BIOSPECTRA
Premium Pharmaceutical Ingredients

May 9th, 2023
Revision 1

GENOTOXIC IMPURITY 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. The results of these analyses will be summarized in a Degradation and Impurity Profile Report upon completion.

Bis-Tris, Bio Excipient Grade manufactured by BioSpectra will be analyzed for Elemental Impurities for compliance with the limits established in USP <232>, USP <233>, and ICH Q3D guidance for Elemental Impurities. Bis-Tris, Bio Excipient Grade will additionally be analyzed for the residual solvent Methanol during degradation and impurity profiling for compliance with the specifications listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents.

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

Current Product Number	Historic Product Number
BTRI-3250	BT3250

For further information, please contact info@biospectra.us

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