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

Class 1 Residual Solvents

- 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

- Methylcyclohexane
- Methylene chloride
- N-Methylpyrrolidone
- Nitromethane
- Pyridine
- Sulfolane
- Tetrahydrofuran
- Tetralin
- Toluene
- Trichloroethylene
- Xylenes

Class 3 Residual Solvents

- Acetic acid
- Acetone
- Anisole
- 1-Butanol
- 2-Butanol
- Butyl acetate
- tert-Butylmethyl ether
- Dimethyl Sulfoxide (DMSO)
- Ethanol
- Ethyl acetate
- Ethyl ether
- Ethyl formate
- Formic acid
- Heptane
- Isobutyl acetate
- Isopropyl acetate
- Methyl acetate
- 3-methyl-1-butanol
- Methylethylketone
- Methylisobutylketone

- 2-Methyl-1-propanol
- Pentane
- 1-Pentanol
- 1-Propanol
- 2-Propanol
- Propyl acetate



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