



## Residual Solvents



### RESIDUAL SOLVENTS

A range of organic solvents are used for manufacturing pharmaceuticals and herbal medicines. These solvents can be detected as residues of such processing in the final products. Solvent residues should be controlled through Good Manufacturing Practice (GMP) and proper quality control.

### CANNABIS EXTRACTS

In the last few years, there has been a boost in the use of cannabis-based extracts for medicinal purposes. The preparation procedure, however, has not been standardized but is decided by individual groups of scientists.

As cannabis-based products are accepted more for medicinal and recreational uses, standardized methods of analysis must be developed, validated and harmonized. The complexity of cannabis drives the need for advanced analysis of this product's components.

To improve the quality of cannabis-based products, scientists and manufacturers must educate customers. People do die from contaminated cannabis. For now, customers cannot rely on government regulations to ensure proper analysis of cannabis-based products. The patients need to be their own best advocates.

This combination of customer knowledge and advancing analytical methods will increase the safety of products in this industry. Proper quality control of these products is thus the starting point to producing safe medical cannabis.

### LEGISLATION

Solvents are classified by International Community for Harmonization (ICH) (CPMP/ICH 283/95) and the United States Pharmacopeia (USP 467), according to their potential risk.

**Class 1** (solvents to be avoided such as benzene)

**Class 2** (limited toxic potential such as methanol)

**Class 3** (low toxic potential such as ethanol).

By law these solvent residues should be minimized as well as adhere to regulatory limits imposed for any process involving the use of such solvents.

### TEST PANELS

#### Class 1

<i>Solvent</i>	<i>Limit (ppm)</i>
Benzene	2
Carbon tetrachloride	4
1,2-Dichloroethane	5
1,1-Dichloroethene	8
1,1,1-Trichloroethane	1500

#### Class 2

<i>Solvent</i>	<i>Limit (ppm)</i>
1,4-Dioxane	380
Acetonitrile	410
Chlorobenzene	360
Cyclohexane	3880
Ethylbenzen	2170
Cumene	70
Methanol	3000



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### TEST PANELS

#### Class 2 Continued

<b>Solvent</b>	<b>Limit (ppm)</b>
Methyl Cyclohexane	1180
Methylene chloride	600
o-Xylene	2170
p+m-Xylene	2170
Total Xylenes	2170
Tetrahydrofuran	720
Cis 1,2 Dichloroethene	1870
Trans 1,2 Dichloroethene	1870
Total Dichloroethenes	1870
Toluene	890

#### Class 3

<b>Solvent</b>	<b>Limit (ppm)</b>
2-Butanol	5000
Acetone	5000
Butanone/ Methylene Ketone	5000
Ethanol	5000
Ethyl Acetate	5000
Isopropanol	5000
tert-Butylmethyl Ether	5000

Residual solvents are analyzed by Headspace GC-MS or liquid injection GC-MS. The use of MS provides additional selectivity for co-eluting solvents.

The listed Residual Solvent analysis Panels are offered by NAFS to ensure the safety of your product. The Residual Solvent Class 3 Panel are the solvents that are mostly employed by medicinal cannabis producers.

These solvents cover an extensive range of compounds and may even include gasses such as butane, propane or isobutane. It is thus imperative to develop a standardized test method catering exclusively for the medicinal cannabis market since modern Pharmacopeia excludes some of these solvents/gases mentioned.

### PRICING

Residual Solvents Class 1	-See Pricelist
Residual Solvents Class 2	-See Pricelist
Residual Solvents Class 3	-See Pricelist
Bulk samples	-Discounted

### CONTACT US

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