BIOSPECTRA
Premium Pharmaceutical Ingredients

January 22nd, 2025
Revision 1

GENOTOXIC IMPURITIES STATEMENT

Tris 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.

Tris, Bio Pharma Grade manufactured by BioSpectra conforms to the limits established in USP <232>, USP <233>, and ICH Q3D Guidance for Elemental Impurities. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Tris, Bio Pharma Grade complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

Tris, Bio Pharma Grade manufactured by BioSpectra was analyzed for additional impurities during process validation and has met the pre-established specifications. BioSpectra does not specifically analyze Tris, Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
TRIS-4223

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun
Senior Compliance Specialist