

August 5th, 2021 Revision 2

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	Historic Product Number
TRIS-3201	TR3201
TRIS-3220	TR3220
TRIS-3221	TR3221
TRIS-3251	TR3251
TRIS-3252	TR3252
TRIS-3254	TR3254
TRIS-3255	TR3255
TRIS-3256	TR3256
TRIS-3257	TR3257
TRIS-4220	TR4220
TRIS-4221	TR4221

For further information, please contact info@biospectra.us

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