



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

ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: UREA 6M 2021 & 2022

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT	Analytical Method: BSI-ATM-0073, Method Validation Report: BSI-RPT-0780 Manufacturing Process: BSI-PRL-0455 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-0455 Parenteral Specifications (10g/day MDD)	
Element	Class	Limits 1.0J Target ppm (µg/g)	RM Result Lot: UREA-0221-00011 ppm (µg/g)	IP Result Lot: UREA-0121-00041-PV Pre-filtration (Time 1410) ppm (µg/g)	FG Result Lot: UREA-0121-00041-PV FG Beginning Tote #1 ppm (µg/g)
Cd	1	0.20	<0.06	<0.06	<0.06
Pb	1	0.50	<0.15	<0.15	<0.15
As	1	1.5	<0.45	<0.45	<0.45
Hg	1	0.30	<0.09	<0.09	<0.09
Co	2A	0.50	<0.15	<0.15	<0.15
V	2A	1.0	<0.30	<0.30	<0.30
Ni	2A	2.0	<0.60	<0.60	<0.60
Tl	2B	0.80	<0.24	<0.24	<0.24
Au	2B	10	<3.0	<3.0	<3.0
Pd	2B	1.0	<0.30	<0.30	<0.30
Ir	2B	1.0	<0.30	<0.30	<0.30
Os	2B	1.0	<0.30	<0.30	<0.30
Rh	2B	1.0	<0.30	<0.30	<0.30
Ru	2B	1.0	<0.30	<0.30	<0.30
Se	2B	8.0	<2.4	<2.4	<2.4
Ag	2B	1.0	<0.30	<0.30	<0.30
Pt	2B	1.0	<0.30	<0.30	<0.30

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Element	Class	Limits 1.0J Target ppm (µg/g)	RM Result Lot: UREA-0221-00011 ppm (µg/g)	IP Result Lot: UREA-0121-00041-PV Pre-filtration (Time 1410) ppm (µg/g)	FG Result Lot: UREA-0121-00041-PV FG Beginning Tote #1 ppm (µg/g)
Li	3	25	<7.5	<7.5	<7.5
Sb	3	9.0	<2.7	<2.7	<2.7
Ba	3	14	<4.2	<4.2	<4.2
Mo	3	15	<4.5	<4.5	<4.5
Cu	3	3.0	<0.90	<0.90	<0.90
Sn	3	60	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5
Fe	4	3.0	<0.90	<0.90	<0.90
K	4	50	<15	<15	<15
Na	4	50	<15	<15	<15

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TABLE 3: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0073 Manufacturing Process: BSI-PRL-0455 Parenteral Specifications (10g/day MDD)	
Element	Class	Limits 1.0J Target ppm (µg/g)	FG Result Lot: UREA-0121-00041-PV Composite ppm (µg/g)	FG Result Lot: UREA-0121-00042-PV Composite ppm (µg/g)	FG Result Lot: UREA-0121-00045-PV Composite ppm (µg/g)	FG Result Lot: UREA-0122-00003-PV Composite ppm (µg/g)
Cd	1	0.20	<0.06	<0.06	<0.06	<0.06
Pb	1	0.50	<0.15	<0.15	<0.15	<0.15
As	1	1.5	<0.45	<0.45	<0.45	<0.45
Hg	1	0.30	<0.09	<0.09	<0.09	<0.09
Co	2A	0.50	<0.15	<0.15	<0.15	<0.15
V	2A	1.0	<0.30	<0.30	<0.30	<0.30
Ni	2A	2.0	<0.60	<0.60	<0.60	<0.60
Tl	2B	0.80	<0.24	<0.24	<0.24	<0.24
Au	2B	10	<3.0	<3.0	<3.0	<3.0
Pd	2B	1.0	<0.30	<0.30	<0.30	<0.30
Ir	2B	1.0	<0.30	<0.30	<0.30	<0.30
Os	2B	1.0	<0.30	<0.30	<0.30	<0.30
Rh	2B	1.0	<0.30	<0.30	<0.30	<0.30
Ru	2B	1.0	<0.30	<0.30	<0.30	<0.30
Se	2B	8.0	<2.4	<2.4	<2.4	<2.4
Ag ¹	2B	1.0	<0.30	<0.30	<0.30	<0.30
Pt	2B	1.0	<0.30	<0.30	<0.30	<0.30

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Element	Class	Limits 1.0J Target ppm (µg/g)	FG Result Lot: UREA-0121-00041-PV Composite ppm (µg/g)	FG Result Lot: UREA-0121-00042-PV Composite ppm (µg/g)	FG Result Lot: UREA-0121-00045-PV Composite ppm (µg/g)	FG Result Lot: UREA-0122-00003-PV Composite ppm (µg/g)
Li	3	25	<7.5	<7.5	<7.5	<7.5
Sb	3	9.0	<2.7	<2.7	<2.7	<2.7
Ba	3	14	<4.2	<4.2	<4.2	<4.2
Mo	3	15	<4.5	<4.5	<4.5	<4.5
Cu	3	3.0	<0.90	<0.90	<0.90	<0.90
Sn	3	60	<18	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5	<1.5
Fe	4	3.0	<0.90	<0.90	<0.90	<0.90
K	4	50	<15	<15	<15	<15
Na	4	50	<15	<15	<15	<15

¹Ag failed QC check standard high for lots UREA-0121-00045-PV and UREA-0122-00003-PV. Results for report use only.

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