



100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: HEPES ZONE E 2022

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT		Analytical Method: BSI-ATM-0054, Method Validation Report: BSI-RPT-0544 Degradation and Impurity Protocol: BSI-PRL-0558 Manufacturing Process: BSI-PRL-0539 Parenteral Specifications (10g/day MDD)	
Element	Class	¹Limits 1.0J Target ppm (µg/g)	Limits 0.3J ppm (µg/g)
Cadmium (Cd)	1	0.20	0.06
Lead (Pb)	1	0.50	0.15
Arsenic (As)	1	1.5	0.45
Mercury (Hg)	1	0.30	0.09
Cobalt (Co)	2A	0.50	0.15
Vanadium (V)	2A	1.0	0.30
Nickel (Ni)	2A	2.0	0.60
Thallium (Tl)	2B	0.80	0.24
Gold (Au)	2B	10	3.0
Palladium (Pd)	2B	1.0	0.30
Iridium (Ir)	2B	1.0	0.30
Osmium (Os)	2B	1.0	0.30
Rhodium (Rh)	2B	1.0	0.30
Ruthenium (Ru)	2B	1.0	0.30
Selenium (Se)	2B	8.0	2.4
Silver (Ag)	2B	1.0	0.30
Platinum (Pt)	2B	1.0	0.30
Lithium (Li)	3	25	7.5

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Element	Class	¹Limits 1.0J Target ppm (µg/g)	Limits 0.3J ppm (µg/g)
Antimony (Sb)	3	9.0	2.7
Barium (Ba)	3	70	21
Molybdenum (Mo)	3	15	4.5
Copper (Cu)	3	5.0	1.5
Tin (Sn)	3	60	18
Chromium (Cr)	3	5.0	1.5
Iron (Fe)	4	5.0	1.5
Manganese (Mn)	4	5.0	1.5
Zinc (Zn)	4	5.0	1.5
Calcium (Ca)	4	50	15
Potassium (K)	4	50	15
Magnesium (Mg)	4	5.0	1.5

¹Limits derived from Analytical Method BSI-ATM-0054

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0054 Degradation and Impurity Protocol: BSI-PRL-0558 Manufacturing Process: BSI-PRL-0539 Parenteral Specifications (10g/day MDD)	
Element	Class	Limits 1.0J Target ppm (µg/g)	RM Result Lot: RMAT-1021-0038 ppm (µg/g)	RM Result Lot: RMAT-1021-0042 ppm (µg/g)	ML Result Lot: HEPE-0122-00036-PV ppm (µg/g)
Cd	1	0.20	<0.06	<0.06	<0.06
Pb	1	0.50	<0.15	<0.15	<0.15
As	1	1.5	<0.45	<0.45	<0.45
Hg	1	0.30	<0.09	<0.09	<0.09
Co	2A	0.50	<0.15	<0.15	<0.15
V	2A	1.0	<0.30	<0.30	<0.30
Ni	2A	2.0	<0.60	<0.60	<0.60
Tl	2B	0.80	<0.24	<0.24	<0.24
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
Rh	2B	1.0	<0.30	<0.30	<0.30
Ru	2B	1.0	<0.30	<0.30	<0.30
Se	2B	8.0	<2.4	<2.4	<2.4
Ag	2B	1.0	<0.30	<0.30	<0.30
Pt	2B	1.0	<0.30	<0.30	<0.30

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0054 Degradation and Impurity Protocol: BSI-PRL-0558 Manufacturing Process: BSI-PRL-0539 Parenteral Specifications (10g/day MDD)	
Element	Class	Limits 1.0J Target ppm (µg/g)	RM Result Lot: RMAT-1021-0038 ppm (µg/g)	RM Result Lot: RMAT-1021-0042 ppm (µg/g)	ML Result Lot: HEPE-0122-00036-PV ppm (µg/g)
Li	3	25	<7.5	<7.5	<7.5
Sb	3	9.0	<2.7	<2.7	<2.7
Ba	3	70	<21	<21	<21
Mo	3	15	<4.5	<4.5	<4.5
Cu	3	5.0	<1.5	<1.5	<1.5
Sn	3	60	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5
Fe	4	5.0	<1.5	<1.5	<1.5
Mg	4	5.0	<1.5	<1.5	<1.5
Mn	4	5.0	<1.5	<1.5	<1.5
Zn	4	5.0	<1.5	<1.5	<1.5
Ca	4	50	<15	<15	<15
K	4	50	<15	<15	<15

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TABLE 3: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0054 Manufacturing Process: BSI-PRL-0539 Parenteral Specifications (10g/day MDD)	
Element	Class	Limits 1.0J Target ppm (µg/g)	WC Result Lot: HEPE-0122-00036-PV Top ppm (µg/g)	WC Result Lot: HEPE-0122-00036-PV Bottom ppm (µg/g)	FG Result Lot: HEPE-0122-00036-PV Beginning ppm (µg/g)
Cd	1	0.20	<0.06	<0.06	<0.06
Pb	1	0.50	<0.15	<0.15	<0.15
As	1	1.5	<0.45	<0.45	<0.45
Hg	1	0.30	<0.09	<0.09	<0.09
Co	2A	0.50	<0.15	<0.15	<0.15
V	2A	1.0	<0.30	<0.30	<0.30
Ni	2A	2.0	<0.60	<0.60	<0.60
Tl	2B	0.80	<0.24	<0.24	<0.24
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
Rh	2B	1.0	<0.30	<0.30	<0.30
Ru	2B	1.0	<0.30	<0.30	<0.30
Se	2B	8.0	<2.4	<2.4	<2.4
Ag	2B	1.0	<0.30	<0.30	<0.30
Pt	2B	1.0	<0.30	<0.30	<0.30

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Li	3	25	<7.5	<7.5	<7.5
Sb	3	9.0	<2.7	<2.7	<2.7
Ba	3	70	<21	<21	<21
Mo	3	15	<4.5	<4.5	<4.5
Cu	3	5.0	<1.5	<1.5	<1.5
Sn	3	60	<18	<18	<18
Cr	3	5.0	<1.5	<1.5	<1.5
Fe	4	5.0	<1.5	<1.5	<1.5
Mg	4	5.0	<1.5	<1.5	<1.5
Mn	4	5.0	<1.5	<1.5	<1.5
Zn	4	5.0	<1.5	<1.5	<1.5
Ca	4	50	<15	<15	<15
K	4	50	<15	<15	<15

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