



ANALYSIS OF RESIDUAL SOLVENTS

Solvents for HEADSPACE

The International Conference on Harmonization (ICH) adopted a document named "impurities": this is an explicative note related to residual solvents, which prescribes the maximum amount of solvent in active substances, excipients, and medications after their synthesis. The methods used for their identification are described in the chapters 467 of USP and 2.4.24 of the European Pharmacopeia.

Three classes of solvents are defined:

Class 1 : Solvents to be avoided

Class 2 : Solvents to be limited

Class 3 : Solvents with low toxic potential

The technique used to determine these Organic Volatile Impurities (OVI) is **GC-Headspace** which requires the use of organic solvents to dissolve and/or extract the sample. These solvents need to be free of impurities that could interfere with the GC trace.

CARLO ERBA Reagents offers, in addition to the ATRASOL® grade, a specific product line dedicated to the GC-Headspace technique. Utilizing our solvents developed and tested specifically for GC-headspace ensure the highest quality and batch to batch consistency for your tests.

Advantages :

- Purity greater than 99%
- Controlled water content

Product	Pkg	Code
n,n-Dimethylacetamide	1l	444311
n,n-Dimethylacetamide	6 x 1l	444311X6
n,n-Dimethylformamide	1l	444991
n,n-Dimethylformamide	6 x 1l	444991X6
n,n-Dimethylsulfoxide	1l	445121
n,n-Dimethylsulfoxide	6 x 1l	445121X6
n-Methyl-2-Pyrrolidone	1l	462881
Benzyl alcohol	500ml	414035



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Reference Standards

CARLO ERBA Reagents developed a range of solvent mixtures class 1 and 2, with concentration within the allowable limits established in chapter 467 of the USP and 2.4.24 of the European Pharmacopeia. These mix allow you to determine the amount of residual solvents in your raw material that can be used for API synthesis.

Advantages :

All the standards come with certificate of analysis insuring total traceability.

- Batch number
- Expiration date
- CAS number of each component
- Molecular formula of each component
- Lot number of each bulk material used
- Concentration of each component
- Expanded uncertainties

Product	Pkg	Size	Code
Mix (Recommended by European Pharmacopeia / ICH class 1) : 5 elements <i>Benzene 4 mg/ml, 1,2-Dichloroethane 10 mg/ml, Tetrachloromethane 8 mg/ml, 1,1-Dichloroethene 16 mg/ml, 1,1,1-Trichloroethane 20 mg/ml in DMSO</i>	Sealed ampule	1 ml	507688
Mix (Recommended by USP < 467 > class 1) : 5 elements <i>Benzene 10 mg/ml, 1,2-Dichloroethane 25 mg/ml, Tetrachloromethane 20 mg/ml, 1,1-Dichloroethene 40 mg/ml, 1,1,1-Trichloroethane 50 mg/ml in DMSO</i>	Sealed ampule	1 ml	507692
Mix 1 (Recommended by European Pharmacopeia / ICH class 2) : 14 elements <i>Chlorobenzene 360 µg/ml, Cyclohexane 3880 µg/ml, cis-1,2-Dichloroethene 1870 µg/ml, Dichloromethane 600 µg/ml, n,n-Dimethylformamide 880 µg/ml, Ethylbenzene 369 µg/ml, Hexane 290 µg/ml, Methylcyclohexane 1180 µg/ml, Toluene 890 µg/ml, 1,1,2-Trichloroethene 80 µg/ml, m-Xylene 1302 µg/ml, o-Xylene 195 µg/ml, p-Xylene 304 µg/ml, Tetrahydrofuran 720 µg/ml in DMSO / water</i>	Sealed ampule	1 ml	507689
Mix 2 (Recommended by European Pharmacopeia / ICH class 2) : 11 elements <i>Acetonitrile 410 µg/ml, Chloroform 60 µg/ml, 1,2-Diméthoxyéthane 100 µg/ml, n,n-Dimethylacetamide 1090 µg/ml, 1,4-Dioxane 380 µg/ml, Methylbutylketone 50 µg/ml, Methanol 3000 µg/ml, Nitromethane 50 µg/ml, Pyridine 200 µg/ml, 1,2,3,4-Tétrahydronaphtalène 100 µg/ml, Cumene 70 µg/ml in DMSO / water</i>	Sealed ampule	1 ml	507690
Mix 3 (Recommended by European Pharmacopeia / ICH class 2) : 6 elements <i>2-Ethoxyéthanol 160 µg/ml, Ethyleneglycol 620 µg/ml, Formamide 220 µg/ml, 2-Methoxyéthanol 50 µg/ml, n-Methylpyrrolidone 4840 µg/ml, Sulfolane 160 µg/ml in water</i>	Sealed ampule	1 ml	507691
Mix 1 (Recommended by USP < 467 > class 2) : 16 elements <i>Acetonitrile 2.05mg/ml, Chlorobenzene 1.8mg/ml, Cumene 0.34mg/ml, Cyclohexane 19.4mg/ml, cis-1,2-Dichloroethene 4.7mg/ml, trans-1,2-Dichloroethene 4.7mg/ml, 1,4-Dioxane 1.9mg/ml, Ethylbenzene 1.84mg/ml, Methanol 15mg/ml, Methylcyclohexane 5.9 mg/ml, Dichloromethane 3mg/ml, Tetrahydrofuran 3.6mg/ml, Toluene 4.45mg/ml, m-Xylene 6.51mg/ml, o-Xylene 0.98mg/ml, p-Xylene 1.52mg/ml in DMSO</i>	Sealed ampule	1 ml	507693
Mix 2 (Recommended by USP < 467 > class 2) : 6 elements <i>Chloroform 60µg/ml, 1,2-Diméthoxyéthane 100µg/ml, n-Hexane 290µg/ml, 2-Hexanone 50µg/ml, Nitromethane 50µg/ml, Pyridine 200µg/ml, 1,2,3,4-Tétrahydronaphtalène (Tetraline) 100µg/ml, Trichloroethene 80µg/ml in DMSO</i>	Sealed ampule	1 ml	507694



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