

DCN: BSI-RPT-1382 . . . Revision: 1.0 , Effective Date: 09 Feb 2024 .



100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

ELEMENTAL IMPURITY ASSESSMENT  
MATERIAL NAME: URIDINE  
N02 PROCESS VALIDATION 2023

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-SOP-0420; Analytical Validation Report: BSI-RPT-0800 Process Validation Protocol: BSI-PRL-0678 Degradation and Impurity Protocol: BSI-PRL-0557 Degradation and Impurity Report: BSI-RPT-1392 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: URID-0123-00005-PV Beginning Drum 1 ppm (µg/g)	WC Result Lot: URID-0123-00005-PV WC Basket 1 ppm (µg/g)	RM Result Lot: RMAT-0523-0008 ppm (µg/g)	RM Result Lot: RMAT-0322-0014 ppm (µg/g)	ML Result Lot: PMAT-0523-00701 ppm (µg/g)
Cd	1	0.20	0.06	<0.06	<0.06	<0.06	<0.06	<0.06
Pb	1	0.50	0.15	<0.15	<0.15	<0.15	<0.15	<0.15
As	1	1.5	0.45	<0.45	<0.45	<0.45	<0.45	<0.45
Hg	1	0.30	0.09	<0.09	<0.09	<0.09	<0.09	<0.09
Co	2A	0.50	0.15	<0.15	<0.15	<0.15	<0.15	<0.15
V	2A	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ni	2A	2.0	0.60	<0.60	<0.60	<0.60	<0.60	<0.60
Tl	2B	0.80	0.24	<0.24	<0.24	<0.24	<0.24	<0.24
Au	2B	10	3.0	<3.0	<3.0	<3.0	<3.0	<3.0
Pd	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ir	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Os	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Rh	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Ru	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30

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<sup>1</sup> Se	2B	8.0	2.4	<2.4	<2.4	<2.4	<2.4	<2.4
Ag	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Pt	2B	1.0	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Li	3	25	7.5	<7.5	<7.5	<7.5	<7.5	<7.5
Sb	3	9.0	2.7	<2.7	<2.7	<2.7	<2.7	<2.7
Ba	3	70	21	<21	<21	<21	<21	<21
<sup>1</sup> Mo	3	15	4.5	<4.5	<4.5	<4.5	<4.5	<4.5
<sup>1</sup> Cu	3	5.0	1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Sn	3	60	18	<18	<18	<18	<18	<18
<sup>1</sup> Cr	3	5.0	1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Fe	4	5.0	1.5	<1.5	<1.5	3.8	<1.5	12
Mn	4	5.0	1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Zn	4	5.0	1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Ca	4	50	15	<15	<15	<15	<15	<15

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K	4	50	15	<15	<15	<15	<15	<15
Mg	4	5.0	1.5	<1.5	<1.5	2.3	<1.5	<1.5
Na	4	50	15	<15	<15	<15	<15	<15

<sup>1</sup>Specification calculated based on lower internal specification.