BI BUFFER SOLUTIONS

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

May 28th, 2025 Revision 2

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 Qualified Grade, with the material complying with the ICH Q3C required concentration limit of 5000ppm for a Class 3 solvent.

Current Product Number LCYS-6350

For further information, please contact info@biospectra.us

Cassie Bour.

Cassie Baun Senior Compliance Specialist

The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure, copying or alteration. Decision based on the use of this information is the sole responsibility and liability of the recipient. If you would like a controlled version of this document, please contact info@biospectra.us