

RESIDUAL SOLVENTS STATEMENT

Tris Hydrochloride GMP – Bangor Manufactured

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Tris Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

BioSpectra does not intentionally add or use any solvents in the manufacturing process of Tris Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade. BioSpectra has evaluated the raw material supply through the Supplier Approval 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 will analyze Tris Hydrochloride finished good for residual solvents during Degradation and Impurity Profiling for Process Validation in order to confirm that the product complies to the limits of 3000 ppm max Methanol and 50 ppm max Nitromethane.

For further information, please contact info@biospectra.us

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