

DCN: BSI-RPT-1334 , , Revision: 1.0 , Effective Date: 19 Sep 2023 .



100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

ELEMENTAL IMPURITY ASSESSMENT  
MATERIAL NAME: SODIUM CHLORIDE 5M SOLUTION 2023

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<b>Table 1: Elemental Impurity Risk Assessment</b>		Analytical Method: BSI-ATM-0078 Method Validation Report: BSI-RPT-0808 Batch Record DCN: BSI-MPR-0031 Manufacturing Process DCN: BSI-PRL-0673 Degradation and Impurity Protocol: BSI-PRL-0287 Degradation and Impurity Report: BSI-RPT-1353 Parenteral Specifications (10 g/day MDD)	
<b>Element</b>	<b>Class</b>	<b><sup>1</sup>Limits 1.0J Target ppm (µg/g)</b>	<b>Control Threshold Limits 0.3J Target ppm (µg/g)</b>
Cadmium (Cd)	1	0.20	0.06
Lead (Pb)	1	0.50	0.15
Arsenic (As)	1	1.5	0.45
Mercury (Hg)	1	0.30	0.09
Cobalt (Co)	2A	0.50	0.15
Vanadium (V)	2A	1.0	0.30
Nickel (Ni)	2A	2.0	0.60
Thallium (Tl)	2B	0.80	0.24
Gold (Au)	2B	10	3.0
Palladium (Pd)	2B	1.0	0.30
Iridium (Ir)	2B	1.0	0.30
Osmium (Os)	2B	1.0	0.30
Rhodium (Rh)	2B	1.0	0.30
Ruthenium (Ru)	2B	1.0	0.30
Selenium (Se)	2B	8.0	2.4

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<b>Element</b>	<b>Class</b>	<b><sup>1</sup>Limits 1.0J Target ppm (µg/g)</b>	<b>Control Threshold Limits 0.3J Target ppm (µg/g)</b>
Silver (Ag)	2B	1.0	0.30
Platinum (Pt)	2B	1.0	0.30
Lithium (Li)	3	25	7.5
Antimony (Sb)	3	9.0	2.7
Barium (Ba)	3	70	21
Molybdenum (Mo)	3	150	45
Copper (Cu)	3	5.0	1.5
Tin (Sn)	3	60	18
Chromium (Cr)	3	110	33
Aluminum (Al)	4	0.65	0.195
Calcium (Ca)	4	50	15
Iron (Fe)	4	5.0	1.5
Potassium (K)	4	50	15
Magnesium (Mg)	4	50	15

<sup>1</sup>Limits are derived from Validated Analytical Method BSI-ATM-0078

<b>TABLE 2: ELEMENTAL IMPURITY ASSESSMENT</b>				Analytical Method: BSI-ATM-0078 Method Validation Report: BSI-RPT-0808 Batch Record DCN: BSI-MPR-0031 Manufacturing Process DCN: BSI-PRL-0673 Degradation and Impurity Protocol: BSI-PRL-0287 Degradation and Impurity Report: BSI-RPT-1353 Parenteral Specifications (10 g/day MDD)			
<b>Element</b>	<b>Class</b>	<b>Limits 1.0J Target ppm (µg/g)</b>	<b>Result RM Lot: RMAT-0522-0016 ppm (µg/g)</b>	<b>Result FG Lot: NACL-0123-00002-PV Beginning ppm (µg/g)</b>	<b>Result FG Lot: NACL-0123-00002-PV Middle ppm (µg/g)</b>	<b>Result FG Lot: NACL-0123-00002-PV End ppm (µg/g)</b>	<b>Result FG Lot: NACL-0123-00002-PV Composite ppm (µg/g)</b>
Cd	1	0.20	<0.06	<0.06	<0.06	<0.06	<0.06
Pb	1	0.50	<0.15	<0.15	<0.15	<0.15	<0.15
As	1	1.5	<0.45	<0.45	<0.45	<0.45	<0.45
Hg	1	0.30	<0.09	<0.09	<0.09	<0.09	<0.09
Co	2A	0.50	<0.15	<0.15	<0.15	<0.15	<0.15
V	2A	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Ni	2A	2.0	<0.60	<0.60	<0.60	<0.60	<0.60
Tl	2B	0.80	<0.24	<0.24	<0.24	<0.24	<0.24
Au	2B	10	<3.0	<3.0	<3.0	<3.0	<3.0
Pd	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Ir	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Os	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Rh	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Ru	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Se	2B	8.0	<2.4	<2.4	<2.4	<2.4	<2.4

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<b>Element</b>	<b>Class</b>	<b>Limits 1.0J Target ppm (µg/g)</b>	<b>Result RM Lot: RMAT-0522-0016 ppm (µg/g)</b>	<b>Result FG Lot: NACL-0123-00002-PV Beginning ppm (µg/g)</b>	<b>Result FG Lot: NACL-0123-00002-PV Middle ppm (µg/g)</b>	<b>Result FG Lot: NACL-0123-00002-PV End ppm (µg/g)</b>	<b>Result FG Lot: NACL-0123-00002-PV Composite ppm (µg/g)</b>
Ag	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Pt	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Li	3	25	<7.5	<7.5	<7.5	<7.5	<7.5
Sb	3	9.0	<2.7	<2.7	<2.7	<2.7	<2.7
Ba	3	70	<21	<21	<21	<21	<21
Mo	3	150	<45	<45	<45	<45	<45
Cu	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Sn	3	60	<18	<18	<18	<18	<18
Cr	3	110	<33	<33	<33	<33	<33
Al	4	0.65	<0.195	<0.195	<0.195	<0.195	<0.195
Ca	4	50	<15	<15	<15	<15	<15
Fe	4	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
K	4	50	26	<15	<15	<15	<15
Mg	4	50	<15	<15	<15	<15	<15

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