

GENOTOXIC IMPURITIES STATEMENT

L-Arginine Hydrochloride

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-Arginine Hydrochloride, 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. Ethyl Acetate is used in the manufacture of L-Arginine Hydrochloride, Bio Qualified Grade, with the material complying with the ICH Q3C required concentration limit of 5000ppm for a Class 3 solvent.

Current Product Number
LARH-6350

For further information, please contact info@biospectra.us



Cassie Baun

Senior Compliance Specialist