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ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: CYSTEAMINE HCl N02 2022

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT		Analytical Method: BSI-ATM-0061, Method Validation Report: BSI-RPT-0590 Degradation and Impurity Protocol: BSI-PRL-0415 Degradation and Impurity Report: BSI-RPT-1100 Manufacturing Process: BSI-PRL-0475 and BSI-PRL-0529 Parenteral Specifications (10 g/day MDD)	
Element	**Class**	**[1]Limits 1.0J Target ppm (µg/g)**	**Limits 0.1J ppm (µg/g)**
Cadmium (Cd)	1	0.04	0.004
Lead (Pb)	1	0.10	0.01
Arsenic (As)	1	0.30	0.03
Mercury (Hg)	1	0.06	0.006
Cobalt (Co)	2A	0.10	0.01
Vanadium (V)	2A	0.20	0.02
Nickel (Ni)	2A	0.40	0.04
Thallium (Tl)	2B	0.16	0.016
Gold (Au)	2B	2.0	0.20
Palladium (Pd)	2B	0.20	0.02
Iridium (Ir)	2B	0.20	0.02
Osmium (Os)	2B	0.20	0.02
Rhodium (Rh)	2B	0.20	0.02
Ruthenium (Ru)	2B	0.20	0.02
Selenium (Se)	2B	1.0	0.10
Silver (Ag)	2B	0.20	0.02
Platinum (Pt)	2B	0.20	0.02
Lithium (Li)	3	5.0	0.50

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Element	**Class**	**[1]Limits 1.0J Target ppm (µg/g)**	**Limits 0.1J ppm (µg/g)**
Antimony (Sb)	3	1.8	0.18
Barium (Ba)	3	14	1.4
Molybdenum (Mo)	3	1.0	0.10
Copper (Cu)	3	0.50	0.05
Tin (Sn)	3	12	1.2
Chromium (Cr)	3	1.0	0.10
Aluminum (Al)	4	8.0	0.80
Calcium (Ca)	4	15	1.5
Iron (Fe)	4	4.0	0.40
Potassium (K)	4	40	4.0
Magnesium (Mg)	4	4.0	0.40
Manganese (Mn)	4	0.50	0.05
Sodium (Na)	4	40	4.0
Zinc (Zn)	4	4.0	0.40
Bismuth (Bi)	Not Applicable	4.0	0.40
Strontium (Sr)	Not Applicable	4.0	0.40

[1]Limits derived from Analytical Method BSI-ATM-0061

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT				Analytical Test Method: BSI-ATM-0061, Degradation and Impurity Protocol: BSI-PRL-0415 Degradation and Impurity Report: BSI-RPT-1100 Manufacturing Process: BSI-PRL-0475 and BSI-PRL-0529 Parenteral Specifications (10g/day MDD)		
Element	**Limits 1.0J Target ppm (µg/g)**	**RM Result Lot: RMAT-0222-0098 ppm (µg/g)**	**RM Result Lot: RMAT-0222-0099 ppm (µg/g)**	**RM Result Lot: RMAT-0222-0100 ppm (µg/g)**	**ML Result Lot: CSMH-0122-00033-PV ML ppm (µg/g)**	**ML Result Lot: PMAT-0322-00375 ppm (µg/g)**
Cd	0.04	<0.004	<0.004	<0.004	<0.004	<0.004
Pb	0.10	<0.01	<0.01	<0.01	<0.01	<0.01
As	0.30	<0.03	<0.03	<0.03	<0.03	<0.03
Hg	0.06	0.04	0.03	0.04	<0.018	<0.018
Co	0.10	<0.01	<0.01	<0.01	<0.01	<0.01
V	0.20	<0.02	<0.02	<0.02	<0.02	<0.02
Ni	0.40	<0.04	0.06	0.07	<0.04	<0.04
Tl	0.16	<0.016	<0.016	<0.016	<0.016	<0.016
Au	2.0	<0.20	<0.20	<0.20	<0.20	<0.20
Pd	0.20	<0.02	<0.02	<0.02	<0.02	<0.02
Ir	0.20	<0.02	<0.02	<0.02	<0.02	<0.02
Os	0.20	<0.02	<0.02	<0.02	<0.02	<0.02
Rh	0.20	<0.02	<0.02	<0.02	<0.02	<0.02
Ru	0.20	<0.02	<0.02	<0.02	<0.02	<0.02
Se	1.0	<0.10	<0.10	<0.10	<0.10	<0.10
Ag	0.20	<0.02	<0.02	<0.02	<0.02	<0.02
Pt	0.20	<0.02	<0.02	<0.02	<0.02	<0.02

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT				Analytical Test Method: BSI-ATM-0061, Degradation and Impurity Protocol: BSI-PRL-0415 Degradation and Impurity Report: BSI-RPT-1100 Manufacturing Process: BSI-PRL-0475 and BSI-PRL-0529 Parenteral Specifications (10g/day MDD)		
Element	**Limits 1.0J Target ppm (µg/g)**	**RM Result Lot: RMAT-0222-0098 ppm (µg/g)**	**RM Result Lot: RMAT-0222-0099 ppm (µg/g)**	**RM Result Lot: RMAT-0222-0100 ppm (µg/g)**	**ML Result Lot: CSMH-0122-00033-PV ML ppm (µg/g)**	**ML Result Lot: PMAT-0322-00375 ppm (µg/g)**
Li	5.0	<0.50	<0.50	<0.50	<0.50	<0.50
Sb	1.8	<0.18	<0.18	<0.18	<0.18	<0.18
Ba	14	<1.4	<1.4	<1.4	<1.4	<1.4
Mo	1.0	<0.10	<0.10	<0.10	<0.10	<0.10
Cu	0.50	<0.05	<0.05	<0.05	<0.05	<0.05
Sn	12	<1.2	<1.2	<1.2	<1.2	<1.2
Cr	1.0	<0.10	0.15	0.17	<0.10	<0.10
Al	8.0	<0.80	<0.80	<0.80	<0.80	<0.80
Ca	15	<1.5	<1.5	<1.5	<1.5	<1.5
Fe	4.0	3.0	2.0	2.3	<0.40	0.96
K	40	<4.0	<4.0	<4.0	<4.0	<4.0
Mg	4.0	<0.40	<0.40	<0.40	<0.40	<0.40
Mn	0.50	<0.05	<0.05	<0.05	<0.05	<0.05
Na	40	<4.0	<4.0	<4.0	<4.0	<4.0
Zn	4.0	<0.40	<0.40	<0.40	<0.40	<0.40
Bi	4.0	<0.40	<0.40	<0.40	<0.40	<0.40
Sr	4.0	<0.40	<0.40	<0.40	<0.40	<0.40

TABLE 3: ELEMENTAL IMPURITY ASSESSMENT					Analytical Test Method: BSI-ATM-0061 Degradation and Impurity Protocol: BSI-PRL-0415 Degradation and Impurity Report: BSI-RPT-1100 Manufacturing Process: BSI-PRL-0475 and BSI-PRL-0529 Parenteral Specifications (10g/day MDD)		
Element	**Limits 1.0J Target ppm (µg/g)**	**WC Result Lot: CSMH-0122-00033-PV WC Basket 1 ppm (µg/g)**	**WC Result Lot: CSMH-0122-00033-PV WC Basket 2 ppm (µg/g)**	**WC Result Lot: CSMH-0122-00033-PV WC Basket 3 ppm (µg/g)**	**WC Result Lot: CSMH-0122-00038-PV WC Basket 1 ppm (µg/g)**	**FG Result Lot: CSMH-0122-00033-PV FG Beginning ppm (µg/g)**	**FG Result Lot: CSMH-0122-00038-PV FG Beginning ppm (µg/g)**
Cd	0.04	<0.004	<0.004	<0.004	<0.004	<0.004	<0.004
Pb	0.10	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
As	0.30	<0.03	<0.03	<0.03	<0.03	<0.03	<0.03
Hg	0.06	0.05	0.04	0.05	0.04	0.05	0.03
Co	0.10	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
V	0.20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Ni	0.40	0.10	0.10	0.09	0.04	0.11	0.04
Tl	0.16	<0.016	<0.016	<0.016	<0.016	<0.016	<0.016
Au	2.0	<0.20	<0.20	<0.20	<0.20	<0.20	<0.20
Pd	0.20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Ir	0.20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Os	0.20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Rh	0.20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Ru	0.20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Se	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Ag	0.20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Pt	0.20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02

TABLE 3: ELEMENTAL IMPURITY ASSESSMENT					Analytical Test Method: BSI-ATM-0061 Degradation and Impurity Protocol: BSI-PRL-0415 Degradation and Impurity Report: BSI-RPT-1100 Manufacturing Process: BSI-PRL-0475 and BSI-PRL-0529 Parenteral Specifications (10g/day MDD)		
Element	**Limits 1.0J Target ppm (µg/g)**	**WC Result Lot: CSMH-0122-00033-PV WC Basket 1 ppm (µg/g)**	**WC Result Lot: CSMH-0122-00033-PV WC Basket 2 ppm (µg/g)**	**WC Result Lot: CSMH-0122-00033-PV WC Basket 3 ppm (µg/g)**	**WC Result Lot: CSMH-0122-00038-PV WC Basket 1 ppm (µg/g)**	**FG Result Lot: CSMH-0122-00033-PV FG Beginning ppm (µg/g)**	**FG Result Lot: CSMH-0122-00038-PV FG Beginning ppm (µg/g)**
Li	5.0	<0.50	<0.50	<0.50	<0.50	<0.50	<0.50
Sb	1.8	<0.18	<0.18	<0.18	<0.18	<0.18	<0.18
Ba	14	<1.4	<1.4	<1.4	<1.4	<1.4	<1.4
Mo	1.0	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Cu	0.50	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Sn	12	<1.2	<1.2	<1.2	<1.2	<1.2	<1.2
Cr	1.0	<0.10	<0.10	<0.10	<0.10	0.12	<0.10
Al	8.0	<0.80	<0.80	<0.80	<0.80	<0.80	<0.80
Ca	15	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Fe	4.0	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40
K	40	<4.0	<4.0	<4.0	<4.0	<4.0	<4.0
Mg	4.0	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40
Mn	0.50	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Na	40	<4.0	<4.0	<4.0	<4.0	<4.0	<4.0
Zn	4.0	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40
Bi	4.0	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40
Sr	4.0	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40

TABLE 4: ELEMENTAL IMPURITY ASSESSMENT		Analytical Test Method: BSI-ATM-0061 Degradation and Impurity Protocol: BSI-PRL-0415 Degradation and Impurity Report: BSI-RPT-1100 Manufacturing Process: BSI-PRL-0475 and BSI-PRL-0529 Parenteral Specifications (10g/day MDD)	
Element	**Limits 1.0J Target ppm (µg/g)**	**WC Result Lot: CSMH-0122-00038-PV WC Basket 2 ppm (µg/g)**	**WC Result Lot: CSMH-0122-00038-PV WC Basket 3 ppm (µg/g)**
Cd	0.04	<0.004	<0.004
Pb	0.10	<0.01	<0.01
As	0.30	<0.03	<0.03
Hg	0.06	0.04	0.04
Co	0.10	<0.01	<0.01
V	0.20	<0.02	<0.02
Ni	0.40	0.04	0.04
Tl	0.16	<0.016	<0.016
Au	2.0	<0.20	<0.20
Pd	0.20	<0.02	<0.02
Ir	0.20	<0.02	<0.02
Os	0.20	<0.02	<0.02
Rh	0.20	<0.02	<0.02
Ru	0.20	<0.02	<0.02
Se	1.0	<0.10	<0.10
Ag	0.20	<0.02	<0.02
Pt	0.20	<0.02	<0.02

TABLE 4: ELEMENTAL IMPURITY ASSESSMENT		Analytical Test Method: BSI-ATM-0061 Degradation and Impurity Protocol: BSI-PRL-0415 Degradation and Impurity Report: BSI-RPT-1100 Manufacturing Process: BSI-PRL-0475 and BSI-PRL-0529 Parenteral Specifications (10g/day MDD)	
Element	**Limits 1.0J Target ppm (µg/g)**	**WC Result Lot: CSMH-0122-00038-PV WC Basket 2 ppm (µg/g)**	**WC Result Lot: CSMH-0122-00038-PV WC Basket 3 ppm (µg/g)**
Li	5.0	<0.50	<0.50
Sb	1.8	<0.18	<0.18
Ba	14	<1.4	<1.4
Mo	1.0	<0.10	<0.10
Cu	0.50	<0.05	<0.05
Sn	12	<1.2	<1.2
Cr	1.0	<0.10	<0.10
Al	8.0	<0.80	<0.80
Ca	15	<1.5	<1.5
Fe	4.0	<0.40	<0.40
K	40	<4.0	<4.0
Mg	4.0	<0.40	<0.40
Mn	0.50	<0.05	<0.05
Na	40	<4.0	<4.0
Zn	4.0	<0.40	<0.40
Bi	4.0	<0.40	<0.40
Sr	4.0	<0.40	<0.40