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Initiated By:	Goheen, Joshua		: Supersedes																				
Reason for Revision:	New Document																						
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>06-Aug-2021</td> <td>01:46:04 PM</td> <td>QUALITY</td> <td>Lippman, Jason C</td> </tr> <tr> <td></td> <td>06-Aug-2021</td> <td>02:02:37 PM</td> <td>EDITOR</td> <td>Goheen, Joshua</td> </tr> <tr> <td></td> <td>09-Aug-2021</td> <td>10:49:34 AM</td> <td>SNR MGMT</td> <td>Yencho, Amy M</td> </tr> </tbody> </table>			Approvers	Date	Time	Group	Name		06-Aug-2021	01:46:04 PM	QUALITY	Lippman, Jason C		06-Aug-2021	02:02:37 PM	EDITOR	Goheen, Joshua		09-Aug-2021	10:49:34 AM	SNR MGMT	Yencho, Amy M
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## ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: HEPES  
 VALIDATION 2021

VIEW ONLY

Printed On:	27-Aug-2021 12:42:44 PM	Yencho, Amy M	: Printed By
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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT			Manufacturing Process Validation DCN: 21-003050 Degradation and Impurity Protocol: 21-003680 Report: DCN:21-003656 Parenteral Specifications: 10g/day MDD				
Element	Class	<sup>1</sup> Limits 1.0J Target ppm (µg/g)	Raw Material Result Lot: S211 1001 ppm (µg/g)	Raw Material Result Lot: S212 1001 ppm (µg/g)	Raw Material Result Lot: S213 1001 ppm (µg/g)	Raw Material Result Lot: S214 1001 ppm (µg/g)	Result Lot: PMAT-0421-00018 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
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
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

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Os	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	9.0	<2.7	<2.7	<2.7	<2.7	<2.7
Ba	3	70	<21	<21	<21	<21	<21
Mo	3	15	<4.5	<4.5	<4.5	<4.5	<4.5
Cu	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Sn	3	60	<18	<18	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Fe	4	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Mn	4	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Zn	4	5.0	<1.5	<1.5	<1.5	<1.5	<1.5
Ca	4	50	<15	<15	<15	<15	<15
K	4	50	<15	<15	<15	<15	<15
Mg	4	5.0	<1.5	<1.5	<1.5	<1.5	<1.5

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<sup>1</sup>1.0J Target Specifications from Analytical Method: 20-003520

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Manufacturing Process Validation DCN: 21-003050 Degradation and Impurity Protocol: 21-003680 Report: DCN:21-003656 Parenteral Specifications: 10g/day MDD			
Element	Class	<sup>1</sup> Limits 1.0J Target ppm (µg/g)	Result Lot: HEPE-0221- 00015-PV FF1 WC Top ppm (µg/g)	Result Lot: HEPE-0221- 00015-PV FF1 WC Bottom ppm (µg/g)	Result Lot: HEPE-0221- 00015-PV FF1 Drum 1 ppm (µg/g)	Result Lot: HEPE-0221- 00015-PV FF2 Drum 31 ppm (µg/g)	Result Lot: HEPE-0221- 00009-PV ppm (µg/g)	Result Lot: HEPE-0221- 00010-PV 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
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
Os	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	<1.5	<1.5	<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

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Mg	4	5.0	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5

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