Expires 12-2017

150

Residual Solvents Testing

Solvents are used in the production and purification process of some drug substances, excipients, botanical extracts, and other products for the drug and dietary supplement industry. When solvents are used for the manufacturing process, the USP <467> lists residual solvent levels using tables for Class 1, 2 & 3.

Class 1 lists solvents to be avoided and this list has known carcinogens or strongly suspected human carcinogens and solvents that could cause environmental hazards.

Class 2 lists solvents that should have limited use in the manufacturing process. These solvents are nongenotoxic animal carcinogens or solvents suspected of other significant but reversible toxicities.

Class 3 lists solvents with low toxic potential to humans and no health-based exposure limit is needed.

Residual Solvents USP <467> Class 1, 2, & 3 Pricing:

Methylcyclohexane

Methylene chloride

Nitromethane

Tetrahydrofuran

Trichloroethylene

Pyridine

Sulfolane

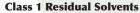
Tetralin

Toluene

Xvlenes

N-Methylpyrrolidone

Class 1, 2 - \$300 • Class 3 - \$150 • Class 1, 2, & 3 - \$450



Benzene

Carbon Tetrachloride

1,2-Dichloroethane 1.1-Dichloroethene

1,1,1-Trichloroethane

Class 2 Residual Solvents

Acetonitrile Chlorobenzene

Chloroform Cumene

Cyclohexane

1,2-Dichloroethene

1,2-Dimethoxyethane

N.N-

Dimethylacetamide

N,N-

Dimethylformamide

1.4-Dioxane

2-Ethoxyethanol Ethylene glycol

Formamide Hexane

Methanol

2-Methoxyethanol Methylbutylketone

Ethanol

Heptane

Methyl acetate

Methylethylketone

Class 3 Residual Solvents

Acetic acid

Acetone

Anisole 1-Butanol

2-Butanol

Butyl acetate tert-Butylmethyl ether

Dimethyl Sulfoxide

(DMSO)

Ethyl acetate Ethyl ether

Ethyl formate Formic acid

Isobutyl acetate Isopropyl acetate

3-methyl-1-butanol

Methylisobutylketone



2-Methyl-1-propanol

Pentane

1-Pentanol

1-Propanol

2-Propanol

Propyl acetate

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