BIOSPECTRA
Premium Pharmaceutical Ingredients

July 27th, 2021
Revision 2

GENOTOXIC IMPURITY STATEMENT

Guanidine Hydrochloride GMP

BioSpectra performs process validation in accordance with the approved Manufacturing Process Validation Master Plan, which includes Degradation and Impurity Profiling to identify and quantify potential impurities.

Guanidine Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade manufactured by BioSpectra conforms to the limits established in USP <232>, USP <233>, and ICH Q3D guidance for Elemental Impurities. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Guanidine Hydrochloride, Bio Excipient Grade, and Bio Pharma complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents.

Guanidine Hydrochloride manufactured by BioSpectra was analyzed for additional impurities during process validation and met the pre-established specifications. BioSpectra does not specifically analyze Guanidine Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

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

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