

RESIDUAL SOLVENT STATEMENT

Bis-Tris GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Bis-Tris, Bio Excipient Grade manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

BioSpectra does not use any solvents in the manufacturing process of Bis-Tris, Bio Excipient Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the Class 2 solvent Methanol is used in the manufacture of the Bis-Tris raw material supplied to BioSpectra. BioSpectra's approved Raw Material Supplier has stated that the Bis-Tris raw material is controlled to conform to the ICH Q3C requirements of <3000 ppm Methanol. BioSpectra has additionally analyzed Bis-Tris for Methanol during degradation and impurity profiling for manufacturing process validation, with results meeting specification.

Current Product Number
BTRI-3250

For further information, please contact info@biospectra.us

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