BIOSPECTRA
Premium Pharmaceutical Ingredients

December 12th, 2024
Revision 1

GENOTOXIC IMPURITIES STATEMENT

Bis-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.

BioSpectra does not intentionally add any of the elements listed in ICH Q3D, USP <232>, and USP <233> to the product or the manufacturing process. BioSpectra's Bis-Tris material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D, with results reported in the associated Elemental Impurity Profile.

Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Bis-Tris, Bio Pharma Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents. Bis-Tris, Bio Pharma Grade has additionally been analyzed for the residual solvent Methanol during degradation and impurity profiling, with results meeting specification.

BioSpectra does not specifically analyze Bis-Tris, Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
BTRI-4250

For further information, please contact info@biospectra.us

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