BIOSPECTRA
Premium Pharmaceutical Ingredients

October 5th, 2022
Revision 1

GENOTOXIC IMPURITY STATEMENT

Tris Hydrochloride GMP – Bangor Manufactured

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. Tris Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade manufactured by BioSpectra will be analyzed to the limits established in USP <232>, USP <233>, and ICH Q3D guidance for Elemental Impurities. Tris Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade will also be analyzed for applicable solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents, based on the manufacturing process. Tris Hydrochloride manufactured by BioSpectra will further be analyzed for additional trace metal impurities during process validation. BioSpectra does not specifically analyze Tris Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun
Compliance Supervisor