

NITROSAMINE STATEMENT

Tris Bio Active Bio Excipient Bio Pharma

TR2220 TR2250 TR3201 TR3220 TR3221 TR3251 TR3252 TR3254 TR3255 TR3256 TR4220 TR4221

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 Active Grade, Bio Excipient Grade, and Bio Pharma Grade product codes TR2220, TR2250, TR3201, TR3220, TR3221, TR3251, TR3252, TR3254, TR3255, TR3256, TR4220, TR4221.

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