

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>03-Nov-2021</td> <td>11:44:18 AM</td> <td>EDITOR</td> <td>Goheen, Joshua</td> </tr> <tr> <td></td> <td>03-Nov-2021</td> <td>11:45:16 AM</td> <td>SNR MGMT</td> <td>Yencho, Amy M</td> </tr> <tr> <td></td> <td>03-Nov-2021</td> <td>05:39:13 PM</td> <td>QUALITY</td> <td>Lippman, Jason C</td> </tr> </tbody> </table>			Approvers	Date	Time	Group	Name		03-Nov-2021	11:44:18 AM	EDITOR	Goheen, Joshua		03-Nov-2021	11:45:16 AM	SNR MGMT	Yencho, Amy M		03-Nov-2021	05:39:13 PM	QUALITY	Lippman, Jason C
Approvers	Date	Time	Group	Name																			
	03-Nov-2021	11:44:18 AM	EDITOR	Goheen, Joshua																			
	03-Nov-2021	11:45:16 AM	SNR MGMT	Yencho, Amy M																			
	03-Nov-2021	05:39:13 PM	QUALITY	Lippman, Jason C																			

ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: MOPS 2021

Printed On:	10-Nov-2021 12:29:09 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 Batch Process DCN: 16-000626 Method Validation Protocol: 21-004047 Method Validation Report: DCN:21-003661 Parenteral Specifications: 10g/day MDD		
Element	Class	¹Limits 1.0J Target ppm (µg/g)	Result Lot: MOPS-0221-0145 ppm (µg/g)	Result Lot: MOPS-0221-0146 ppm (µg/g)	Result Lot: MOPS-0221-0147 ppm (µg/g)
As	1	1.5	<0.45	<0.45	<0.45
Cd	1	0.20	<0.06	<0.06	<0.06
Hg	1	0.30	<0.09	<0.09	<0.09
Pb	1	0.50	<0.15	<0.15	<0.15
Co	2A	0.50	<0.15	<0.15	<0.15
Ni	2A	2.0	<0.60	<0.60	<0.60
V	2A	1.0	<0.30	<0.30	<0.30
Tl	2B	0.80	<0.24	<0.24	<0.24
Se	2B	8.0	<2.4	<2.4	<2.4
Ag	2B	1.0	<0.30	<0.30	<0.30
Au	2B	10	<3.0	<3.0	<3.0
Pd	2B	1.0	<0.30	<0.30	<0.30
Ir	2B	1.0	<0.30	<0.30	<0.30
Os	2B	1.0	<0.30	<0.30	<0.30

Printed On:	10-Nov-2021 12:29:09 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 Batch Process DCN: 16-000626 Method Validation Protocol: 21-004047 Method Validation Report: DCN:21-003661 Parenteral Specifications: 10g/day MDD		
Element	Class	¹ Limits 1.0J Target ppm (µg/g)	Result Lot: MOPS-0221-0145 ppm (µg/g)	Result Lot: MOPS-0221-0146 ppm (µg/g)	Result Lot: MOPS-0221-0147 ppm (µg/g)
Pt	2B	1.0	<0.30	<0.30	<0.30
Rh	2B	1.0	<0.30	<0.30	<0.30
Ru	2B	1.0	<0.30	<0.30	<0.30
Ba	3	14	<4.2	<4.2	<4.2
Sb	3	9.0	<2.7	<2.7	<2.7
Li	3	25	<7.5	<7.5	<7.5
Mo	3	15	<4.5	<4.5	<4.5
Cu	3	3.0	<0.90	<0.90	<0.90
Sn	3	60	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5
Fe	4	3.0	0.94	<0.90	<0.90
K	4	50	<15	<15	<15
Na	4	50	<15	<15	<15

¹1.0J Target Specifications from Analytical Validation Protocol: 21-004047

Printed On:	10-Nov-2021 12:29:09 PM	Ledergerber, Alissa L	: Printed By
Print Expiration:	Not Applicable		
Notice:	The Information contained herein is the property of BioSpectra and is Confidential.		