



100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: SODIUM DECANOATE BIO EXCIPIENT
L10 PROCESS VALIDATION 2026

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0082, BSI-ATM-0083 Method Validation Report: BSI-RPT-0866, BSI-RPT-0884 Manufacturing Process Validation: BSI-PRL-0950 v1.0 Degradation and Impurity Protocol: BSI-PRL-0201 v3.1 Parenteral Specifications (10 g/day MDD)		
Element	Class	Method Limit of Quantitation ppm (µg/g)	RMAT-1221-0039 ppm (µg/g)	NDEC-L10-0426-0002-PV Pre Filtration ppm (µg/g)	NDEC-L10-0426-0002-PV Post Filtration ppm (µg/g)	NDEC-E06-0426-0003-PV Pre Filtration ppm (µg/g)	NDEC-E06-0426-0003-PV Post Filtration ppm (µg/g)
Cd	1	0.06	<0.06	<0.06	<0.06	<0.06	<0.06
Pb	1	0.15	<0.15	<0.15	<0.15	<0.15	<0.15
As	1	0.45	<0.45	<0.45	<0.45	<0.45	<0.45
Hg	1	0.09	<0.09	<0.09	<0.09	<0.09	<0.09
Co	2A	0.15	<0.15	<0.15	<0.15	<0.15	<0.15
V	2A	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ni	2A	0.60	<0.60	<0.60	<0.60	<0.60	<0.60
Tl	2B	0.24	<0.24	<0.24	<0.24	<0.24	<0.24
Au	2B	3.0	<3.0	<3.0	<3.0	<3.0	<3.0
Pd	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ir	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Os	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Rh	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ru	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Se	2B	2.4	<2.4	<2.4	<2.4	<2.4	<2.4

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0082, BSI-ATM-0083 Method Validation Report: BSI-RPT-0866, BSI-RPT-0884 Manufacturing Process Validation: BSI-PRL-0950 v1.0 Degradation and Impurity Protocol: BSI-PRL-0201 v3.1 Parenteral Specifications (10 g/day MDD)		
Element	Class	Method Limit of Quantitation ppm (µg/g)	RMAT-1221-0039 ppm (µg/g)	NDEC-L10-0426-0002-PV Pre Filtration ppm (µg/g)	NDEC-L10-0426-0002-PV Post Filtration ppm (µg/g)	NDEC-E06-0426-0003-PV Pre Filtration ppm (µg/g)	NDEC-E06-0426-0003-PV Post Filtration ppm (µg/g)
Ag	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Pt	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Li	3	7.5	<7.5	<7.5	<7.5	<7.5	<7.5
Sb	3	2.7	<2.7	<2.7	<2.7	<2.7	<2.7
Ba	3	21	<21	<21	<21	<21	<21
Mo	3	45	<45	<45	<45	<45	<45
Cu	3	9.0	<9.0	<9.0	<9.0	<9.0	<9.0
Sn	3	18	<18	<18	<18	<18	<18
Cr	3	33	<33	<33	<33	<33	<33
Fe	4	1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Na	4	Not Applicable	117100	12270	12270	12420	12540

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0082, BSI-ATM-0083 Method Validation Report: BSI-RPT-0866, BSI-RPT-0884 Manufacturing Process Validation: BSI-PRL-0950 v1.0 Degradation and Impurity Protocol: BSI-PRL-0201 v3.1 Parenteral Specifications (10 g/day MDD)		
Element	Class	Method Limit of Quantitation ppm (µg/g)	NDEC-E06-0526-0005-PV Pre Filtration ppm (µg/g)	NDEC-E06-0526-0005-PV Post Filtration ppm (µg/g)	NDEC-L10-0426-0002-PV Beginning ppm (µg/g)	NDEC-L10-0426-0004-PV Middle ppm (µg/g)	NDEC-L10-0526-0006-PV End ppm (µg/g)
Cd	1	0.06	<0.06	<0.06	<0.06	<0.06	<0.06
Pb	1	0.15	<0.15	<0.15	<0.15	<0.15	<0.15
As	1	0.45	<0.45	<0.45	<0.45	<0.45	<0.45
Hg	1	0.09	<0.09	<0.09	<0.09	<0.09	<0.09
Co	2A	0.15	<0.15	<0.15	<0.15	<0.15	<0.15
V	2A	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ni	2A	0.60	<0.60	<0.60	<0.60	<0.60	<0.60
Tl	2B	0.24	<0.24	<0.24	<0.24	<0.24	<0.24
Au	2B	3.0	<3.0	<3.0	<3.0	<3.0	<3.0
Pd	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ir	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Os	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Rh	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ru	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Se	2B	2.4	<2.4	<2.4	<2.4	<2.4	<2.4

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0082, BSI-ATM-0083 Method Validation Report: BSI-RPT-0866, BSI-RPT-0884 Manufacturing Process Validation: BSI-PRL-0950 v1.0 Degradation and Impurity Protocol: BSI-PRL-0201 v3.1 Parenteral Specifications (10 g/day MDD)		
Element	Class	Method Limit of Quantitation ppm (µg/g)	NDEC-E06-0526-0005-PV Pre Filtration ppm (µg/g)	NDEC-E06-0526-0005-PV Post Filtration ppm (µg/g)	NDEC-L10-0426-0002-PV Beginning ppm (µg/g)	NDEC-L10-0426-0004-PV Middle ppm (µg/g)	NDEC-L10-0526-0006-PV End ppm (µg/g)
Ag	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Pt	2B	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Li	3	7.5	<7.5	<7.5	<7.5	<7.5	<7.5
Sb	3	2.7	<2.7	<2.7	<2.7	<2.7	<2.7
Ba	3	21	<21	<21	<21	<21	<21
Mo	3	45	<45	<45	<45	<45	<45
Cu	3	9.0	<9.0	<9.0	<9.0	<9.0	<9.0
Sn	3	18	<18	<18	<18	<18	<18
Cr	3	33	<33	<33	<33	<33	<33
Fe	4	1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Na	4	Not Applicable	12800	13050	117800	116700	121500

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TABLE 3: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0082, BSI-ATM-0083 Method Validation Report: BSI-RPT-0866, BSI-RPT-0884 Manufacturing Process Validation: BSI-PRL-0950 v1.0 Degradation and Impurity Protocol: BSI-PRL-0201 v3.1 Parenteral Specifications (10 g/day MDD)	
Element	Class	Method Limit of Quantitation ppm (µg/g)	NDEC-L10-0426-0002-PV Composite ppm (µg/g)	NDEC-L10-0426-0004-PV Composite ppm (µg/g)	NDEC-L10-0526-0006-PV Composite ppm (µg/g)
Cd	1	0.06	<0.06	<0.06	<0.06
Pb	1	0.15	<0.15	<0.15	<0.15
As	1	0.45	<0.45	<0.45	<0.45
Hg	1	0.09	<0.09	<0.09	<0.09
Co	2A	0.15	<0.15	<0.15	<0.15
V	2A	0.30	<0.30	<0.30	<0.30
Ni	2A	0.60	<0.60	<0.60	<0.60
Tl	2B	0.24	<0.24	<0.24	<0.24
Au	2B	3.0	<3.0	<3.0	<3.0
Pd	2B	0.30	<0.30	<0.30	<0.30
Ir	2B	0.30	<0.30	<0.30	<0.30
Os	2B	0.30	<0.30	<0.30	<0.30
Rh	2B	0.30	<0.30	<0.30	<0.30
Ru	2B	0.30	<0.30	<0.30	<0.30
Se	2B	2.4	<2.4	<2.4	<2.4

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Element	Class	Method Limit of Quantitation ppm (µg/g)	NDEC-L10-0426-0002-PV Composite ppm (µg/g)	NDEC-L10-0426-0004-PV Composite ppm (µg/g)	NDEC-L10-0526-0006-PV Composite ppm (µg/g)
Ag	2B	0.30	<0.30	<0.30	<0.30
Pt	2B	0.30	<0.30	<0.30	<0.30
Li	3	7.5	<7.5	<7.5	<7.5
Sb	3	2.7	<2.7	<2.7	<2.7
Ba	3	21	<21	<21	<21
Mo	3	45	<45	<45	<45
Cu	3	9.0	<9.0	<9.0	<9.0
Sn	3	18	<18	<18	<18
Cr	3	33	<33	<33	<33
Fe	4	4.5	<1.5	<1.5	<1.5
Na	4	Not Applicable	117800	116500	123900

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