

RESIDUAL SOLVENTS STATEMENT

Trehalose, Dihydrate GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Trehalose, Dihydrate, Bio Pharma Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

BioSpectra has evaluated the raw material supply through the Supplier Qualification Program, and can state that the Class 3 solvent Ethanol is used in the manufacture of the raw material supplied to BioSpectra, and is stated to comply with the <5000 ppm limit. BioSpectra uses the Class 3 solvent Isopropyl Alcohol in the manufacture of Trehalose, Dihydrate, Bio Pharma Grade with the product adhering to the specification of <5000 ppm. BioSpectra additionally analyzes Trehalose, Dihydrate annually for residual solvents.

Current Product Number
TRED-4250

For further information, please contact info@biospectra.us



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