Reference Standards

Pharmaceutical

Diethylene & Ethylene Glycol
Fatty Acids
Pharmaceutical Compounds in Drinking Water
Plastic Container Testing
Residual Solvents

Diethylene & Ethylene Glycol

Meet FDA Guidance for Industry: Testing of Glycerin for Diethylene Glycol with our diethylene glycol (DEG) and ethylene glycol limit standards. This guidance emphasizes the importance of screening raw material for the presence of diethylene glycol. Under cGMPs, drug manufacturers—not just glycerin manufacturers—must test glycerin prior to use to prevent DEG contamination in finished products. The FDA has worked extensively with the USP to modify the glycerin monograph, and these standards support the revised USP method.

Glycerin Standard Mix (3 components)

Diethylene glycol (111-46-6)	0.5 mg/mL
Ethylene glycol (107-21-1)	0.5
Glycerin (56-81-5)	20

In P&T methanol, 1 mL/ampul

cat.# 31891 (ea.)

Propylene Glycol Standard Mix (3 components)

Diethylene glycol (111-46-6)	0.5 mg/mL
Ethylene glycol (107-21-1)	0.5
Propylene glycol (57-55-6)	20

In P&T methanol, 1 mL/ampul

cat.# 31892 (ea.)

Sorbitol Standard Mix (2 components)

Diethylene glycol (111-46-6)
Ethylene glycol (107-21-1)

0.8 mg/mL each in acetone:water (96:4), 1 mL/ampul

cat.# 31893 (ea.)

Glycol Internal Standard Mix

2,2,2-Trichloroethanol (115-20-8)

10 mg/mL in P&T methanol, 1 mL/ampul

cat.# 31894 (ea.)

Fatty Acids

Composition of Fatty Acids by GC

EP 2.4.22 Composition of Fatty Acids by GC Mix 1

(6 components)

Description	% by Weight	Description	% by Weight
Methyl arachidate (C20:0)	40	Methyl oleate (C18:1 [*cis*9])	20
Methyl dodecanoate (C12:0)	5	Methyl palmitate (C16:0)	10
Methyl myristate (C14:0)	5	Methyl stearate (C18:0)	20

100 mg total

cat.# 35100 (ea.)

No data pack available.

EP 2.4.22 Composition of Fatty Acids by GC Mix 2

(5 components)

Description	% by Weight	Description	% by Weight
Methyl caproate (C6:0)	10	Methyl dodecanoate (C12:0)	20
Methyl caprylate (C8:0)	10	Methyl myristate (C14:0)	40
Methyl decanoate (C10:0)	20		

100 mg total

cat.# 35101 (ea.)

No data pack available.

Pharmaceutical Compounds in Drinking Water

Pharmaceuticals Mix #1 (8 components)

Acetaminophen (103-90-2)	Erythromycin USP (114-07-8)
Caffeine (58-08-2)	Fluoxetine HCl (56296-78-7)
Carbamazepine (298-46-4)	Sulfamethoxazole (723-46-6)
Ciprofloxacin HCL (86393-32-0)	Trimethoprim (738-70-5)

200 µg/mL each in P&T methanol, 1 mL/ampul

cat.# 31116 (ea.)

Steroids and Mixed Pharmaceuticals Mix

(10 components)

Bisphenol A (80-05-7)	4-para-Nonylphenol (84852-15-3)
Diclofenac sodium salt (15307-79-6)	4-*tert*-Octylphenol (140-66-9)
17-beta-Estradiol (50-28-2)	Primidone (125-33-7)
Estrone (53-16-7)	Progestrone (57-83-0)
17-alpha-Ethynylestradiol (57-63-6)	Testosterone (58-22-0)

200 µg/mL each in acetonitrile, 1 mL/ampul

cat.# 31117 (ea.)

Pharmaceuticals Mix #2 (4 components)

Gemfibrozil (25812-30-0)	Naproxen (22204-53-1)
Ibuprofen (15687-27-1)	Triclosan (3380-34-5)

200 µg/mL each in P&T methanol, 1 mL/ampul

cat.# 31118 (ea.)

Plastic Container Testing

ASTM Method D6042-96 (Plastic Container Testing)

American Society for Testing and Materials (ASTM International) Method D6042-96—Test Method for Determination of Phenolic Antioxidants and Erucamide Slip Additives in Polypropylene Homopolymer Formulations Using Liquid Chromatography—is a "consensus" or "referee" method used among plastic manufacturers and the pharmaceutical companies that purchase plastic containers. Plastic container manufacturers use this test to ensure the quality of their product for their pharmaceutical customers. Pharmaceutical companies also specify this test and provide their own lists of target compounds and concentration limits in purchase agreements.

This test calls for isopropanol extraction, LC separation, and UV detection. Restek offers a variety of reversed-phase LC columns suitable for these separations. Restek also designed a reference standard to validate this method. This mixture contains the common antioxidants and slips listed in ASTM D6042-96, along with BHT.

ASTM D6042-96 Calibration Mix (7 components)

BHT (128-37-0)	Irganox 3114 (27676-62-6)
Erucamide slip (112-84-5)	Irganox 1010 (6683-19-8)
Vitamin E (59-02-9)	Irganox 1076 (2082-79-3)
Irgafos 168 (31570-04-4)	

50 µg/mL each in isopropanol, 1 mL/ampul

cat.# 31628 (ea.)

Residual Solvents

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 1 mL/ampul.

Compound	CAS #	Solvent	Conc.	cat.#
acetonitrile	75-05-8	DMSO	2.05 mg/mL	36281
benzene	71-43-2	DMSO	10 mg/mL	36282
carbon tetrachloride	56-23-5	DMSO	20 mg/mL	36283
chlorobenzene	108-90-7	DMSO	1.8 mg/mL	36284
chloroform	67-66-3	DMSO	0.3 mg/mL	36285
cyclohexane	110-82-7	DMSO	19.4 mg/mL	36286
1,1-dichloroethene	75-35-4	DMSO	40 mg/mL	36287
1,2-dichloroethane	107-06-2	DMSO	25 mg/mL	36288
cis-1,2-dichloroethylene	156-59-2	DMSO	4.67 mg/mL	36289
trans-1,2-dichloroethylene	156-60-5	DMSO	4.67 mg/mL	36290
1,2-dimethoxyethane	110-71-4	DMSO	0.5 mg/mL	36291
N,N-dimethylacetamide	127-19-5	DMSO	5.45 mg/mL	36292
N,N-dimethylformamide	68-12-2	DMSO	4.4 mg/mL	36293
1,4-dioxane	123-91-1	DMSO	1.9 mg/mL	36294
2-ethoxyethanol	110-80-5	DMSO	0.8 mg/mL	36295
ethylbenzene	100-41-4	DMSO	1.84 mg/mL	36296
ethylene glycol	3775-85-7	DMSO	3.1 mg/mL	36297
formamide	75-12-7	DMSO	1.1 mg/mL	36298
hexane	8031-34-3	DMSO	1.45 mg/mL	36299
methanol	67-56-1	DMSO	15 mg/mL	36401
2-methoxyethanol	109-86-4	DMSO	0.25 mg/mL	36402
methylbutylketone	591-78-6	DMSO	0.25 mg/mL	36400
methylcyclohexane	108-87-2	DMSO	5.9 mg/mL	36403
methylene chloride (dichloromethane)	75-09-2	DMSO	3 mg/mL	36404
N-methylpyrrolidone	872-50-4	DMSO	2.65 mg/mL	36405
nitromethane	75-52-5	DMSO	0.25 mg/mL	36406
pyridine	110-86-1	DMSO	1 mg/mL	36407
sulfolane	126-33-0	DMSO	0.8 mg/mL	36413
tetrahydrofuran (THF)	109-99-9	DMSO	3.6 mg/mL	36408
tetralin	119-64-2	DMSO	0.5 mg/mL	36409
toluene	108-88-3	DMSO	4.45 mg/mL	36410
1,1,1-trichloroethane	71-55-6	DMSO	50 mg/mL	36411
trichloroethene	79-01-6	DMSO	0.4 mg/mL	36412
m-xylene	108-38-3	DMSO	6.51 mg/mL	36414
o-xylene	95-47-6	DMSO	0.97 mg/mL	36415
p-xylene	106-42-3	DMSO	1.52 mg/mL	36416

DMSO = dimethyl sulfoxide

Residual Solvents Class 2 - Mix A (2013 Rev)

NEW!

(16 components)

This mixture reflects the changes made in USP <467> effective August 2013 and replaces Restek® cat.# 36271.

Acetonitrile (75-05-8)	2.05 mg/mL	Methanol (67-56-1)	15
Chlorobenzene (108-90-7)	1.8	Methylcyclohexane (108-87-2)	5.9
Cyclohexane (110-82-7)	19.4	Methylene chloride (dichloromethane) (75-09-2)	3
cis-1,2-Dichloroethene (156-59-2)	4.675	Tetrahydrofuran (109-99-9)	3.6
trans-1,2-Dichloroethene (156-60-5)	4.675	Toluene (108-88-3)	4.45
1,4-Dioxane (123-91-1)	1.9	*m*-Xylene (108-38-3)	6.51
Ethylbenzene (100-41-4)	1.84	*o*-Xylene (95-47-6)	0.98
Isopropylbenzene (cumene) (98-82-8)	0.35	*p*-Xylene (106-42-3)	1.52

In dimethyl sulfoxide, 1 mL/ampul

cat.# 36012 (ea.)

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

Residual Solvents - Class 1 (5 components)

Benzene (71-43-2)	10 mg/mL	1,1-Dichloroethene (75-35-4)	40
Carbon tetrachloride (56-23-5)	20	1,1,1-Trichloroethane (71-55-6)	50
1,2-Dichloroethane (107-06-2)	25		

In dimethyl sulfoxide, 1 mL/ampul

cat.# 36279 (ea.)

Residual Solvents Class 2 - Mix A (15 components)

Note: The USP <467> Class 2 residual solvents list was updated to add cumene in August 2013. See cat.# 36012 (above) for our updated reference standard.

Acetonitrile (75-05-8)	2.05 mg/mL	Methylcyclohexane (108-87-2)	5.90
Chlorobenzene (108-90-7)	1.80	Methylene chloride (dichloromethane) (75-09-2)	3.00
Cyclohexane (110-82-7)	19.40	Tetrahydrofuran (109-99-9)	3.45
cis-1,2-Dichloroethene (156-59-2)	4.70	Toluene (108-88-3)	4.45
trans-1,2-Dichloroethene (156-60-5)	4.70	*m*-Xylene (108-38-3)	6.51
1,4-Dioxane (123-91-1)	1.90	*o*-Xylene (95-47-6)	0.98
Ethylbenzene (100-41-4)	1.84	*p*-Xylene (106-42-3)	1.52
Methanol (67-56-1)	15.00		

In dimethyl sulfoxide, 1 mL/ampul

cat.# 36271 (ea.)

Residual Solvents Class 2 - Mix B (8 components)

n-Hexane (C6) (110-54-3)	290 µg/mL	Nitromethane (75-52-5)	50
Chloroform (67-66-3)	60	Pyridine (110-86-1)	200
1,2-Dimethoxyethane (110-71-4)	100	Tetralin (119-64-2)	100
2-Hexanone (591-78-6)	50	Trichloroethene (79-01-6)	80

In dimethyl sulfoxide, 1 mL/ampul

cat.# 36280 (ea.)

Residual Solvents Class 2 - Mix C (8 components)

2-Ethoxyethanol (110-80-5)	800 µg/mL	2-Methoxyethanol (Methyl Cellosolve) (109-86-4)	250
Ethylene glycol (107-21-1)	3,100	N-Methylpyrrolidone (872-50-4)	2,650
Formamide (75-12-7)	1,100	Sulfolane (126-33-0)	800
N,N-Dimethylacetamide (127-19-5)	5,450		
N,N-Dimethylformamide (68-12-2)	4,400		

In dimethyl sulfoxide, 1 mL/ampul

cat.# 36273 (ea.)

Residual Solvents, *cont.*

USP <467>, *cont.*

The Class 1 mixtures below reflect the requirements of USP23/NF18 effective January 1, 1995 to December 31, 1999. While these mixtures do not meet the current USP guidelines, many still use these mixtures to obtain a detectable benzene peak for the direct injection methods, Method I and Method V.

USP <467> Calibration Mixture #3 (5 components)

Benzene (71-43-2)	100 µg/mL	Methylene chloride (dichloromethane) (75-09-2)	500
Chloroform (67-66-3)	50	Trichloroethene (79-01-6)	100
1,4-Dioxane (123-91-1)	100		

In dimethyl sulfoxide, 1 mL/ampul

cat.# 36004 (ea.)

USP <467> Calibration Mixture #4 (5 components)

Benzene (71-43-2)	2 µg/mL	Methylene chloride (dichloromethane) (75-09-2)	600
Chloroform (67-66-3)	60	Trichloroethene (79-01-6)	80
1,4-Dioxane (123-91-1)	380		

In methanol, 1 mL/ampul

cat.# 36006 (ea.)

USP <467> Calibration Mixture #5 (5 components)

Benzene (71-43-2)	2 µg/mL	Methylene chloride (dichloromethane) (75-09-2)	600
Chloroform (67-66-3)	60	Trichloroethene (79-01-6)	80
1,4-Dioxane (123-91-1)	380		

In dimethyl sulfoxide, 1 mL/ampul

cat.# 36007 (ea.)

USP <467> Calibration Mix #6 (4 components)

Chloroform (67-66-3)	60 µg/mL	Methylene chloride (dichloromethane) (75-09-2)	600
1,4-Dioxane (123-91-1)	380	Trichloroethene (79-01-6)	80

In methanol, 1 mL/ampul

cat.# 36008 (ea.)

USP <467> Calibration Mix #7 (4 components)

Chloroform (67-66-3)	60 µg/mL	Methylene chloride (dichloromethane) (75-09-2)	600
1,4-Dioxane (123-91-1)	380	Trichloroethene (79-01-6)	80

In dimethyl sulfoxide, 1 mL/ampul

cat.# 36009 (ea.)

Ethylene Oxide

The test for ethylene oxide is specified in many individual drug monographs of USP24/NF19. The limit test concentration is currently 10 ppm. While the specific test solution and method will vary depending on the particular drug monograph, the solution below is suitable for most tests.

Ethylene oxide (75-21-8)

500 µg/mL in dimethyl sulfoxide, 1 mL/ampul

cat.# 36005 (ea.)

50 mg/mL in methylene chloride, 1 mL/ampul

cat.# 30620 (ea.)

Ethylene oxide is available in other solvents and concentrations. Request your custom formulation at **www.restek.com/solutions**

European Pharmacopoeia Method

Residual Solvents - Class 1 (5 components)

Benzene (71-43-2)	10 mg/mL	1,1-Dichloroethene (75-35-4)	40
Carbon tetrachloride (56-23-5)	20	1,1,1-Trichloroethane (71-55-6)	50
1,2-Dichloroethane (107-06-2)	25		

In dimethyl sulfoxide, 1 mL/ampul

cat.# 36279 (ea.)

European Pharmacopoeia/ICH Q3C(M) Class 2 Mix A, Revised (14 components)

n-Hexane (C6) (110-54-3)	290 µg/mL	Tetrahydrofuran (109-99-9)	720
Chlorobenzene (108-90-7)	360	Toluene (108-88-3)	890
Cyclohexane (110-82-7)	3,880	Trichloroethene (79-01-6)	80
cis-1,2-Dichloroethene (156-59-2)	1,870	*m*-Xylene (108-38-3)	1,302
N,N-Dimethylformamide (68-12-2)	880	*o*-Xylene (95-47-6)	195
Ethylbenzene (100-41-4)	369	*p*-Xylene (106-42-3)	304
Methylcyclohexane (108-87-2)	1,180		
Methylene chloride (dichloromethane) (75-09-2)	600		

In dimethyl sulfoxide, 1 mL/ampul

cat.# 36274 (ea.)

European Pharmacopoeia/ICH Class 2 Mix B, Revised (10 components)

Acetonitrile (75-05-8)	410 µg/mL	2-Hexanone (591-78-6)	50
Chloroform (67-66-3)	60	Methanol (67-56-1)	3,000
1,2-Dimethoxyethane (110-71-4)	100	Nitromethane (75-52-5)	50
N,N-Dimethylacetamide (127-19-5)	1,090	Pyridine (110-86-1)	200
1,4-Dioxane (123-91-1)	380	Tetralin (119-64-2)	100

Prepared in water:dimethyl sulfoxide (80:20), 1 mL/ampul

cat.# 36270 (ea.)