

January 23<sup>rd</sup>, 2025 Revision 1

## **CATALYST STATEMENT**

Tris Hydrochloride GMP

BioSpectra can state that metal catalysts and metal reagents are not intentionally added or introduced to the BioSpectra manufacturing process of Tris Hydrochloride, 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 small amount of a nickel compound in the manufacture of that ingredient. BioSpectra additionally analyzes Tris Hydrochloride, Bio Pharma Grade for elemental impurities during Degradation and Impurity Profiling as part of manufacturing process validation.

Current Product Number THCL-4251

For further information, please contact info@biospectra.us

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