

GENOTOXIC IMPURITY STATEMENT

Tris Bio Active Bio Excipient Bio Pharma

TR2220 TR2250 TR3201 TR3220 TR3221 TR3251 TR3252 TR3254 TR3255 TR3256 TR4220 TR4221

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, 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 Active Grade, 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 Active Grade, Bio Excipient Grade, and Bio Pharma Grade product codes TR2220, TR2250, TR3201, TR3220, TR3221, TR3251, TR3252, TR3254, TR3255, TR3256, TR4220, TR4221 for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun
Compliance Specialist