

ELEMENTAL IMPURITY STATEMENT

Tris Hydrochloride Bio Excipient Bio Pharma

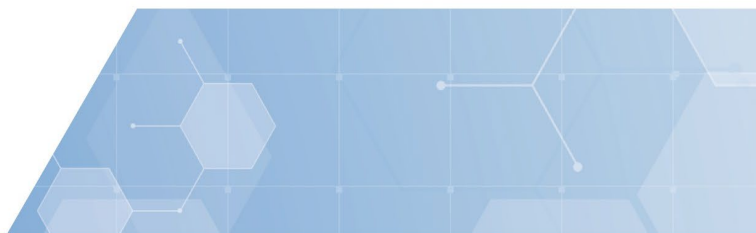
TH3202 TH3203 TH3220 TH3250 TH3251 TH3252 TH3253 TH3254 TH3255 TH3256 TH4220 TH4221

BioSpectra's Tris Hydrochloride Bio Excipient and Bio Pharma Grade material was profiled for elemental impurity via ICP-MS utilizing USP <232> and <233> in accordance with ICHQ3D with reference to parenteral application and associated limits. Osmium is not required for parenteral use and was excluded from these analyses. In addition to Osmium being excluded from parenteral limits as per USP <232>, USP <233> and ICH Q3D, the standard preparation of Osmium stock solution could potentially produce Osmium Tetroxide and for safety considerations, should not be attempted to be analyzed utilizing a nitric acid based ICP-MS system. The results comply with the limits as per USP <232>, USP <233> and ICH Q3D.

Table 1. Parenteral limits as per USP <232> and <233>

Element	Class	Impurity Limit (µg/g)	Result:
Cadmium (Cd)	1	0.2	<0.2 µg/g
Lead (Pb)	1	0.5	<0.5 µg/g
Arsenic (As)	1	1.5	<1.5 µg/g
Mercury (Hg)	1	0.3	<0.3 µg/g
Cobalt (Co)	2A	0.5	<0.5 µg/g
Vanadium (V)	2A	1	<1 µg/g
Nickel (Ni)	2A	2	<2 µg/g
Thallium (Tl)	2B	0.8	<0.8 µg/g
Gold (Au)	2B	10	<10 µg/g
Palladium (Pd)	2B	1	<1 µg/g
Iridium (Ir)	2B	1	<1 µg/g
Rhodium (Rh)	2B	1	<1 µg/g
Ruthenium (Ru)	2B	1	<1 µg/g
Selenium (Se)	2B	8	<8 µg/g
Silver (Ag)	2B	1	<1 µg/g
Platinum (Pt)	2B	1	<1 µg/g
Lithium (Li)	3	25	<25 µg/g
Antimony (Sb)	3	9	<9 µg/g

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Barium (Ba)	3	70	<70 µg/g
Molybdenum (Mo)	3	150	<150 µg/g
Copper (Cu)	3	30	<30 µg/g
Tin (Sn)	3	60	<60 µg/g
Chromium (Cr)	3	110	<110 µg/g

For further information, please contact info@biospectra.us

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