

RE: Residual Solvents - Labetalol Hydrochloride, USP (Cat# L1069)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
1,2-Dichloroethane	1	< 5.0 ppm
Methanol	2	< 3000 ppm
2-Propanol	3	< 5000 ppm

^{* 1,4-}Dioxane is present below the limit of 10 μg/g under the specification *Limit of Free Ethylene Oxide and Dioxane* as required by the NF monograph. ** Ethylene Glycol is present below the limit of 0.25% under the specification *Limit of Ethylene Glycol and Diethylene Glycol* as required by the NF monograph.

No other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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CORPORATE HEADQUARTERS

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