

NITROSAMINE STATEMENT

Guanidine Hydrochloride & 6M Solution Bio Excipient Bio Pharma

GH3101 GH3201 GH3202 GH3220 GH3250 GH4101 GH4120 GH4121 GH4201 GH4220 GH4221 GH4222 GH4250

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 Guanidine Hydrochloride and Guanidine Hydrochloride 6M Solution, Bio Excipient Grade, and Bio Pharma Grade product codes GH3101, GH3201, GH3202, GH3220, GH3250, GH4101, GH4120, GH4121, GH4201, GH4220, GH4221, GH4222, GH4250.

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