BIOSPECTRA
Premium Pharmaceutical Ingredients

March 15th, 2021
Revision 2

GENOTOXIC IMPURITY STATEMENT

Guanidine Thiocyanate 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 has analyzed Guanidine Thiocyanate for Arsenic (As), Copper (Cu), Iron (Fe), and Lead (Pb) and results met the 5-ppm maximum specification. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Guanidine Thiocyanate, Bio Excipient Grade, and 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. BioSpectra does not specifically analyze Guanidine Thiocyanate, 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
GTHI-3220	GT3220
GTHI-4205	GT4205
GTHI-4220	GT4220

For further information, please contact info@biospectra.us

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