

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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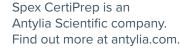














USP <467> Residual Solvents

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.





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



Supplied with a Certificate of Analysis



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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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