

RESIDUAL SOLVENTS STATEMENT

Tris Hydrochloride GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Tris Hydrochloride, Bio Pharma Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

BioSpectra does not intentionally add or use any solvents in the manufacturing process of Tris Hydrochloride, Bio Pharma Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the Class 2 solvents Methanol and Nitromethane are used in the manufacture of the Tris raw material supplied to BioSpectra. BioSpectra's approved Raw Material Supplier has stated that the Tris raw material complies with the allowed limit of 3000 ppm Methanol, and that no nitromethane is expected to remain in the final Tris raw material. BioSpectra analyzes Tris Hydrochloride finished good for residual solvents annually as well as during process validation, and has confirmed that the product complies to the limits of 3000 ppm max Methanol and 50 ppm max Nitromethane.

Current Product Number
THCL-4251

For further information, please contact info@biospectra.us

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