

GENOTOXIC IMPURITIES STATEMENT

Tris Hydrochloride

BioSpectra can state that none of the elements listed in ICH Q3D, USP <232>, and USP <233>, with the exception of Nickel, are added to the Tris Hydrochloride, Bio Qualified Grade material or manufacturing process. Raney nickel is used as a catalyst in the Tris Hydrochloride, Bio Qualified Grade manufacturing process. Tris Hydrochloride, Bio Qualified Grade is manufactured using residual solvents Methanol and Nitromethane. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Tris Hydrochloride, Bio Qualified Grade complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

Current Product Number
THCL-6201

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



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