

NITROSAMINE STATEMENT

Tris Hydrochloride Bio Excipient Bio Pharma

TH3202 TH3203 TH3220 TH3250 TH3251 TH3252 TH3253 TH3254 TH3255 TH3256 TH4220 TH4221

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 product codes TH3202, TH3203, TH3220, TH3250, TH3251, TH3252, TH3253, TH3254, TH3255, TH3256, TH4220, TH4221.

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