

ELEMENTAL IMPURITY STATEMENT

Trehalose Dihydrate LBLE Bio Excipient

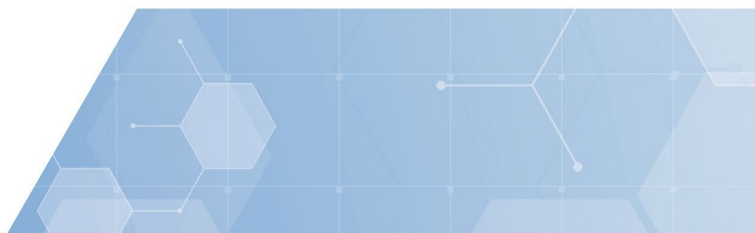
TE3250, TE3251, TE3252, TE3253

BioSpectra's Trehalose Dihydrate 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, which represent the most stringent specification for application of this material. Osmium is not required for parenteral use and was excluded from these analyses in accordance with DCN 18-002592. 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

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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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