

RESIDUAL SOLVENTS STATEMENT

Trehalose Dihydrate LBLE GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Trehalose, Dihydrate, Bio Excipient Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents. BioSpectra uses Isopropyl Alcohol in the Trehalose, Dihydrate, Bio Excipient Grade manufacturing process, with the product adhering to the ICH Q3C specification of ≤ 5000 ppm for a Class 3 solvent.

Current Product Number
TRED-3250
TRED-3251
TRED-3252
TRED-3253

For further information, please contact Customer.Service@BioSpectra.us



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