

April 29th, 2025 Revision 4

ELEMENTAL IMPURITIES STATEMENT

Guanidine Hydrochloride GMP

BioSpectra's Guanidine Hydrochloride, Bio Excipient Grade material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D. The results are reported in the associated Guanidine Hydrochloride Elemental Impurity Profile and are available upon request. BioSpectra does not intentionally add any elemental impurities to the product or manufacturing process, and therefore none are expected to be present in Guanidine Hydrochloride.

Current Product Number
GHCL-3202
GHCL-3220
GHCL-3221
GHCL-3224
GHCL-3225
GHCL-3250
GHCL-3251
GHCL-3253

For further information, please contact info@biospectra.us

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