

January 22nd, 2025 Revision 1

CATALYST STATEMENT

Tris GMP

BioSpectra can state that metal catalysts and metal reagents are not intentionally added or introduced to the BioSpectra manufacturing process of Tris, Bio Pharma Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the Tris raw material is made from an ingredient which uses a nickel compound in the manufacture of that ingredient. BioSpectra additionally analyzes Tris, Bio Pharma Grade for elemental impurities during Degradation and Impurity Profiling as part of manufacturing process validation.

Current Product Number

TRIS-4223

For further information, please contact info@biospectra.us

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