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ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: L-CYSTINE DiHCl
BIO PHARMA GRADE BLEND 2024

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0085 L-Cystine di HCl Process Validation Protocol: BSI-PRL-0821 v1.0 Parenteral Specifications: 10 g/day MDD				
Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	LCYS-0124-00022-PV Sample 1 ppm (µg/g)	LCYS-0124-00022-PV Sample 2 ppm (µg/g)	LCYS-0124-00022-PV Sample 3 ppm (µg/g)	LCYS-0124-00022-PV Sample 4 ppm (µg/g)	LCYS-0124-00022-PV Sample 5 ppm (µg/g)	LCYS-0124-00022-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	0.87	1.2	1.1	0.96	1.2	1.1
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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Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	LCYS-0124- 00022-PV Sample 1 ppm (µg/g)	LCYS-0124- 00022-PV Sample 2 ppm (µg/g)	LCYS-0124- 00022-PV Sample 3 ppm (µg/g)	LCYS-0124- 00022-PV Sample 4 ppm (µg/g)	LCYS-0124- 00022-PV Sample 5 ppm (µg/g)	LCYS-0124- 00022-PV Composite ppm (µg/g)
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	7.1	9.0	7.1	6.9	9.5	7.6
Fe	4	5.0	1.5	23	42	27	27	36	28
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	100	30	<30	<30	<30	<30	<30	<30

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