

GENOTOXIC IMPURITIES STATEMENT

Trehalose, Dihydrate 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 Pharma 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 Pharma Grade complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

Trehalose, Dihydrate, Bio Pharma 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 Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
TRED-4250

For further information, please contact info@biospectra.us



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