

RESIDUAL SOLVENTS STATEMENT

Trehalose Dihydrate LBLE Bio Excipient

TE3250 TE3251 TE3252 TE3253

BioSpectra can state that based on the manufacturing process and the controlled handling, storage, and analysis of this product, the Trehalose, Dihydrate, Bio Excipient Grade, product codes TE3250, TE3251, TE3252, TE3253 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, product codes TE3250, TE3251, TE3252, TE3253, with the exception of Isopropyl Alcohol. Isopropyl Alcohol is used in the manufacture of the Trehalose, Dihydrate Finished Good and the product adheres to the specification of <5000 ppm.

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun
Compliance Specialist