



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

ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: GUANIDINE THIOCYANATE 2022

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT	Analytical Method: BSI-ATM-0073, Method Validation Report: BSI-RPT-0778 Manufacturing Process: BSI-PRL-0551 Parenteral Specifications (10g/day MDD)	
Element	Class	¹Limits 1.0J Target ppm (µg/g)
Cadmium (Cd)	1	0.20
Lead (Pb)	1	0.50
Arsenic (As)	1	1.5
Mercury (Hg)	1	0.30
Cobalt (Co)	2A	0.50
Vanadium (V)	2A	1.0
Nickel (Ni)	2A	2.0
Thallium (Tl)	2B	0.80
Gold (Au)	2B	10
Palladium (Pd)	2B	1.0
Iridium (Ir)	2B	1.0
Osmium (Os)	2B	1.0
Rhodium (Rh)	2B	1.0
Ruthenium (Ru)	2B	1.0
Selenium (Se)	2B	8.0
Silver (Ag)	2B	1.0
Platinum (Pt)	2B	1.0
Lithium (Li)	3	25

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Element	Class	¹Limits 1.0J Target ppm (µg/g)
Antimony (Sb)	3	9.0
Barium (Ba)	3	14
Molybdenum (Mo)	3	15
Copper (Cu)	3	3.0
Tin (Sn)	3	60
Chromium (Cr)	3	5.0
Iron (Fe)	4	3.0
Potassium (K)	4	50
Sodium (Na)	4	50

¹Limits derived from Analytical Method BSI-ATM-0073

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0073 Manufacturing Process: BSI-PRL-0551 Parenteral Specifications (10g/day MDD)		
Element	Class	Limits 1.0J Target ppm (µg/g)	RM Result Lot: RMAT-0921-0062 ppm (µg/g)	ML Result Lot: PMAT-0622-00613 ppm (µg/g)	Result Lot: GTHI-0122-00008-PV WC Top ppm (µg/g)	Result Lot: GTHI-0122-00008-PV WC Bottom ppm (µg/g)	Result Lot: GTHI-0122-00008-PV FG Beginning ppm (µg/g)
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
Ag	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30

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Element	Class	Limits 1.0J Target ppm (µg/g)	RM Result Lot: RMAT-0921-0062 ppm (µg/g)	ML Result Lot: PMAT-0622-00613 ppm (µg/g)	Result Lot: GTHI-0122-00008-PV WC Top ppm (µg/g)	Result Lot: GTHI-0122-00008-PV WC Bottom ppm (µg/g)	Result Lot: GTHI-0122-00008-PV FG Beginning ppm (µg/g)
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	14	<4.2	<4.2	<4.2	<4.2	<4.2
Mo	3	15	<4.5	<4.5	<4.5	<4.5	<4.5
Cu	3	3.0	<0.90	<0.90	<0.90	<0.90	<0.90
Sn	3	60	<18	<18	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Fe	4	3.0	<0.90	<0.90	<0.90	<0.90	<0.90
K	4	50	<15	<15	<15	<15	<15
Na	4	50	97	280	<15	<15	15

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