

January 23rd, 2025 Revision 1

NITROSAMINE STATEMENT

Tris Hydrochloride GMP

BioSpectra can state that a Nitrosamine Risk Evaluation prepared in accordance with European Medicines Agency (EMA) requirements and US FDA Control of Nitrosamine Impurities in Human Drugs Guidance for Industry is available upon request for Tris Hydrochloride, Bio Pharma Grade manufactured by BioSpectra.

Current Product Number THCL-4251

For further information, please contact info@biospectra.us

Cassie Baun

Senior Compliance Specialist