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ELEMENTAL IMPURITY ASSESSMENT  
MATERIAL NAME: HEPES SODIUM

<b>TABLE 1: ELEMENTAL IMPURITY ASSESSMENT</b>				Analytical Method Validation Protocol: BSI-PRL-0595 Analytical Method Validation Report: BSI-RPT-1214 Analytical Method SOP: BSI-ATM-0104 Parenteral Specifications: 10 g/day MDD		
<b>Element</b>	<b>Class</b>	<b><sup>1</sup>Limits 1.0J Target ppm (µg/g)</b>	<b>Method Limit of Quantitation ppm (µg/g)</b>	<b>RM Result Lot: RMAT-1021-0144 ppm (µg/g)</b>	<b>RM Result Lot: RMAT-1021-0145 ppm (µg/g)</b>	<b>RM Result Lot: RMAT-1021-0146 ppm (µg/g)</b>
Cd	1	0.20	0.02	<0.02	<0.02	<0.02
Pb	1	0.50	0.05	<0.05	<0.05	<0.05
As	1	1.50	0.15	<0.15	<0.15	<0.15
Hg	1	0.30	0.03	<0.03	<0.03	<0.03
Co	2A	0.50	0.05	<0.05	<0.05	<0.05
V	2A	1.0	0.10	<0.10	<0.10	<0.10
Ni	2A	2.0	0.20	<0.20	<0.20	<0.20
Tl	2B	0.80	0.08	<0.08	<0.08	<0.08
Au	2B	10	1.0	<1.0	<1.0	<1.0
Pd	2B	1.0	0.10	<0.10	<0.10	<0.10
Ir	2B	1.0	0.10	<0.10	<0.10	<0.10
Os	2B	1.0	0.10	<0.10	<0.10	<0.10
Rh	2B	1.0	0.10	<0.10	<0.10	<0.10
Ru	2B	1.0	0.10	<0.10	<0.10	<0.10
Se	2B	8.0	0.80	<0.80	<0.80	<0.80
Ag	2B	1.0	0.10	<0.10	<0.10	<0.10
Pt	2B	1.0	0.10	<0.10	<0.10	<0.10

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Li	3	25	2.5	<2.5	<2.5	<2.5
Sb	3	9.0	0.90	<0.90	<0.90	<0.90
Ba	3	70	7.0	<7.0	<7.0	<7.0
Mo	3	150	15	<15	<15	<15
Cu	3	30	3.0	<3.0	<3.0	<3.0
Sn	3	60	6.0	<6.0	<6.0	<6.0
Cr	3	110	11	<11	<11	<11
Fe	<sup>2</sup> 4	20	2.0	<2.0	<2.0	<2.0

<sup>1</sup>1.0J limits derived from Analytical Method Validation Protocol BSI-PRL-0595.

<sup>2</sup>No PDE limits for Class 4 elements; limit was derived from other internal product specifications.