



April 28th, 2023
Revision 1

ELEMENTAL IMPURITY STATEMENT

Bis-Tris GMP

BioSpectra's Bis-Tris, Bio Excipient Grade material will be profiled for elemental impurities via ICP-MS utilizing USP <232> and <233> in accordance with ICHQ3D with reference to parenteral application and associated limits. The results will be reported in a Bis-Tris Elemental Impurity Profile upon completion of the analysis.

Current Product Number	Historic Product Number
BTRI-3250	BT3250

For further information, please contact info@biospectra.us

Cassie Baun
Senior Compliance Specialist