

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 Excipient Grade, and Bio Pharma Grade.

Current Product Number	Historic Product Number
THCL-3203	TH3203
THCL-3220	TH3220
THCL-3221	TH3221
THCL-3250	TH3250
THCL-3251	TH3251
THCL-3252	TH3252
THCL-3253	TH3253
THCL-3254	TH3254
THCL-3255	TH3255
THCL-3256	TH3256
THCL-3257	TH3257
THCL-3258	TH3258
THCL-3259	TH3259
THCL-3260	N/A
THCL-4220	TH4220
THCL-4221	TH4221

For further information, please contact info@biospectra.us

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