

BIOSPECTRA

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Initiated By:	Goheen, Joshua	N/A	: Supersedes																				
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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>04:20:47 PM</td> <td>QUALITY</td> <td>Lippman, Jason C</td> </tr> <tr> <td></td> <td>04-Nov-2021</td> <td>06:35:02 AM</td> <td>EDITOR</td> <td>Goheen, Joshua</td> </tr> <tr> <td></td> <td>05-Nov-2021</td> <td>08:38:07 AM</td> <td>SNR MGMT</td> <td>Yencho, Amy M</td> </tr> </tbody> </table>			Approvers	Date	Time	Group	Name		03-Nov-2021	04:20:47 PM	QUALITY	Lippman, Jason C		04-Nov-2021	06:35:02 AM	EDITOR	Goheen, Joshua		05-Nov-2021	08:38:07 AM	SNR MGMT	Yencho, Amy M
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ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: MES, MONOHYDRATE
2021

Printed On:	10-Nov-2021 12:26:39 PM	Ledergerber, Alissa L	: Printed By
Print Expiration:	Not Applicable		
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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT					Manufacturing Process DCN: 16-001113 Degradation and Impurity Protocol: 17-002088, Report: 21-003673 Parenteral Specifications: 10g/day MDD			
Element	Class	Limits 1.0J Target ppm (µg/g)	Raw Material Result Lot: 1120047121 ppm (µg/g)	Raw Material Result Lot: 1120035073 ppm (µg/g)	Result Lot: ME3200-232-0221- PV Bottom WC ppm (µg/g)	Result Lot: ME3200-232-0221- PV Top WC ppm (µg/g)	Result Lot: ME3200-232-0221- PV ML ppm (µg/g)	Result Lot: ME3200-232-0221- PV FG Drum#1 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
Se	2B	8.0	<2.4	<2.4	<2.4	<2.4	<2.4	<2.4

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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
Mo	3	15	<4.5	<4.5	<4.5	<4.5	<4.5	<4.5
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
Cr	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Fe	4	5.0	3.4	2.6	<1.5	<1.5	<1.5	<1.5
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
K	4	50	<15	<15	<15	<15	<15	<15
Na ¹	4	N/A	5.1	64	0.39	0.24	14	0.43

¹Sodium Results are reported for informational purposes only.

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