

January 22nd, 2025 Revision 1

NITROSAMINE STATEMENT

Tris 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, Bio Pharma Grade manufactured by BioSpectra.

Current Product Number TRIS-4223

For further information, please contact info@biospectra.us

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