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ELEMENTAL IMPURITY ASSESSMENT: 2023 MES HYDRATE SAMPLES

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0115 Analytical Method Validation Protocol: BSI-PRL-0764 Analytical Method Validation Report: BSI-RPT-1619 Parenteral Specifications: 10 g/day MDD		
Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	FG Result Lot: MESM-0123-00147 ppm (µg/g)	FG Result Lot: MESM-0123-00151 ppm (µg/g)	FG Result Lot: MESM-0123-00152 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	1.50	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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Pt	2B	1.0	0.30	<0.30	<0.30	<0.30
Li	3	5.0	1.5	<1.5	<1.5	<1.5
Sb	3	5.0	1.5	<1.5	<1.5	<1.5
Ba	3	5.0	1.5	<1.5	<1.5	<1.5
Mo	3	5.0	1.5	<1.5	<1.5	<1.5
Cu	3	5.0	1.5	<1.5	<1.5	<1.5
Sn	3	5.0	1.5	<1.5	<1.5	<1.5
Cr	3	5.0	1.5	<1.5	<1.5	<1.5
Al	4	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
Mn	4	5.0	1.5	<1.5	<1.5	<1.5
Mg	4	5.0	1.5	<1.5	<1.5	<1.5
Na	4	20	6.0	<6.0	<6.0	<6.0
Zn	4	5.0	1.5	<1.5	<1.5	<1.5
Bi	Not Applicable	5.0	1.5	<1.5	<1.5	<1.5

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