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Initiated By:	Hosein, Amy	1.0	: 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>18-Oct-2021</td> <td>03:46:39 PM</td> <td>EDITOR</td> <td>Goheen, Joshua</td> </tr> <tr> <td></td> <td>18-Oct-2021</td> <td>03:53:43 PM</td> <td>QUALITY</td> <td>Lippman, Jason C</td> </tr> <tr> <td></td> <td>01-Nov-2021</td> <td>10:52:33 AM</td> <td>SNR MGMT</td> <td>Yencho, Amy M</td> </tr> </tbody> </table>			Approvers	Date	Time	Group	Name		18-Oct-2021	03:46:39 PM	EDITOR	Goheen, Joshua		18-Oct-2021	03:53:43 PM	QUALITY	Lippman, Jason C		01-Nov-2021	10:52:33 AM	SNR MGMT	Yencho, Amy M
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ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: WATER FOR INJECTION
2020

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TABLE 1: ELEMENTAL IMPURITY RISK ASSESSMENT			Degradation and Impurity Protocol: 19-003064, Report: 21-002123 Parenteral Specifications: 10g/day MDD				
Element	Class	Limits 1.0J Target ppm (µg/g)	Result 1 Lot: E06DI01-061320 ppm (µg/g)	Result 2 Lot: E06DI01-061420 ppm (µg/g)	Result 3 Lot: E06DI01-080920 ppm (µg/g)	Result 4 Lot: E06DI01-081020 ppm (µg/g)	Result 5 Lot: E06DI01-081920 ppm (µg/g)
Cd	1	0.20	<0.20	<0.20	<0.20	<0.20	<0.20
Pb	1	0.50	<0.50	<0.50	<0.50	<0.50	<0.50
As	1	1.5	<1.5	<1.5	<1.5	<1.5	<1.5
Hg	1	0.30	<0.30	<0.30	<0.30	<0.30	<0.30
Co	2A	0.50	<0.50	<0.50	<0.50	<0.50	<0.50
V	2A	1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Ni	2A	2.0	<2.0	<2.0	<2.0	<2.0	<2.0
Tl	2B	0.80	<0.80	<0.80	<0.80	<0.80	<0.80
Au	2B	10	<10	<10	<10	<10	<10
Pd	2B	1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Ir	2B	1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Rh	2B	1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Ru	2B	1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Se	2B	8.0	<8.0	<8.0	<8.0	<8.0	<8.0

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Ag	2B	1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Pt	2B	1.0	<1.0	<1.0	<1.0	<1.0	<1.0
Li	3	25	<25	<25	<25	<25	<25
Sb	3	9.0	<9.0	<9.0	<9.0	<9.0	<9.0
Ba	3	70	<70	<70	<70	<70	<70
Mo	3	150	<150	<150	<150	<150	<150
Cu	3	30	<30	<30	<30	<30	<30
Sn	3	60	<60	<60	<60	<60	<60
Cr	3	110	<110	<110	<110	<110	<110
Al ¹	4	N/A	<0.001	<0.001	<0.001	<0.001	<0.001
Fe ¹	4	N/A	<0.001	<0.001	<0.001	<0.001	<0.001

*Osmium not analyzed

¹Al, Fe included to fulfill Degradation/Impurity Protocol

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