

ELEMENTAL IMPURITY STATEMENT

Tris Hydrochloride GMP

BioSpectra's Tris Hydrochloride Bio Excipient Grade and Bio Pharma Grade material was profiled for elemental impurities 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.

Current Product Number	Historic Product Number
THCL-3203	TH3203
THCL-3220	TH3220
THCL-3221	TH3221
THCL-3250	TH3250
THCL-3251	TH3251
THCL-3252	TH3252
THCL-3253	TH3253
THCL-3254	TH3254
THCL-3255	TH3255
THCL-3256	TH3256
THCL-3257	TH3257
THCL-3258	TH3258
THCL-3259	TH3259
THCL-3260	N/A
THCL-4220	TH4220
THCL-4221	TH4221

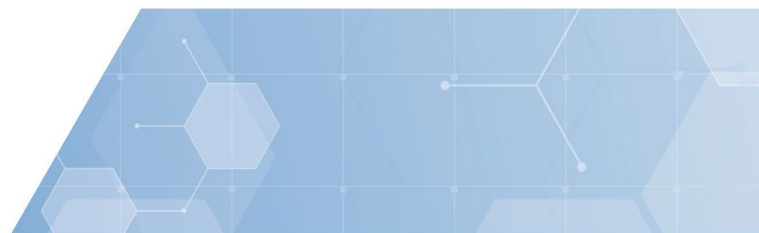


Table 1. Parenteral limits as per USP <232> and <233>

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
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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