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We prepare Rtx®-1301 (cat.# 16085) and Stabilwax® (cat.# 10640) capillary columns and the analytical reference materials to meet the requirements for European Pharmacopoeia. Download lit. cat.# 59107, *European Pharmacopoeia Analysis of Residual Solvents* from our website for more information.

free literature

GC Analysis of Organic Volatile Impurities According to USP <467> Supplement Two of USP 25-NF 20, effective January, 2002

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Applications Note
lit. cat.# 59577C

USP <467> cont'd

These Class 1 mixtures represent 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 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

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

USP <467> Calibration Mix #6

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

USP <467> Calibration Mixture #5

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

USP <467> Calibration Mixture #4

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

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

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

Ethylene Oxide

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

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

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

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

European Pharmacopoeia/ICH Class 1 Mix (revised)

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

European Pharmacopoeia/ICH Q3C(M) Class 2 Mix A

2-ethoxyethanol	160µg/mL	N-methylpyrrolidone	530
ethylene glycol	620	sulfolane	160
formamide	220		
2-methoxyethanol (methyl Cellosolve®)	50		
In dimethyl sulfoxide, 1mL/ampul			
cat. # 36275 (ea.)			

European Pharmacopoeia/ICH Class 2

Mix B (10 components)			
acetonitrile	410µg/mL	methanol	3,000
chloroform	60	nitromethane	50
1,2-dimethoxyethane	100	pyridine	200
N,N-dimethylacetamide	1,090	1,2,3,4-tetrahydronaphthalene (tetraline)	100
1,4-dioxane	380		
2-hexanone	50		
Prepared in water:dimethylsulfoxide (90:10), 1mL/ampul			
cat. # 36230 (ea.)			

European Pharmacopoeia/ICH Q3C(M)

Class 2 Mix C (14 components)			
chlorobenzene	360µg/mL	methylene chloride	600
cyclohexane	3,880	tetrahydrofuran	720
cis-1,2-dichloroethene	1,870	toluene	890
N,N-dimethylformamide	880	trichloroethene	80
ethylbenzene	369	m-xylene	1,302
n-hexane (C6)	290	o-xylene	195
methylcyclohexane	1,180	p-xylene	304
In dimethyl sulfoxide, 1mL/ampul			
cat. # 36274 (ea.)			