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ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: MOPS 2022
SUITE 1 VALIDATION

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT	Manufacturing Process: BSI-PRL-0525 Degradation and Impurity Protocol: BSI-PRL-0196, Degradation and Impurity Report: BSI-RPT-1071 Analytical Method: BSI-ATM-0073 Parenteral Specifications (10g/day MDD)		
Element	**Class**	**[1]Limits 1.0J Target ppm (µg/g)**	**Method of Quantitation ppm (µg/g)**
Cadmium (Cd)	1	0.20	0.06
Lead (Pb)	1	0.50	0.15
Arsenic (As)	1	1.5	0.45
Mercury (Hg)	1	0.30	0.09
Cobalt (Co)	2A	0.50	0.15
Vanadium (V)	2A	1.0	0.30
Nickel (Ni)	2A	2.0	0.60
Thallium (Tl)	2B	0.80	0.24
Gold (Au)	2B	10	3.0
Palladium (Pd)	2B	1.0	0.30
Iridium (Ir)	2B	1.0	0.30
Osmium (Os)	2B	1.0	0.30
Rhodium (Rh)	2B	1.0	0.30
Ruthenium (Ru)	2B	1.0	0.30
Selenium (Se)	2B	8.0	2.4
Silver (Ag)	2B	1.0	0.30
Platinum (Pt)	2B	1.0	0.30
Lithium (Li)	3	25	7.5

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Element	**Class**	**[1]Limits 1.0J Target ppm (µg/g)**	**Method of Quantitation ppm (µg/g)**
Antimony (Sb)	3	9.0	2.7
Barium (Ba)	3	14	4.2
Molybdenum (Mo)	3	15	4.5
Copper (Cu)	3	3.0	0.90
Tin (Sn)	3	60	18
Chromium (Cr)	3	5.0	1.5
Iron (Fe)	4	3.0	0.90
Potassium (K)	4	50	15
Sodium (Na)	4	50	15

[1]Limits derived from Analytical Method BSI-ATM-0073

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Manufacturing Process: BSI-PRL-0525 Degradation and Impurity Protocol: BSI-PRL-0196, Degradation and Impurity Report: BSI-RPT-1071 Analytical Method: BSI-ATM-0073 Parenteral Specifications (10g/day MDD)		
Element	**Class**	**Limits 1.0J Target ppm (µg/g)**	**RM Result Lot: RMAT-0122-0033 ppm (µg/g)**	**RM Result Lot: RMAT-0122-0034 ppm (µg/g)**	**ML Result Lot: PMAT-0222-00460-PD ppm (µg/g)**	**Result Lot: MOPS-0222-00075-PV WC First Basket Bottom ppm (µg/g)**	**Result Lot: MOPS-0222-00075-PV FG Drum #1 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

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Element	**Class**	**Limits 1.0J Target ppm (µg/g)**	**RM Result Lot: RMAT-0122-0033 ppm (µg/g)**	**RM Result Lot: RMAT-0122-0034 ppm (µg/g)**	**ML Result Lot: PMAT-0222-00460-PD ppm (µg/g)**	**Result Lot: MOPS-0222-00075-PV WC First Basket Bottom ppm (µg/g)**	**Result Lot: MOPS-0222-00075-PV FG Drum #1 ppm (µg/g)**
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	14	<4.2	<4.2	<4.2	<4.2	<4.2
Mo	3	15	<4.5	<4.5	<4.5	<4.5	<4.5
Cu	3	3.0	<0.90	<0.90	<0.90	<0.90	<0.90
Sn	3	60	<18	<18	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Fe	4	3.0	<0.90	<0.90	<0.90	<0.90	<0.90
K	4	50	<15	<15	<15	<15	<15
Na	4	50	<15	<15	<15	<15	<15