BIOSPECTRA
Premium Pharmaceutical Ingredients

January 2nd, 2025
Revision 1

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.

BioSpectra does not intentionally add any of the elements listed in ICH Q3D, USP <232>, and USP <233> to the product or the manufacturing process. BioSpectra's Guanidine Hydrochloride material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D, with results reported in the associated Elemental Impurity Profile.

Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Guanidine Hydrochloride, Bio Pharma Grade 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 Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
GHCL-4223

For further information, please contact info@biospectra.us

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