



April 14th, 2026
Revision 4

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 Excipient Grade, and Bio Pharma Grade manufactured by BioSpectra.

Current Product Number
TRIS-3201
TRIS-3220
TRIS-3221
TRIS-3251
TRIS-3252
TRIS-3254
TRIS-3255
TRIS-3256
TRIS-3257
TRIS-4221
TRIS-4224

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

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