USP <467>

The United States Pharmacopeia (USP) general chapter <467> Residual Solvents is a widely used compendial method intended for identifying and quantifying residual solvents in drug substances, drug products, and excipients. In an attempt to better mirror the International Conference on Harmonization (ICH) guidelines, the USP has adopted a more comprehensive methodology in residual solvent testing—the current USP30/NF25. The ICH publishes a guideline (Q3C) listing the acceptable amounts of solvent residues that can be present. In the ICH guideline, residual solvents are summarized by class, according to their toxicity. Class 1 compounds are carcinogenic compounds that pose a risk to both the consumer and the environment. The use of these solvents is to be avoided, but if they are used, they must be tightly controlled. Class 2 compounds are nongenotoxic animal carcinogens, and concentrations of these compounds should be limited. Chromatographic analysis is needed for both the Class 1 and Class 2 residual solvents.

USP <467> Singles

Volume is 1mL/ampul.

Compound	Solvent	Conc.	cat.# (ea.)	price
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	
cis-1,2-dichloroethylene	DMSO	4.67mg/mL	36289	
trans-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	
m-xylene	DMSO	6.51mg/mL	36414	
o-xylene	DMSO	0.97mg/mL	36415	
p-xylene	DMSO	1.52mg/mL	36416	

DMSO = dimethyl sulfoxide

These mixtures reflect the changes made in USP30/NF25 effective July 1, 2008.

Residual Solvents - Class 1 (5 components)

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 (15 components)

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

In dimethyl sulfoxide, 1mL/ampul

cat. # 36271 (ea.)

Residual Solvents Class 2 - Mix B (8 components)

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

In dimethyl sulfoxide, 1mL/ampul

cat. # 36280 (ea.)

Residual Solvents Class 2 - Mix C (8 components)

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

In dimethyl sulfoxide, 1mL/ampul

cat. # 36273 (ea.)

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OVI retention index

For a list of OVI retention times, see **pages 693 and 696**.