide is used as the diluent.

Figure 6 USP residual solvent Class 2 Mixture A standard solution on a Stabilwax® column (G16).

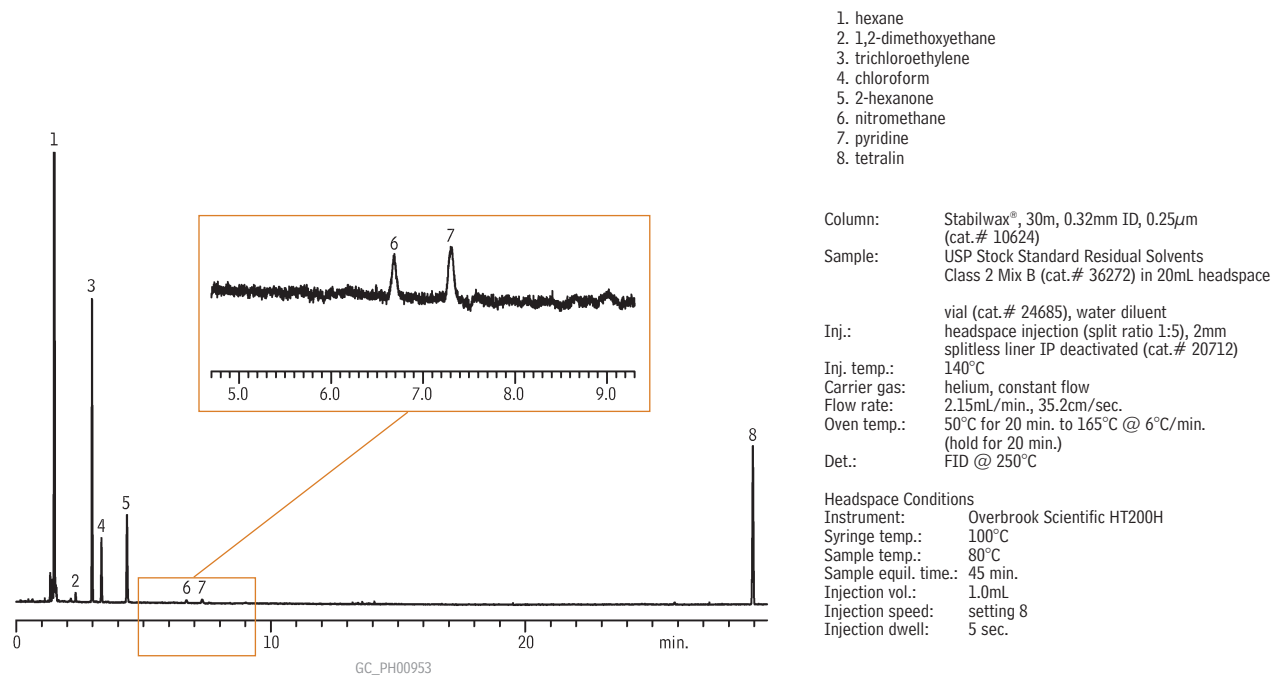


Column:	Stabilwax®, 30m, 0.32mm ID, 0.25µm (cat.# 10624)
Sample:	USP Stock Standard Residual Solvents Class 2 Mix A (cat.# 36271) in 20mL headspace vial (cat.# 24685), water diluent
Inj.:	headspace injection (split ratio 1:5), 2mm splitless liner IP deactivated (cat.# 20712)
Inj. temp.:	140°C
Carrier gas:	helium, constant flow
Flow rate:	2.15mL/min., 35.2cm/sec.
Oven temp.:	50°C for 20 min. to 165°C @ 6°C/min. (hold for 20 min.)
Det.:	FID @ 250°C

Headspace Conditions	
Instrument:	Overbrook Scientific HT200H
Syringe temp.:	100°C
Sample temp.:	80°C
Sample equil. time.:	45 min.
Injection vol.:	1.0mL
Injection speed:	setting 8
Injection dwell:	5 sec.



Figure 7 USP residual solvent Class 2 Mixture B standard solution on a Stabilwax® column (G16).



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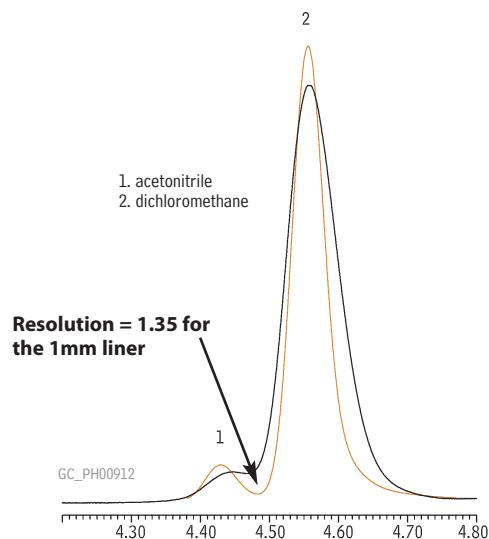
Keep system dead volume low by using a 1mm split liner for systems using a transfer line.

Use Smaller Bore Liners for Better Resolution and Sensitivity

The function of an injection port in headspace analysis is very different than in direct liquid injection. In direct injection, the sample is vaporized in the injection port and larger volume liners (e.g., 4mm) are typically used since the liner must be able to accommodate the solvent expansion volume. In contrast, in headspace analysis, the sample is vaporized inside the headspace vial and the resulting gas sample is simply transferred into the injection port via a transfer line or syringe injection. Since solvent vaporization does not occur in the liner, a large volume liner is not needed and, in fact, the use of one can cause deleterious effects such as band broadening and decreased peak efficiency. For headspace applications, a smaller bore liner, preferably 1mm, is recommended. The smaller liner volume reduces band broadening by increasing linear velocity in the liner allowing faster sample transfer and improving resolution (Figure 8).

Figure 8 Improve system suitability pass rates using smaller bore liners.

Resolution passes system suitability when using a 1mm liner (red line), but fails if a 4mm liner is used due to a loss of peak efficiency (black line).



USP-equivalent Standards

Residual Solvents - Class 1

benzene	10mg/mL	1,1-dichloroethene	40
carbon tetrachloride	20	1,1,1-trichloroethane	50
1,2-dichloroethane	25		

In dimethyl sulfoxide, 1mL/ampul
cat. # 36279 (ea.)

Residual Solvents Class 2 - Mix A

acetonitrile	2.05mg/mL	methylcyclohexane	5.90
chlorobenzene	1.80	methylene chloride	3.00
cyclohexane	19.40	tetrahydrofuran	3.45
<i>cis</i> -1,2-dichloroethene	4.70	toluene	4.45
<i>trans</i> -1,2-dichloroethene	4.70	<i>m</i> -xylene	6.51
1,4-dioxane	1.90	<i>o</i> -xylene	0.98
ethylbenzene	1.84	<i>p</i> -xylene	1.52
methanol	15.00		

In dimethyl sulfoxide, 1mL/ampul
cat. # 36271 (ea.)

Residual Solvents Class 2 - Mix B

chloroform	60µg/mL	nitromethane	50
1,2-dimethoxyethane	100	pyridine	200
<i>n</i> -hexane (C6)	290	tetralin	100
2-hexanone	50	trichloroethene	80

In dimethyl sulfoxide, 1mL/ampul
cat. # 36280 (ea.)

Residual Solvents Class 2 - Mix C

2-ethoxyethanol	800µg/mL	2-methoxyethanol (methyl	
ethylene glycol	3,100	Cellosolve)	250
formamide	1,100	N-methylpyrrolidone	2,650
N,N-dimethylacetamide	5,450	sulfolane	800
N,N-dimethylformamide	4,400		

In dimethyl sulfoxide, 1mL/ampul
cat. # 36273 (ea.)

USP <467> Singles

Volume is 1mL/ampul.

Compound	Solvent	Conc.	cat.# (ea.)
acetonitrile	DMSO	2.05mg/mL	36281
benzene	DMSO	10mg/mL	36282
carbon tetrachloride	DMSO	20mg/mL	36283
chlorobenzene	DMSO	1.8mg/mL	36284
chloroform	DMSO	0.3mg/mL	36285
cyclohexane	DMSO	19.4mg/mL	36286
1,1-dichloroethene	DMSO	40mg/mL	36287
1,2-dichloroethane	DMSO	25mg/mL	36288
<i>cis</i> -1,2-dichloroethylene	DMSO	4.67mg/mL	36289
<i>trans</i> -1,2-dichloroethylene	DMSO	4.67mg/mL	36290
1,2-dimethoxyethane	DMSO	0.5mg/mL	36291
N,N-dimethylacetamide	DMSO	5.45mg/mL	36292
N,N-dimethylformamide	DMSO	4.4mg/mL	36293
1,4-dioxane	DMSO	1.9mg/mL	36294
2-ethoxyethanol	DMSO	0.8mg/mL	36295
ethylbenzene	DMSO	1.84mg/mL	36296
ethylene glycol	DMSO	3.1mg/mL	36297
formamide	DMSO	1.1mg/mL	36298
hexane	DMSO	1.45mg/mL	36299
methanol	DMSO	15mg/mL	36401
2-methoxyethanol	DMSO	0.25mg/mL	36402
methylbutylketone	DMSO	0.25mg/mL	36400
methylcyclohexane	DMSO	5.9mg/mL	36403
methylene chloride			
(dichloromethane)	DMSO	3mg/mL	36404
N-methylpyrrolidone	DMSO	2.65mg/mL	36405
nitromethane	DMSO	0.25mg/mL	36406
pyridine	DMSO	1mg/mL	36407
sulfolane	DMSO	0.8mg/mL	36413
tetrahydrofuran (THF)	DMSO	3.6mg/mL	36408
tetralin	DMSO	0.5mg/mL	36409
toluene	DMSO	4.45mg/mL	36410
1,1,1-trichloroethane	DMSO	50mg/mL	36411
trichloroethene	DMSO	0.4mg/mL	36412
<i>m</i> -xylene	DMSO	6.51mg/mL	36414
<i>o</i> -xylene	DMSO	0.97mg/mL	36415
<i>p</i> -xylene	DMSO	1.52mg/mL	36416

DMSO=dimethyl sulfoxide

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ALL mixtures are produced in accordance with our ISO 9001:2008 registration.

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ALL raw materials used are a minimum of 97% pure; otherwise, their weight is corrected.



Capillary Columns & Accessories

Capillary Columns

Capillary Column—Procedure A

Rxi®-624Sil MS Columns (fused silica)
(mid polarity Crossbond® silarylene phase; equivalent to 6% cyanopropylphenyl/94% dimethyl polysiloxane)

ID	df (μm)	temp. limits	length	cat. #
0.32mm	1.80	-20 to 300/320°C	30-Meter	13870
0.53mm	3.00	-20 to 280/300°C	30-Meter	13871

Highest thermal limit for G43s!

Capillary Column—Procedure B

Stabilwax® Columns (fused silica)
(polar phase; Crossbond® Carbowax® polyethylene glycol)

ID	df (μm)	temp. limits	length	cat. #
0.32mm	0.25	40 to 250/260°C	30-Meter	10624
0.53mm	0.25	40 to 250/260°C	30-Meter	10625



Eliminate Retention Time Shifts with Restek's Stabilwax® Columns

Simplify Lab Work with Innovative Accessories

Quickly switch from Procedure A to B!

Hot Swap Capillary Column Nuts

The Hot Swap Capillary Column Nut allows you to change your capillary column while the injector temp is still hot.

Description	qty.	cat. #
For use with "compact" Agilent-style ferrules.		
Hot Swap Capillary Column Nut	ea.	22348
For use with standard 1/8"-type ferrules.		
Hot Swap Capillary Column Nut	ea.	22347



NOTE: For proper operation, oven fan must be kept operational during change out or risk of burn may occur.

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- Vespel® ring embedded in top surface reduces operator variability by requiring minimal torque to seal.
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Siltek Treated	21242	21243
Stainless Steel	21238	21239
1.2mm ID Dual Vespel Ring Inlet Seal	2-pk.	10-pk.
Gold-Plated	21246	21247
Siltek Treated	21248	21249
Stainless Steel	21244	21245



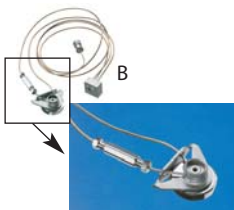
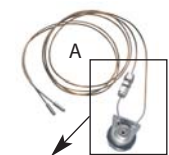
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- Washerless, leak-tight seals.

0.8mm ID Dual Vespel Ring Cross-Disk Inlet Seal	2-pk.	10-pk.
Gold-Plated	22083	22084
Siltek Treated	22085	22086
Stainless Steel	22087	22088





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Injection Port Weldments

for Agilent GCs with Tekmar Purge and Trap Systems

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Weldment for Agilent 6890 GCs with large canister type filter	ea.	22668
Weldment for Agilent 5890 GCs	ea.	22666

Injection Port Weldments

for Agilent GCs with OI Purge and Trap Systems

Description	qty.	cat.#
B) Weldment for Agilent 6890 GCs	ea.	22665
Weldment for Agilent 6890 GCs with large canister type filter	ea.	22669
Weldment for Agilent 5890 GCs	ea.	22667

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for Agilent 5890/6890/6850 GCs

0.011-Inch ID Tip	Similar to		qty.	cat.#	qty.	cat.#
	Agilent part #					
Standard, 0.011-Inch ID Tip	19244-80560	ea.	20670		3-pk.	20671
High-Performance Siltek Treated, 0.011-Inch ID Tip	19244-80560	ea.	20672		3-pk.	20673

Capillary Dedicated FID Replacement Jet

for Agilent 6890/6850/7890 GCs

0.011-Inch ID Tip	Similar to		qty.	cat.#	qty.	cat.#
	Agilent part #					
Standard, 0.011-Inch ID Tip	G1531-80560	ea.	21621		3-pk.	21682
High-Performance Siltek Treated, 0.011-Inch ID Tip	G1531-80560	ea.	21620		3-pk.	21683

FID Collector Assembly Kit for Agilent 6890/6850/7890 GCs

- Constructed of high-quality stainless steel.
- Meets or exceeds original manufacturer's performance.

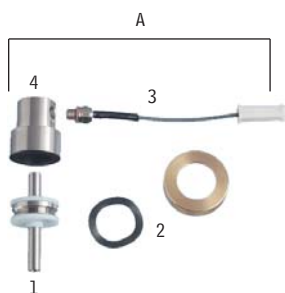
Description	Similar to Agilent part #	qty.	cat.#
A) FID Collector Assembly Kit (includes insulator)	G1531-60690	kit	21699
FID Collector Assembly Kit w/Siltek Ignitor Castle		kit	21132

Replacement FID Parts for Agilent 6890/6850/7890 GCs

- Meets or exceeds manufacturer's performance.

Description	Similar to Agilent part #		qty.	cat.#
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2) FID Collector Nut and Washer	19231-20940	5181-3311	set	21136
3) FID Ignitor*	19231-60680		ea.	21001
4) FID Ignitor Castle	19231-20910		ea.	21137
Siltek FID Ignitor Castle			ea.	21135

*Also fits OI Analytical 4410 detector (similar to OI part # 191833).



Use Smaller Bore Liners for Better Resolution and Sensitivity

1mm Split Liners for Agilent GCs

ID* x OD & Length	qty.	cat.#
1mm Split**		
1.0mm x 6.3mm x 78.5mm	ea.	20972
1.0mm x 6.3mm x 78.5mm	5-pk.	20973

Split Liners for Varian 1075/1077 GCs

ID* x OD & Length	qty.	cat.#
1mm Split		
1.0mm x 6.3mm x 72mm	ea.	20970
1.0mm x 6.3mm x 72mm	5-pk.	20971

Split Liners for Shimadzu GCs

ID* x OD & Length	qty.	cat.#
1mm Split		
1.0mm x 5.0mm x 95mm	ea.	20976
1.0mm x 5.0mm x 95mm	5-pk.	20977
1.0mm x 5.0mm x 95mm	25-pk.	20978

Zero Dilution Liners for PerkinElmer Auto SYS™ and Clarus GCs

ID* x OD & Length	qty.	cat.#
Zero Dilution Inner Liner		
1.0mm x 2.0mm x 73mm	ea.	22990
1.0mm x 2.0mm x 73mm	5-pk.	22991

Zero Dilution Outer Liner		
2.5mm x 6.2mm x 90mm	ea.	22992
2.5mm x 6.2mm x 90mm	5-pk.	22993

*Nominal ID at syringe needle expulsion point.

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Description	Model #	qty.	cat. #
Gas Station	Model FID-1000 (ideal for 1-2 FIDs)	ea.	20177
Gas Station	Model FID-2500 (ideal for 5-6 FIDs)	ea.	24913
Replacement Components for FID Gas Stations			
Resin Bed Cartridge for Hydrogen Generators in FID-1000 and FID-2500 Gas Stations		ea.	24914
Replacement Desiccant Cartridge		ea.	21671
FID Gas Station Maintenance Kit			
Includes 1 desiccant cartridge, 1 resin bed cartridge, 1 filter cartridge		ea.	24915



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- Easy to clean probe assembly.
- A universal charger set (US, European, UK, and Australian plugs included).

Backed by a 1-year warranty, the new Restek Leak Detector sets an industry standard for performance and affordability in hand-held leak detectors.

Description	qty.	cat.#
Leak Detector with Hard-Sided Carrying Case and Universal Charger Set (US, UK, European, Australian)	ea.	22839
Soft-Side Storage Case	ea.	22657
Small Probe Adaptor	ea.	22658

Avoid using liquid leak detectors on a GC! Liquids can be drawn into the system.

Caution: The Restek Electronic Leak Detector is designed to detect trace amounts of hydrogen in a noncombustible environment. It is NOT designed for determining leaks in a combustible environment. A combustible gas detector should be used for determining combustible gas leaks under any condition. The Restek Electronic Leak Detector may be used for determining trace amounts of hydrogen in a GC environment only.



PATENTS & TRADEMARKS

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RESTEK

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