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ELEMENTAL IMPURITY ASSESSMENT: TREHALOSE, DIHYDRATE 2024

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT			Analytical Method: BSI-ATM-0084 Analytical Method Validation Protocol: BSI-PRL-0468 Analytical Method Validation Report: BSI-RPT-0893 Parenteral Specifications: 100 g/day MDD		
Element	Class	Method Limit of Quantitation ppm (µg/g)	TRED-N02-0924-0025 ppm (µg/g)	TRED-N02-0924-0026 ppm (µg/g)	TRED-N02-0924-0027 ppm (µg/g)
Cd	1	0.002	<0.002	<0.002	<0.002
Pb	1	0.005	<0.005	<0.005	<0.005
As	1	0.015	<0.015	<0.015	<0.015
Hg	1	0.003	<0.003	<0.003	<0.003
Co	2A	0.005	<0.005	<0.005	<0.005
V	2A	0.01	<0.01	<0.01	<0.01
Ni	2A	0.02	<0.02	<0.02	<0.02
Tl	2B	0.008	<0.008	<0.008	<0.008
Au	2B	0.10	<0.10	<0.10	<0.10
Pd	2B	0.01	<0.01	<0.01	<0.01
Ir	2B	0.01	<0.01	<0.01	<0.01
Os	2B	0.01	<0.01	<0.01	<0.01
Rh	2B	0.01	<0.01	<0.01	<0.01
Ru	2B	0.01	<0.01	<0.01	<0.01
Se	2B	0.08	<0.08	<0.08	<0.08
Ag	2B	0.01	<0.01	<0.01	<0.01
Pt	2B	0.01	<0.01	<0.01	<0.01

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Li	3	0.25	<0.25	<0.25	<0.25
Sb	3	0.09	<0.09	<0.09	<0.09
Ba	3	0.70	<0.70	<0.70	<0.70
Mo	3	0.05	<0.05	<0.05	<0.05
Cu	3	0.05	<0.05	<0.05	<0.05
Sn	3	0.60	<0.60	<0.60	<0.60
Cr	3	0.05	<0.05	<0.05	<0.05
Al	4	0.05	<0.05	<0.05	<0.05
Fe	4	0.05	<0.05	<0.05	<0.05
Zn	4	0.05	<0.05	<0.05	<0.05

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