

BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

Effective Date:	03-Nov-2021	02-Nov-2024	: Date of Next Review																				
Initiated By:	Goheen, Joshua	N/A	: Supersedes																				
Reason for Print:	Placement on Website																						
Approval:	<table border="1"> <thead> <tr> <th>Approvers</th> <th>Date</th> <th>Time</th> <th>Group</th> <th>Name</th> </tr> </thead> <tbody> <tr> <td></td> <td>01-Nov-2021</td> <td>03:06:08 PM</td> <td>SNR MGMT</td> <td>Yencho, Amy M</td> </tr> <tr> <td></td> <td>01-Nov-2021</td> <td>03:09:18 PM</td> <td>EDITOR</td> <td>Goheen, Joshua</td> </tr> <tr> <td></td> <td>03-Nov-2021</td> <td>05:26:18 PM</td> <td>QUALITY</td> <td>Lippman, Jason C</td> </tr> </tbody> </table>			Approvers	Date	Time	Group	Name		01-Nov-2021	03:06:08 PM	SNR MGMT	Yencho, Amy M		01-Nov-2021	03:09:18 PM	EDITOR	Goheen, Joshua		03-Nov-2021	05:26:18 PM	QUALITY	Lippman, Jason C
Approvers	Date	Time	Group	Name																			
	01-Nov-2021	03:06:08 PM	SNR MGMT	Yencho, Amy M																			
	01-Nov-2021	03:09:18 PM	EDITOR	Goheen, Joshua																			
	03-Nov-2021	05:26:18 PM	QUALITY	Lippman, Jason C																			

ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: GUANIDINE HYDROCHLORIDE 6M
BANGOR 2021

Printed On:	10-Nov-2021 12:27:22 PM	Ledergerber, Alissa L	: Printed By
Print Expiration:	Not Applicable		
Notice:	The Information contained herein is the property of BioSpectra and is Confidential.		

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT				Manufacturing Process DCN: 20-001778 Process Validation Protocol: 20-003025 Degradation and Impurity Protocol: 20-003027 Degradation and Impurity Report: 21-002124 Parenteral Specifications: 10g/day MDD			
Element	Class	Limits 1.0J Target ppm (µg/g)	Raw Material Result Lot: GH200806 ppm (µg/g)	Raw Material Result Lot: GH200805 ppm (µg/g)	Result Lot: GH3100-026-0221-PV L09PT01 (pre-filtration) ppm (µg/g)	Result Lot: GH3100-026-0221-PV L09PT02 (post-filtration) ppm (µg/g)	Result Lot: GH3100-026-0221-PV FG Drum #1 ppm (µg/g)
Cd	1	0.20	<0.06	<0.06	<0.06	<0.06	<0.06
Pb	1	0.50	<0.15	<0.15	<0.15	<0.15	<0.15
As	1	1.5	<0.45	<0.45	<0.45	<0.45	<0.45
Hg	1	0.30	<0.09	<0.09	<0.09	<0.09	<0.09
Co	2A	0.50	<0.15	<0.15	<0.15	<0.15	<0.15
V	2A	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Ni	2A	2.0	<0.60	<0.60	<0.60	<0.60	<0.60
Tl	2B	0.80	<0.24	<0.24	<0.24	<0.24	<0.24
Au	2B	10	<3.0	<3.0	<3.0	<3.0	<3.0
Pd	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Os	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Ir	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Rh	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30

Printed On:	10-Nov-2021 12:27:22 PM	Ledergerber, Alissa L	: Printed By
Print Expiration:	Not Applicable		
Notice:	The Information contained herein is the property of BioSpectra and is Confidential.		

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT				Manufacturing Process DCN: 20-001778 Process Validation Protocol: 20-003025 Degradation and Impurity Protocol: 20-003027 Degradation and Impurity Report: 21-002124 Parenteral Specifications: 10g/day MDD			
Element	Class	Limits 1.0J Target ppm (µg/g)	Raw Material Result Lot: GH200806 ppm (µg/g)	Raw Material Result Lot: GH200805 ppm (µg/g)	Result Lot: GH3100-026-0221-PV L09PT01 (pre-filtration) ppm (µg/g)	Result Lot: GH3100-026-0221-PV L09PT02 (post-filtration) ppm (µg/g)	Result Lot: GH3100-026-0221-PV FG Drum #1 ppm (µg/g)
Ru	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Se	2B	8.0	<2.4	<2.4	<2.4	<2.4	<2.4
Ag	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Pt	2B	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Li	3	25	<7.5	<7.5	<7.5	<7.5	<7.5
Sb	3	1.0	<0.30	<0.30	<0.30	<0.30	<0.30
Ba	3	70	<21	<21	<21	<21	<21
Mo	3	15	<4.5	<4.5	<4.5	<4.5	<4.5
Cu	3	0.50	<0.15	<0.15	<0.15	<0.15	<0.15
Sn	3	60	<18	<18	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Fe	4	3.0	<0.90	<0.90	<0.90	<0.90	<0.90

Printed On:	10-Nov-2021 12:27:22 PM	Ledergerber, Alissa L	: Printed By
Print Expiration:	Not Applicable		
Notice:	The Information contained herein is the property of BioSpectra and is Confidential.		