

DCN: BSI-RPT-2245, Revision: 1.0, Effective Date: 21 Jul 2025 .



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ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: L-ARGININE HCl
BIO QUALIFIED GRADE BLEND 2025

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT						Analytical Method: BSI-SOP-0420 L-Arginine HCl Process Verification Protocol: BSI-PRL-0877 v 1.0 Parenteral Specifications: 10 g/day MDD			
Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	LARH-L03- 0525-0004-PV Sample 1 ppm (µg/g)	LARH-L03- 0525-0004-PV Sample 2 ppm (µg/g)	LARH-L03- 0525-0004-PV Sample 3 ppm (µg/g)	LARH-L03- 0525-0004-PV Sample 4 ppm (µg/g)	LARH-L03- 0525-0004-PV Sample 5 ppm (µg/g)	LARH-L03- 0525-0004-PV Composite ppm (µg/g)
Cd	1	0.20	0.06	<0.06	<0.06	<0.06	<0.06	<0.06	<0.06
Pb	1	0.50	0.15	<0.15	<0.15	<0.15	<0.15	<0.15	<0.15
As	1	1.5	0.45	<0.45	<0.45	<0.45	<0.45	<0.45	<0.45
Hg	1	0.30	0.09	<0.09	<0.09	<0.09	<0.09	<0.09	<0.09
Co	2A	0.50	0.15	<0.15	<0.15	<0.15	<0.15	<0.15	<0.15
V	2A	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ni	2A	2.0	0.60	<0.60	<0.60	<0.60	<0.60	<0.60	<0.60
Tl	2B	0.80	0.24	<0.24	<0.24	<0.24	<0.24	<0.24	<0.24
Au	2B	10	3.0	<3.0	<3.0	<3.0	<3.0	<3.0	<3.0
Pd	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ir	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Os	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Rh	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ru	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Se	2B	8.0	2.4	<2.4	<2.4	<2.4	<2.4	<2.4	<2.4
Ag	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30	<0.30

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT						Analytical Method: BSI-SOP-0420 L-Arginine HCl Process Verification Protocol: BSI-PRL-0877 v 1.0 Parenteral Specifications: 10 g/day MDD			
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Pt	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Li	3	25	7.5	<7.5	<7.5	<7.5	<7.5	<7.5	<7.5
Sb	3	9.0	2.7	<2.7	<2.7	<2.7	<2.7	<2.7	<2.7
Ba	3	70	21	<21	<21	<21	<21	<21	<21
Mo	3	15	4.5	<4.5	<4.5	<4.5	<4.5	<4.5	<4.5
Cu	3	5.0	1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Sn	3	60	18	<18	<18	<18	<18	<18	<18
Cr	3	5.0	1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Fe	4	5.0	1.5	2	2	4	2	4	2
Mn	4	5.0	1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Zn	4	5.0	1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Ca	4	50	15	<15	<15	<15	<15	<15	<15
K	4	50	15	<15	<15	<15	<15	<15	<15
Mg	4	5.0	1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Na	4	50	15	<15	<15	<15	<15	<15	<15

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