BIOSPECTRA
Premium Pharmaceutical Ingredients

April 14th, 2026
Revision 6

GENOTOXIC IMPURITIES 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 has been profiled for elemental impurities via ICP utilizing USP <232> and USP <233> in accordance with ICH Q3D. 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 of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

Tris manufactured by BioSpectra was analyzed for additional impurities during process validation and has 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
TRIS-3201
TRIS-3220
TRIS-3221
TRIS-3251
TRIS-3252
TRIS-3254
TRIS-3255
TRIS-3256
TRIS-3257
TRIS-4221
TRIS-4224

For further information, please contact Customer.Service@BioSpectra.us

Cassie Baun

Cassie Baun
Senior Compliance Specialist