

ELEMENTAL IMPURITY STATEMENT

HEPES Bio Excipient Bio Pharma

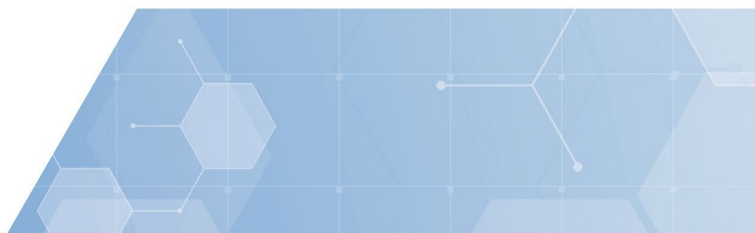
HE3220 HE3250 HE4220

BioSpectra's HEPES Bio Excipient 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 intentionally added and therefore 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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