BIOSPECTRA
Premium Pharmaceutical Ingredients

September 15th, 2021
Revision 3

GENOTOXIC IMPURITY STATEMENT

Trehalose Dihydrate LBLE GMP

BioSpectra performs process validation in accordance with the approved Manufacturing Process Validation Master Plan, which includes Degradation and Impurity Profiling to identify and quantify potential impurities.

Trehalose, Dihydrate, Bio Excipient Grade manufactured by BioSpectra conforms to the limits established in USP <232>, USP <233>, and ICH Q3D guidance for Elemental Impurities. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Trehalose, Dihydrate, Bio Excipient Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents.

Trehalose, Dihydrate, Bio Excipient Grade was analyzed for related Impurities during process validation and met the pre-established specifications at raw material, in-process and finished good stages. BioSpectra does not specifically analyze Trehalose, Dihydrate, Bio Excipient Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

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

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