

July 27th, 2021 Revision 3

NITROSAMINE STATEMENT

Guanidine 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 Guanidine Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade.

Current Product Number	Historic Product Number
GHCL-3201	GH3201
GHCL-3202	GH3202
GHCL-3220	GH3220
GHCL-3221	GH3221
GHCL-3222	GH3222
GHCL-3223	N/A
GHCL-3224	GH3224
GHCL-3250	GH3250
GHCL-3251	N/A
GHCL-3252	GH3252
GHCL-3253	GH3253
GHCL-4201	GH4201
GHCL-4220	GH4220
GHCL-4250	GH4250

For further information, please contact info@biospectra.us

Cassie Baun

Compliance Specialist