BIOSPECTRA
Premium Pharmaceutical Ingredients

July 27th, 2021
Revision 2

GENOTOXIC IMPURITY STATEMENT

Guanidine Hydrochloride 6M Solution

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 6M Solution, 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 6M Solution, 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 6M Solution, 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-3101	GH3101
GHCL-4101	GH4101
GHCL-4120	GH4120
GHCL-4121	GH4121

For further information, please contact info@biospectra.us

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