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ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: 6N HCl IN IPA (FORMOSA GAS)

Table 1: Elemental Impurity Risk Assessment		Analytical Method: BSI-ATM-0087; Method Validation Report: BSI-RPT-0934 Manufacturing Process: BSI-PRL-0582 Degradation and Impurity Protocol: BSI-PRL-0160 Degradation and Impurity Report: BSI-RPT-1354 Parenteral Specifications (10 g/day MDD)	
Element	**Class**	**[1]Limits 1.0J Target ppm (µg/g)**	**Limits 0.1J Method LOQ ppm (µg/g)**
Cadmium (Cd)	1	0.20	0.02
Lead (Pb)	1	0.50	0.05
Arsenic (As)	1	1.5	0.15
Mercury (Hg)	1	0.30	0.03
Cobalt (Co)	2A	0.50	0.05
Vanadium (V)	2A	1.0	0.10
Nickel (Ni)	2A	2.0	0.20
Thallium (Tl)	2B	0.80	0.08
Gold (Au)	2B	10	1.0
Palladium (Pd)	2B	1.0	0.10
Iridium (Ir)	2B	1.0	0.10
Osmium (Os)	2B	1.0	0.10
Rhodium (Rh)	2B	1.0	0.10
Ruthenium (Ru)	2B	1.0	0.10
Selenium (Se)	2B	8.0	0.80
Silver (Ag)	2B	1.0	0.10
Platinum (Pt)	2B	1.0	0.10

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Element	**Class**	**[1]Limits 1.0J Target ppm (µg/g)**	**Limits 0.1J Method LOQ ppm (µg/g)**
Lithium (Li)	3	25	2.5
Antimony (Sb)	3	9.0	0.90
Barium (Ba)	3	70	7.0
Molybdenum (Mo)	3	150	15
Copper (Cu)	3	30	3.0
Tin (Sn)	3	60	6.0
Chromium (Cr)	3	110	11
Calcium (Ca)	4	50	5.0
Iron (Fe)	4	3.0	0.30
Sodium (Na)	4	50	5.0

[1]Limits derived from Analytical Method BSI-ATM-0087

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0087; Method Validation Report: BSI-RPT-0934 Manufacturing Process: BSI-PRL-0582 Degradation and Impurity Protocol: BSI-PRL-0160 Degradation and Impurity Report: BSI-RPT-1354 Parenteral Specifications (10 g/day MDD)			
Element	**Limits 1.0J Target ppm (µg/g)**	**Result IPA RM Lot: RMAT-0422-0059 ppm (µg/g)**	**Result IPA RM Lot: RMAT-0522-0002 ppm (µg/g)**	**Result IPA RM Lot: RMAT-0722-0056 ppm (µg/g)**	**Result IPA RM Lot: RMAT-1022-0029 ppm (µg/g)**	**Result RM Lot: IHCL-0122-00013-PV Reprocessed ppm (µg/g)**	**Result IP Lot: IHCL-0122-00013-PV Confirmation #2 Sample ppm (µg/g)**
Cd	0.20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Pb	0.50	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
As	1.5	<0.15	<0.15	<0.15	<0.15	<0.15	<0.15
Hg	0.30	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03
Co	0.50	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
V	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Ni	2.0	<0.20	<0.20	<0.20	<0.20	0.28	0.58
Tl	0.80	<0.08	<0.08	<0.08	<0.08	<0.08	<0.08
Au	10	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Pd	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Ir	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Os	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Rh	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Ru	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Se	8.0	<0.80	<0.80	<0.80	<0.80	<0.80	<0.80

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0087; Method Validation Report: BSI-RPT-0934 Manufacturing Process: BSI-PRL-0582 Degradation and Impurity Protocol: BSI-PRL-0160 Degradation and Impurity Report: BSI-RPT-1354 Parenteral Specifications (10 g/day MDD)			
Element	**Limits 1.0J Target ppm (µg/g)**	**Result IPA RM Lot: RMAT-0422-0059 ppm (µg/g)**	**Result IPA RM Lot: RMAT-0522-0002 ppm (µg/g)**	**Result IPA RM Lot: RMAT-0722-0056 ppm (µg/g)**	**Result IPA RM Lot: RMAT-1022-0029 ppm (µg/g)**	**Result RM Lot: IHCL-0122-00013-PV Reprocessed ppm (µg/g)**	**Result IP Lot: IHCL-0122-00013-PV Confirmation #2 Sample ppm (µg/g)**
Ag	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Pt	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Li	25	<2.5	<2.5	<2.5	<2.5	<2.5	<2.5
Sb	9.0	<0.90	<0.90	<0.90	<0.90	<0.90	<0.90
Ba	70	<7.0	<7.0	<7.0	<7.0	<7.0	<7.0
Mo	150	<15	<15	<15	<15	<15	<15
Cu	30	<3.0	<3.0	<3.0	<3.0	<3.0	<3.0
Sn	60	<6.0	<6.0	<6.0	<6.0	<6.0	<6.0
Cr	110	<11	<11	<11	<11	<11	<11
Ca	50	6.5	<5.0	5.9	<5.0	9.5	<5.0
Fe	3.0	<0.30	<0.30	<0.30	<0.30	2.1	2.2
Na	50	<5.0	<5.0	<5.0	<5.0	<5.0	<5.0

TABLE 3: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0087; Method Validation Report: BSI-RPT-0934 Manufacturing Process: BSI-PRL-0582 Degradation and Impurity Protocol: BSI-PRL-0160 Degradation and Impurity Report: BSI-RPT-1354 Parenteral Specifications (10 g/day MDD)			
Element	**Limits 1.0J Target ppm (µg/g)**	**Result IP Lot: IHCL-0122-00014-PV Confirmation #2 Sample ppm (µg/g)**	**Result IP Lot: IHCL-0122-00015-PV Confirmation #2 Sample ppm (µg/g)**	**Result FG Lot: IHCL-0122-00013-PV Beginning ppm (µg/g)**	**Result FG Lot: IHCL-0122-00013-PV Composite ppm (µg/g)**	**Result FG Lot: IHCL-0122-00014-PV Composite ppm (µg/g)**	**Result FG Lot: IHCL-0122-00015-PV Composite ppm (µg/g)**
Cd	0.20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Pb	0.50	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
As	1.5	<0.15	<0.15	<0.15	<0.15	<0.15	<0.15
Hg	0.30	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03
Co	0.50	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
V	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Ni	2.0	2.3	2.1	0.69	0.84	2.0	2.2
Tl	0.80	<0.08	<0.08	<0.08	<0.08	<0.08	<0.08
Au	10	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Pd	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Ir	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Os	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Rh	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Ru	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Se	8.0	<0.80	<0.80	<0.80	<0.80	<0.80	<0.80

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Element	**Limits 1.0J Target ppm (µg/g)**	**Result IP Lot: IHCL-0122-00014-PV Confirmation #2 Sample ppm (µg/g)**	**Result IP Lot: IHCL-0122-00015-PV Confirmation #2 Sample ppm (µg/g)**	**Result FG Lot: IHCL-0122-00013-PV Beginning ppm (µg/g)**	**Result FG Lot: IHCL-0122-00013-PV Composite ppm (µg/g)**	**Result FG Lot: IHCL-0122-00014-PV Composite ppm (µg/g)**	**Result FG Lot: IHCL-0122-00015-PV Composite ppm (µg/g)**
Ag	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Pt	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Li	25	<2.5	<2.5	<2.5	<2.5	<2.5	<2.5
Sb	9.0	<0.90	<0.90	<0.90	<0.90	<0.90	<0.90
Ba	70	<7.0	<7.0	<7.0	<7.0	<7.0	<7.0
Mo	150	<15	<15	<15	<15	<15	<15
Cu	30	<3.0	<3.0	<3.0	<3.0	<3.0	<3.0
Sn	60	<6.0	<6.0	<6.0	<6.0	<6.0	<6.0
Cr	110	<11	<11	<11	<11	<11	<11
Ca	50	<5.0	<5.0	<5.0	5.3	<5.0	<5.0
Fe	3.0	6.5	3.0	3.1	3.9	7.0	3.8
Na	50	<5.0	<5.0	<5.0	<5.0	<5.0	<5.0