BIOSPECTRA
Premium Pharmaceutical Ingredients

March 11th, 2021
Revision 2

GENOTOXIC IMPURITY STATEMENT

Tris Hydrochloride 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 Hydrochloride, 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 Hydrochloride, 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 Hydrochloride manufactured by BioSpectra was analyzed for additional trace metal impurities during process validation and met the pre-established specifications. 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.

Current Product Number	Historic Product Number
THCL-3203	TH3203
THCL-3220	TH3220
THCL-3221	TH3221
THCL-3250	TH3250
THCL-3251	TH3251
THCL-3252	TH3252
THCL-3253	TH3253
THCL-3254	TH3254
THCL-3255	TH3255
THCL-3256	TH3256
THCL-3257	TH3257
THCL-3258	TH3258
THCL-3259	TH3259
THCL-3260	N/A
THCL-4220	TH4220
THCL-4221	TH4221

For further information, please contact info@biospectra.us

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