

GENOTOXIC IMPURITY STATEMENT

Trehalose, Dihydrate Bio Excipient

TE3250 TE3251 TE3252 TE3253

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 product codes TE3250, TE3251, TE3252, TE3253 for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

For further information, please contact info@biospectra.us



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