

May 7th, 2021 Revision 2

ELEMENTAL IMPURITY STATEMENT

Sodium Decanoate GMP

BioSpectra's Sodium Decanoate 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.

Current Product Number	Historic Product Number
NDEC-3201	ND3201
NDEC-3220	ND3220
NDEC-3320	ND3320

The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure, copying or alteration. Decision based on the use of this information is the sole responsibility and liability of the recipient. If you would like a controlled version of this document, please contact info@biospectra.us



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

Cassie Baun

Cassie Baun Compliance Specialist

The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure, copying or alteration. Decision based on the use of this information is the sole responsibility and liability of the recipient. If you would like a controlled version of this document, please contact info@biospectra.us