



## 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.

For additional product information, please visit [www.spexcertiprep.com/products/USP](http://www.spexcertiprep.com/products/USP).

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
2 Organic Volatile Impurities: Class 3 Solvents	1,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-RS-C3B

### CERTIFIED REFERENCE MATERIALS

SPEX CertiPrep is the industry leader for over 60 years in the CRM marketplace meeting the needs of laboratories worldwide with innovation and research. Accredited by A2LA to ISO/IEC 17025:2005 & ISO Guide 34:2009. Certified by UL-DQS, ISO 9001:2015.

## USP &lt;467&gt; Residual Solvents (cont'd)

USP <467> Residual Solvent Singles					
Compound	CAS #	Concentration	Volume	Matrix	Part #
Acetonitrile	75-05-8	2,050 µg/mL	1 mL	Dimethyl sulfoxide	USP-S145-DMSO
Benzene	71-43-2	10,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-S405-DMSO
Carbon tetrachloride	56-23-5	20,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-S750-DMSO
Chlorobenzene	108-90-7	1,800 µg/mL	1 mL	Dimethyl sulfoxide	USP-S810-DMSO
Chloroform	67-66-3	300 µg/mL	1 mL	Dimethyl sulfoxide	USP-S865-DMSO
Cyclohexane	110-82-7	19,400 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1015-DMSO
1,2-Dichloroethane	107-06-2	25,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1380-DMSO
1,1-Dichloroethene	75-35-4	40,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1390-DMSO
cis-1,2-Dichloroethene	156-59-2	4,670 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1394-DMSO
trans-1,2-Dichloroethene	156-60-5	4,670 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1400-DMSO
N,N-Dimethylacetamide	127-19-5	5,450 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1597-DMSO
N,N-Dimethylformamide	68-12-2	4,400 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3897-DMSO
1,2-Dimethoxyethane	110-71-4	500 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1572-DMSO
1,4-Dioxane	123-91-1	1,900 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1715-DMSO
2-Ethoxyethanol	110-80-5	800 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1910-DMSO
Ethylbenzene	100-41-4	1,840 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1940-DMSO
Ethylene glycol	107-21-1	3,100 µg/mL	1 mL	Dimethyl sulfoxide	USP-S1952-DMSO
Formamide	75-12-7	1,100 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2062-DMSO
n-Hexane	110-54-3	1,450 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2190-DMSO
2-Hexanone	591-78-6	250 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2200-DMSO
Methanol	67-56-1	15,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2380-DMSO
2-Methoxyethanol	109-86-4	250 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2407-DMSO
Methylcyclohexane	108-87-2	5,900 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2470-DMSO
1-Methyl-2-pyrrolidinone	872-50-4	2,650 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2590-DMSO
Methylene chloride	75-09-2	3,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2480-DMSO
Nitromethane	75-52-5	250 µg/mL	1 mL	Dimethyl sulfoxide	USP-S2722-DMSO
Pyridine	110-86-1	1,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3240-DMSO
Tetrahydrofuran	109-99-9	3,600 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3460-DMSO
1,2,3,4-Tetrahydronaphthalene	119-64-2	500 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3464-DMSO
Tetramethylene sulfone	126-33-0	800 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3877-DMSO
Toluene	108-88-3	4,450 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3505-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
m-Xylene	108-38-3	6,510 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3830-DMSO
o-Xylene	95-47-6	970 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3835-DMSO
p-Xylene	106-42-3	1,520 µg/mL	1 mL	Dimethyl sulfoxide	USP-S3840-DMSO

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