

GENOTOXIC IMPURITY STATEMENT

Tris Hydrochloride GMP – Stroudsburg Manufactured

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. Tris Hydrochloride, Bio Excipient Grade, and 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, Tris Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents. Tris Hydrochloride manufactured by BioSpectra was analyzed for additional trace metal impurities during process validation and met the pre-established specifications. BioSpectra does not specifically analyze Tris Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade 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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