

## USP <467> Residual Solvents

- Identify and quantify residual solvents in drug substances, drug products and excipients
- Trace level impurities of volatile organic compounds in final products or excipients
- For Class 1, Class 2 and Class 3 solvents



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# USP <467> Residual Solvents

## Analytical Standards for USP <467> Residual Solvents

The USP General Chapter <467> Residual Solvents is a method widely used for identifying and quantifying residual solvents, when there is no information available on what solvents are likely to be present. USP <467> is divided into two separate sections based upon sample solubility: water soluble and water insoluble articles.

As required by the analytical procedure given in USP <467> for identifying and quantifying residual solvents in drug substances, drug products and excipients, Spex CertiPrep now offers 35 analytes in dimethyl sulfoxide for Class 1, Class 2 and Class 3 solvents. Our products are manufactured and checked by our QC department in order to validate the Certificate of Analysis, which accompanies each product.

Residual solvents in pharmaceuticals are trace level impurities of volatile organic compounds in final products or excipients. In general, residual solvents originate from manufacturing processes related to the preparation of drug products. They can also form during product packaging and storage.

Spex CertiPrep's USP <467> Residual Solvents Standards are designed for use with: GC (FID, ECD, PID, TCD), GC/MS, LC, and LC/MS.



Organic Certified  
Reference Materials



Designed for use with  
GC (FID, ECD, PID, TCD),  
GC/MS, LC, LC/MS



Supplied with a  
Certificate of Analysis



ISO Accredited  
Standards

# USP <467> Residual Solvents

USP <467> Residual Solvent Mixes				
Compound	Concentration	Volume	Matrix	Part #
5 Organic Volatile Impurities: Class 1 Solvents	Multiple	1 mL	Dimethyl sulfoxide	USP-RS-C1
15 Organic Volatile Impurities: Class 2 Solvents	Multiple	1 mL	Dimethyl sulfoxide	USP-RS-C2A
8 Organic Volatile Impurities: Class 2 Solvents	Multiple	1 mL	Dimethyl sulfoxide	USP-RS-C2B
8 Organic Volatile Impurities: Class 2 Solvents	Multiple	1 mL	Dimethyl sulfoxide	USP-RS-C2C
24 Organic Volatile Impurities: Class 3 Solvents	1,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-RS-C3A
Trimethylamine USP Class 3 Single	1,000 µg/mL	1 mL	Dimethyl sulfoxide	S-3702-DMSO
2 Organic Volatile Impurities: Class 3 Solvents	1,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-RS-C3B

USP <467> Residual Solvent Singles					
Compound	CAS #	Concentration	Volume	Matrix	Part #
Chlorobenzene	108-90-7	1,800 µg/mL	1 mL	Dimethyl sulfoxide	USP-S810-DMSO
Cyclohexane	110-82-7	19,400 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1015-DMSO
1,4-Dioxane	123-91-1	1,900 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1715-DMSO
Ethylene glycol	107-21-1	3,100 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1952-DMSO
Methanol	67-56-1	15,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2380-DMSO
Nitromethane	75-52-5	250 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2722-DMSO
Tetrahydrofuran	109-99-9	3,600 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3460-DMSO
1,1,1-Trichloroethane	71-55-6	50,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3605-DMSO
Trichloroethene	79-01-6	400 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3615-DMSO

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