

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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Page 1 of 4

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<b>TABLE 1: ELEMENTAL IMPURITY ASSESSMENT</b>				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				
<b>Element</b>	<b>Class</b>	<b>Limits 1.0J Target ppm (µg/g)</b>	<b>Method Limit of Quantitation ppm (µg/g)</b>	<b>FG Result Lot: URID-0123-00005-PV Beginning Drum 1 ppm (µg/g)</b>	<b>WC Result Lot: URID-0123-00005-PV WC Basket 1 ppm (µg/g)</b>	<b>RM Result Lot: RMAT-0523-0008 ppm (µg/g)</b>	<b>RM Result Lot: RMAT-0322-0014 ppm (µg/g)</b>	<b>ML Result Lot: PMAT-0523-00701 ppm (µg/g)</b>
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.

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## Signature Manifest

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**Revision:** 1.0

**Title:** Elemental Impurity Assessment: Uridine N02 2023

**Effective Date:** 09 Feb 2024

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### BSI-RPT-1382 Elemental Impurity Assessment: Uridine N02 2023

#### Change Request

Name/Signature	Title	Date	Meaning/Reason
Virginia Pena (VIRGINIA.PENA)	Document Control Specialist	20 Jun 2023, 11:43:44 AM	Approved
Amy Yencho (AMY.YENCHO)	Vice President, Laboratory Services	20 Jun 2023, 07:57:59 PM	Approved

#### Originator and Peer Review Collaboration Workspace

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Joshua Goheen (JOSHUA.GOHEEN)	Laboratory Technology Manager	27 Jun 2023, 05:32:00 PM	Complete & Quit
John Allen (JOHN.ALLEN)	Trace Metals Specialist	18 Jul 2023, 03:55:55 PM	Complete & Quit
Jason Lippman (JASON.LIPPMAN)	Trace Metals Specialist	19 Jul 2023, 01:35:39 PM	Complete

#### Departmental Approval

Name/Signature	Title	Date	Meaning/Reason
Amy Yencho (AMY.YENCHO)	Vice President, Laboratory Services	15 Sep 2023, 01:01:12 PM	Approved

#### Author Approval

Name/Signature	Title	Date	Meaning/Reason
Jason Lippman (JASON.LIPPMAN)	Trace Metals Specialist	19 Jul 2023, 06:00:28 PM	Approved

#### Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Carissa Albert (CARISSA.ALBERT)	Associate Director of Quality, Bangor	18 Sep 2023, 03:17:11 PM	Approved

#### Set Date

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Meghan Skeeihan (MEGHAN.SKEEHAN)	Document Control Technician II	09 Feb 2024, 08:42:46 AM	Approved