

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's Guanidine Thiocyanate 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 Thiocyanate, Bio Pharma Grade complies with the requirements of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

BioSpectra does not specifically analyze Guanidine Thiocyanate, Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
GTHI-4221

For further information, please contact info@biospectra.us

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