

GENOTOXIC IMPURITIES STATEMENT

L-Cystine DiHydrochloride

BioSpectra has evaluated the material supply through the Supplier Qualification Program, and can state that none of the elements listed in ICH Q3D, USP <232>, and USP <233> are intentionally added to the L-Cystine DiHydrochloride, Bio Qualified Grade material or manufacturing process. There are no metal catalysts, metal reagents, or metal residues used in the manufacturing process or present in the raw materials. Isopropyl Alcohol is used in the manufacture of L-Cystine DiHydrochloride, Bio Pharma Grade for BioBuffer Solutions Product line, with the material stated to comply with the ICH Q3C required concentration limit of 5000ppm for a Class 3 solvent.

Current Product Number
LCYS-6250

For further information, please contact info@biospectra.us



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