BIOSPECTRA
Premium Pharmaceutical Ingredients

August 5th, 2021
Revision 2

GENOTOXIC IMPURITY 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 Excipient Grade, and 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 Excipient Grade, and 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.

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

Current Product Number	Historic Product Number
TRIS-3201	TR3201
TRIS-3220	TR3220
TRIS-3221	TR3221
TRIS-3251	TR3251
TRIS-3252	TR3252
TRIS-3254	TR3254
TRIS-3255	TR3255
TRIS-3256	TR3256
TRIS-3257	TR3257
TRIS-4220	TR4220
TRIS-4221	TR4221

For further information, please contact info@biospectra.us

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