

September 15th, 2021 Revision 3

RESIDUAL SOLVENTS STATEMENT

Trehalose Dihydrate LBLE GMP

BioSpectra can state that 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 Finished Good and the product adheres to the specification of <5000 ppm.

| Current Product Number | Historic Product Number |
|-------------------------------|-------------------------|
| TRED-3250 | TE3250 |
| TRED-3251 | TE3251 |
| TRED-3252 | TE3252 |
| TRED-3253 | TE3253 |

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun Compliance Specialist

The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure, copying or alteration. Decision based on the use of this information is the sole responsibility and liability of the recipient. If you would like a controlled version of this document, please contact info@biospectra.us