



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

ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: URACIL 2021

Table 1: Elemental Impurity Risk Assessment		Analytical Method: BSI-ATM-0060, Method Validation Report: BSI-RPT-0591 Degradation and Impurity Protocol: BSI-PRL-0148 Degradation and Impurity Report: BSI-RPT-0106 Manufacturing Process: BSI-PRL-0399 Parenteral Specifications (10g/day MDD)	
Element	Class	¹Limits 1.0J Target ppm (µg/g)	Limits 0.3J Target ppm (µg/g), Method LOQ
Cd	1	0.20	0.06
Pb	1	0.50	0.15
As	1	1.5	0.45
Hg	1	0.30	0.09
Co	2A	0.50	0.15
V	2A	1.0	0.30
Ni	2A	2.0	0.60
Tl	2B	0.80	0.24
Au	2B	10	3.0
Pd	2B	1.0	0.30
Ir	2B	1.0	0.30
Os	2B	1.0	0.30
Rh	2B	1.0	0.30
Ru	2B	1.0	0.30
Se	2B	8.0	2.4
Ag	2B	1.0	0.30
Pt	2B	1.0	0.30

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Table 1: Elemental Impurity Risk Assessment		Analytical Method: BSI-ATM-0060, Method Validation Report: BSI-RPT-0591 Degradation and Impurity Protocol: BSI-PRL-0148 Degradation and Impurity Report: BSI-RPT-0106 Manufacturing Process: BSI-PRL-0399 Parenteral Specifications (10g/day MDD)	
Element	Class	¹Limits 1.0J Target ppm (µg/g)	Limits 0.3J Target ppm (µg/g), Method LOQ
Li	3	25	7.5
Sb	3	9.0	2.7
Ba	3	70	21
Mo	3	15	4.5
Cu	3	5.0	1.5
Sn	3	60	18
Cr	3	5.0	1.5
Fe	4	5.0	1.5
Mn	4	5.0	1.5
Zn	4	5.0	1.5
Ca	4	50	15
K	4	50	15
Mg	4	5.0	1.5
Na	4	100	30

¹Limits derived from Analytical Method BSI-ATM-0060.

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT

Analytical Method: BSI-ATM-0060
 Method Validation Report: BSI-RPT-0591
 Degradation and Impurity Protocol: BSI-PRL-0148
 Degradation and Impurity Report: BSI-RPT-0106
 Manufacturing Process: BSI-PRL-0399
 Parenteral Specifications (10g/day MDD)

Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	Result Batch 1 Lot: URAC-0121-00021-PV Composite ppm (µg/g)	Result Batch 1 Lot: URAC-0121-00022-PV Composite ppm (µg/g)	Result Batch 1 Lot: URAC-0121-00023-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	2B	1.0	0.30	<0.30	<0.30	<0.30

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT

Analytical Method: BSI-ATM-0060
 Method Validation Report: BSI-RPT-0591
 Degradation and Impurity Protocol: BSI-PRL-0148
 Degradation and Impurity Report: BSI-RPT-0106
 Manufacturing Process: BSI-PRL-0399
 Parenteral Specifications (10g/day MDD)

Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	Result Batch 1 Lot: URAC-0121-00021-PV Composite ppm (µg/g)	Result Batch 1 Lot: URAC-0121-00022-PV Composite ppm (µg/g)	Result Batch 1 Lot: URAC-0121-00023-PV Composite ppm (µg/g)
Pt	2B	1.0	0.30	<0.30	<0.30	<0.30
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
Fe	4	5.0	1.5	<1.5	<1.5	<1.5
Mn	4	5.0	1.5	<1.5	<1.5	<1.5
Zn	4	5.0	1.5	<1.5	<1.5	<1.5
Ca	4	50	15	<15	<15	25
K	4	50	15	<15	<15	<15
Mg	4	5.0	1.5	<1.5	<1.5	92
Na	4	100	30	3600	820	2100

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TABLE 3: ELEMENTAL IMPURITY ASSESSMENT

Analytical Method: BSI-ATM-0060
 Method Validation Report: BSI-RPT-0591
 Degradation and Impurity Protocol: BSI-PRL-0148
 Degradation and Impurity Report: BSI-RPT-0106
 Manufacturing Process: BSI-PRL-0399
 Parenteral Specifications (10g/day MDD)

Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	Result RM Lot: S/2101002 ppm (µg/g)	Result ML Lot: UC4200-030-0121-ML ppm (µg/g)	Result WC Lot: URAC-0121-00021-PV WC Wash#3 ppm (µg/g)	Result FG Lot: URAC-0121-00021-PV 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	0.10	<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	0.64	<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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TABLE 3: ELEMENTAL IMPURITY ASSESSMENT

Analytical Method: BSI-ATM-0060
 Method Validation Report: BSI-RPT-0591
 Degradation and Impurity Protocol: BSI-PRL-0148
 Degradation and Impurity Report: BSI-RPT-0106
 Manufacturing Process: BSI-PRL-0399
 Parenteral Specifications (10g/day MDD)

Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	Result RM Lot: S/2101002 ppm (µg/g)	Result ML Lot: UC4200-030-0121-ML ppm (µg/g)	Result WC Lot: URAC-0121-00021-PV WC Wash#3 ppm (µg/g)	Result FG Lot: URAC-0121-00021-PV Beginning ppm (µg/g)
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	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	1.8	<1.5	<1.5	<1.5
Fe	4	5.0	1.5	16	<1.5	<1.5	<1.5
Mn	4	5.0	1.5	<1.5	<1.5	<1.5	<1.5
Zn	4	5.0	1.5	<1.5	<1.5	<1.5	<1.5
Ca	4	50	15	34	30	28	<15
K	4	50	15	<15	<15	<15	<15
Mg	4	5.0	1.5	3.1	<1.5	<1.5	<1.5
Na	4	100	30	<30	15000	940	3400

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