BIOSPECTRA
Premium Pharmaceutical Ingredients

April 20th, 2026
Revision 2

GENOTOXIC IMPURITIES STATEMENT

Tris Hydrochloride 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.

Tris Hydrochloride, Bio Pharma Grade has been profiled for elemental impurities via ICP utilizing USP <232> and USP <233> in accordance with ICH Q3D. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Tris Hydrochloride, Bio Pharma Grade complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

Tris Hydrochloride manufactured by BioSpectra was analyzed for additional impurities during process validation and has met the pre-established specifications. BioSpectra does not specifically analyze Tris Hydrochloride, Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
THCL-4251

For further information, please contact Customer.Service@BioSpectra.us

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