

May 8th, 2024 Revision 4

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 listed in the current USP method <467> Tables 1, 2, 3, or 4. There are no Class 1, 2, 3, or other solvents used or produced in the manufacturing or purification of Trehalose, Dihydrate, Bio Excipient Grade, with the exception of Isopropyl Alcohol. Isopropyl Alcohol is used in the manufacture of the Trehalose, Dihydrate, Bio Excipient Grade Finished Good and product adheres 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 info@biospectra.us

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