

USP <467> cont'd

These Class 1 mixtures reflect the changes made in USP24/NF19 effective January 1, 2000, and USP23/NF18 effective January 1, 1995 to December 31, 1999. While these mixtures do not meet the current USP guidelines, many labs still use these mixtures to obtain a detectable benzene peak for the direct injection methods, Method I and Method V.

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

chloroform	60µg/mL	methylene chloride	600
1,4-dioxane	380	trichloroethene	80
In dimethyl sulfoxide, 1mL/ampul			
cat. # 36009 (ea.)			

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

chloroform	60µg/mL	methylene chloride	600
1,4-dioxane	380	trichloroethene	80
In methanol, 1mL/ampul			
cat. # 36008 (ea.)			

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

benzene	2µg/mL	methylene chloride	600
chloroform	60	trichloroethene	80
1,4-dioxane	380		
In dimethyl sulfoxide, 1mL/ampul			
cat. # 36007 (ea.)			

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

benzene	2µg/mL	methylene chloride	600
chloroform	60	trichloroethene	80
1,4-dioxane	380		
In methanol, 1mL/ampul			
cat. # 36006 (ea.)			

USP <467> Calibration Mixture #2 (5 components)

benzene	100µg/mL	methylene chloride	500
chloroform	50	trichloroethene	100
1,4-dioxane	100		
In methanol, 1mL/ampul			
cat. # 36002 (ea.)			

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

benzene	100µg/mL	methylene chloride	500
chloroform	50	trichloroethene	100
1,4-dioxane	100		
In dimethyl sulfoxide, 1mL/ampul			
cat. # 36004 (ea.)			

Ethylene Oxide

500µg/mL in dimethyl sulfoxide, 1mL/ampul
cat. # 36005 (ea.)

Ethylene oxide is available in other solvents and concentrations. Request your custom formulation at standards@restek.com.

Limit of Diethylene & Ethylene Glycol Standards

Meet new FDA *Guidance for Industry: Testing of Glycerin for Diethylene Glycol* with our new 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 now test glycerin prior to use to prevent DEG-contamination in finished products. FDA has worked extensively with USP to modify the glycerin monograph and these standards support the revised USP method.

Glycerin Standard Mix (3 components)

diethylene glycol	0.5mg/mL	glycerin	20
ethylene glycol	0.5		
In P&T methanol, 1mL/ampul			
cat. # 31891 (ea.)			



Propylene Glycol Standard Mix (3 components)

diethylene glycol	0.5mg/mL	propylene glycol	20
ethylene glycol	0.5		
In P&T methanol, 1mL/ampul			
cat. # 31892 (ea.)			



Sorbitol Standard Mix (2 components)

diethylene glycol		ethylene glycol	
0.8mg/mL each in acetone:water (90:10), 1mL/ampul			
cat. # 31893 (ea.)			



Limit of Diethylene & Ethylene Glycol Internal Standard Mix

2,2,2-trichloroethanol			
10mg/mL in P&T methanol, 1mL/ampul			
cat. # 31894 (ea.)			



European Pharmacopoeia Method

The analysis of residual solvents in pharmaceutical products has changed, particularly for products being sold into Europe. The International Conference on Harmonization (ICH) *Guidelines for Residual Solvents* is becoming the international standard and is being adopted by more pharmacopoeias, including the United States Pharmacopoeia, every year. The ICH method and compound list is more extensive than any method previously used and poses new challenges. Compounds in Class 1 are solvents considered to be of highest risk and to be avoided in pharmaceutical manufacturing. Use of Class 2 compounds is to be limited, as they pose a lower, but present, threat to health. Compounds in Class 3 pose the lowest toxic potential and may be used routinely in manufacturing.

European Pharmacopoeia/ICH Class 1 Mix (5 components)

benzene	2µg/mL	1,1-dichloroethene	8
carbon tetrachloride	4	1,1,1-trichloroethane	1500
1,2-dichloroethane	5		
Prepared in water:dimethyl sulfoxide (90:10), 1mL/ampul			
cat. # 36228 (ea.)			

European Pharmacopoeia/ICH Class 1 Mix (revised)

(5 components)			
benzene	2µg/mL	1,1-dichloroethene	8
carbon tetrachloride	4	1,1,1-trichloroethane	10
1,2-dichloroethane	5		
In water:dimethyl sulfoxide (90:10), 1mL/ampul			
cat. # 36261 (ea.)			

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