



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

ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: URIDINE 2022

N05 VALIDATION

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Page 1 of 9

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT	Analytical Method: BSI-SOP-0420, Method Validation Report: BSI-RPT-0800 Manufacturing Process: BSI-PRL-0543 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	70
Molybdenum (Mo)	3	15
Copper (Cu)	3	5.0
Tin (Sn)	3	60
Chromium (Cr)	3	5.0
Calcium (Ca)	4	50
Iron (Fe)	4	5.0
Potassium (K)	4	50
Magnesium (Mg)	4	5.0
Manganese (Mn)	4	5.0
Sodium (Na)	4	50
Zinc (Zn)	4	5.0

¹Limits derived from Analytical Method BSI-SOP-0420

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-SOP-0420 Manufacturing Process: BSI-PRL-0543 Parenteral Specifications (10g/day MDD)		
Element	Class	Limits 1.0J Target ppm (µg/g)	RM Result Lot: RMAT-0322-0012 ppm (µg/g)	RM Result Lot: RMAT-0322-0013 ppm (µg/g)	ML Result Lot: URID-0122-00005- PV ML ppm (µg/g)	ML Result Lot: PMAT-0622-00726 ppm (µg/g)	ML Result Lot: PMAT-0722-00728 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
Pt	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-SOP-0420 Manufacturing Process: BSI-PRL-0543 Parenteral Specifications (10g/day MDD)		
Element	Class	Limits 1.0J Target ppm (µg/g)	RM Result Lot: RMAT-0322-0012 ppm (µg/g)	RM Result Lot: RMAT-0322-0013 ppm (µg/g)	ML Result Lot: URID-0122-00005- PV ML ppm (µg/g)	ML Result Lot: PMAT-0622-00726 ppm (µg/g)	ML Result Lot: PMAT-0722-00728 ppm (µg/g)
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	15	<4.5	<4.5	<4.5	<4.5	<4.5
Cu	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Sn	3	60	<18	<18	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
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	<15	<15	<15	<15	<15
Mg	4	5.0	<1.5	11	<1.5	<1.5	1.7
Mn	4	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Na	4	50	<15	<15	<15	<15	<15
Zn	4	5.0	<1.5	<1.5	<1.5	<1.5	<1.5

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TABLE 3: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-SOP-0420 Manufacturing Process: BSI-PRL-0543 Parenteral Specifications (10g/day MDD)	
Element	Class	Limits 1.0J Target ppm (µg/g)	WC Result Lot: URID-0122-00005-PV WC Top ppm (µg/g)	WC Result Lot: URID-0122-00005-PV WC Bottom ppm (µg/g)	WC Result Lot: URID-0122-00006-PV WC Top ppm (µg/g)	WC Result Lot: URID-0122-00006-PV WC Bottom 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	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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TABLE 3: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-SOP-0420 Manufacturing Process: BSI-PRL-0543 Parenteral Specifications (10g/day MDD)	
Element	Class	Limits 1.0J Target ppm (µg/g)	WC Result Lot: URID-0122-00005-PV WC Top ppm (µg/g)	WC Result Lot: URID-0122-00005-PV WC Bottom ppm (µg/g)	WC Result Lot: URID-0122-00006-PV WC Top ppm (µg/g)	WC Result Lot: URID-0122-00006-PV WC Bottom 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	70	<21	<21	<21	<21
Mo	3	15	<4.5	<4.5	<4.5	<4.5
Cu	3	5.0	<1.5	<1.5	<1.5	<1.5
Sn	3	60	<18	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5	<1.5
Ca	4	50	<15	<15	<15	<15
Fe	4	5.0	<1.5	<1.5	<1.5	<1.5
K	4	50	<15	<15	<15	<15
Mg	4	5.0	<1.5	<1.5	<1.5	<1.5
Mn	4	5.0	<1.5	<1.5	<1.5	<1.5
Na	4	50	<15	<15	<15	<15
Zn	4	5.0	<1.5	<1.5	<1.5	<1.5

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TABLE 4: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-SOP-0420 Manufacturing Process: BSI-PRL-0543 Parenteral Specifications (10g/day MDD)		
Element	Class	Limits 1.0J Target ppm (µg/g)	WC Result Lot: URID-0122-00007-PV WC Top ppm (µg/g)	WC Result Lot: URID-0122-00007-PV WC Bottom ppm (µg/g)	FG Result Lot: URID-0122-00005- PV Beginning ppm (µg/g)	FG Result Lot: URID-0122-00006- PV Middle ppm (µg/g)	FG Result Lot: URID-0122-00007- PV End 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
Pt	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)	WC Result Lot: URID-0122-00007-PV WC Top ppm (µg/g)	WC Result Lot: URID-0122-00007-PV WC Bottom ppm (µg/g)	FG Result Lot: URID-0122-00005- PV Beginning ppm (µg/g)	FG Result Lot: URID-0122-00006- PV Middle ppm (µg/g)	FG Result Lot: URID-0122-00007- PV End ppm (µg/g)
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	15	<4.5	<4.5	<4.5	<4.5	<4.5
Cu	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Sn	3	60	<18	<18	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
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	<15	<15	<15	<15	<15
Mg	4	5.0	<1.5	1.8	<1.5	<1.5	2.8
Mn	4	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Na	4	50	<15	<15	<15	<15	<15
Zn	4	5.0	<1.5	<1.5	<1.5	<1.5	<1.5

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