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ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: POTASSIUM BROMIDE 2022

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT	Analytical Method: BSI-ATM-0080, Method Validation Report: BSI-RPT-0827 Degradation and Impurity Protocol: BSI-PRL-0154 Degradation and Impurity Report: BSI-RPT-0991 Manufacturing Process: BSI-PRL-0469 Parenteral Specifications (10g/day MDD)	
Element	**Class**	**[1]Limits 1.0J Target ppm (µg/g)**
Cadmium (Cd)	1	0.20
Lead (Pb)	1	0.50
Arsenic (As)	1	1.5
Mercury (Hg)	1	0.30
Cobalt (Co)	2A	0.50
Vanadium (V)	2A	1.0
Nickel (Ni)	2A	2.0
Thallium (Tl)	2B	0.80
Gold (Au)	2B	10
Palladium (Pd)	2B	1.0
Iridium (Ir)	2B	1.0
Osmium (Os)	2B	1.0
Rhodium (Rh)	2B	1.0
Ruthenium (Ru)	2B	1.0
Selenium (Se)	2B	8.0
Silver (Ag)	2B	1.0
Platinum (Pt)	2B	1.0

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Element	**Class**	**[1]Limits 1.0J Target ppm (µg/g)**
Lithium (Li)	3	25
Antimony (Sb)	3	9.0
Barium (Ba)	3	70
Molybdenum (Mo)	3	150
Copper (Cu)	3	10
Tin (Sn)	3	60
Chromium (Cr)	3	110
Iron (Fe)	4	10
Calcium (Ca)	4	50
Magnesium (Mg)	4	10

[1]Limits derived from Analytical Method BSI-ATM-0080

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0080 Method Validation Report: BSI-RPT-0827 Degradation and Impurity Protocol: BSI-PRL-0154 Degradation and Impurity Report: BSI-RPT-0991 Manufacturing Process: BSI-PRL-0469 Parenteral Specifications (10g/day MDD)		
Element	**Class**	**Limits 1.0J Target ppm (µg/g)**	**RM Result Lot: RMAT-1221-0044 ppm (µg/g)**	**ML Result Lot: PMAT-0122-00079 ppm (µg/g)**	**WC Result Lot: KBRO-0122-00024-PV WC Top ppm (µg/g)**	**WC Result Lot: KBRO-0122-00024-PV WC Bottom ppm (µg/g)**	**FG Result Lot: KBRO-0122-00024-PV Drum #1 ppm (µg/g)**
Cd	1	0.20	0.06	<0.06	0.06	0.08	0.08
Pb	1	0.50	<0.15	<0.15	<0.15	<0.15	<0.15
As	1	1.5	<0.45	0.67	<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

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Element	**Class**	**Limits 1.0J Target ppm (µg/g)**	**RM Result Lot: RMAT-1221-0044 ppm (µg/g)**	**ML Result Lot: PMAT-0122-00079 ppm (µg/g)**	**WC Result Lot: KBRO-0122-00024-PV WC Top ppm (µg/g)**	**WC Result Lot: KBRO-0122-00024-PV WC Bottom ppm (µg/g)**	**FG Result Lot: KBRO-0122-00024-PV Drum #1 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	150	<45	<45	<45	<45	<45
Cu	3	10	<3.0	<3.0	<3.0	<3.0	<3.0
Sn	3	60	<18	<18	<18	<18	<18
Cr	3	110	<33	<33	<33	<33	<33
Fe	4	10	<3.0	<3.0	<3.0	<3.0	<3.0
Ca	4	50	<15	<15	<15	<15	<15
Mg	4	10	<3.0	<3.0	<3.0	<3.0	<3.0