BIOSPECTRA
Premium Pharmaceutical Ingredients

March 6th, 2025
Revision 3

GENOTOXIC IMPURITIES STATEMENT

Tris API

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 Active Grade manufactured by BioSpectra is analyzed for conformance 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 Active Grade complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

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

Current Product Number
TRIS-2220
TRIS-2255
TRIS-2256
TRIS-2257

For further information, please contact info@biospectra.us

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