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ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: UREA
S04 PROCESS VALIDATION 2023

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0073 Urea Continuous Batch Record: BSI-MPR-0013 Urea Process Validation Protocol: BSI-PRL-0687 Degradation and Impurity Protocol: BSI-PRL-0136 Degradation and Impurity Report: BSI-RPT-1390 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: UREA-0223-00005-PV Supersack 1 ppm (µg/g)**	**ML Result Lot: PMAT-0523-00760 ppm (µg/g)**	**RM Result Lot: RMAT-0222-0113 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	1.5	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

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Ag	2B	1.0	0.30	<0.30	<0.30	<0.30
Pt	2B	1.0	0.30	<0.30	<0.30	<0.30
Li	3	25	7.5	<7.5	<7.5	<7.5
Sb	3	9.0	2.7	<2.7	<2.7	<2.7
[1]Ba	3	14	4.2	<4.2	<4.2	<4.2
[1]Mo	3	15	4.5	<4.5	<4.5	<4.5
[1]Cu	3	3.0	0.90	<0.90	<0.90	<0.90
Sn	3	60	18	<18	<18	<18
[1]Cr	3	5.0	1.5	<1.5	<1.5	<1.5
Fe	4	3.0	0.90	<0.90	<0.90	<0.90
K	4	50	15	<15	20	<15
Na	4	50	15	<15	<15	<15

[1]Specification calculated based on lower internal specification.