BIOSPECTRA
Premium Pharmaceutical Ingredients

March 6th, 2025
Revision 6

RESIDUAL SOLVENTS STATEMENT

Tris API

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Tris, Bio Active Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

BioSpectra does not intentionally add or use any solvents in the manufacturing process of Tris, Bio Active Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the Class 2 solvents Methanol and Nitromethane are used in the manufacture of the Tris raw material supplied to BioSpectra. BioSpectra's approved raw material supplier has stated that the Tris raw material complies with the allowed limit of 3000 ppm Methanol, and that no Nitromethane is expected to remain in the Tris raw material. BioSpectra analyzes Tris API finished good for residual solvents annually as well as during process validation, and has confirmed that the product complies to the limits of 3000 ppm max Methanol and 50 ppm max Nitromethane.

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

For further information, please contact info@biospectra.us

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