

DCN: BSI-RPT-1828, Revision: 1.0, Effective Date: 31 Jul 2024 .



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

ELEMENTAL IMPURITY ASSESSMENT: 2024 TRIS HCl (S03) RM FORMOSA GAS VALIDATION

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0058, BSI-ATM-0059 Tris Hydrochloride Batch Record: MT-0001 Tris Hydrochloride Process Validation Protocol: BSI-PRL-0802 Degradation and Impurity Protocol: BSI-PRL-0500 v1.1 Degradation and Impurity Report: BSI-RPT-1843 Parenteral Specifications: 100 g/day MDD			
Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	RM Result Lot: THCL-0122-00349 ppm (µg/g)	RM Result Lot: THCL-0123-00031 ppm (µg/g)	RM Result Lot: RMAT-1023-0123 ppm (µg/g)	RM Result Lot: RMAT-1023-0124 ppm (µg/g)
Cd	1	0.02	0.002	<0.002	<0.002	<0.002	<0.002
Pb	1	0.05	0.005	<0.005	<0.005	<0.005	<0.005
As	1	0.15	0.015	0.021	0.015	<0.015	<0.015
Hg	1	0.03	0.003	<0.003	<0.003	<0.003	<0.003
Co	2A	0.05	0.005	<0.005	<0.005	<0.005	<0.005
V	2A	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Ni	2A	0.20	0.02	<0.02	0.024	0.54	0.43
Tl	2B	0.08	0.008	<0.008	<0.008	<0.008	<0.008
Au	2B	1.0	0.10	<0.10	<0.10	<0.10	<0.10
Pd	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Ir	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Os	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Rh	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Ru	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Se	2B	0.50	0.05	<0.05	<0.05	<0.05	<0.05

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TABLE I: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0058, BSI-ATM-0059 Tris Hydrochloride Batch Record: MT-0001 Tris Hydrochloride Process Validation Protocol: BSI-PRL-0802 Degradation and Impurity Protocol: BSI-PRL-0500 v1.1 Degradation and Impurity Report: BSI-RPT-1843 Parenteral Specifications: 100 g/day MDD			
Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	RM Result Lot: THCL-0122-00349 ppm (µg/g)	RM Result Lot: THCL-0123-00031 ppm (µg/g)	RM Result Lot: RMAT-1023-0123 ppm (µg/g)	RM Result Lot: RMAT-1023-0124 ppm (µg/g)
Ag	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Pt	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Li	3	2.5	0.25	<0.25	<0.25	<0.25	<0.25
Sb	3	0.90	0.09	<0.09	<0.09	<0.09	<0.09
Ba	3	7.0	0.70	<0.70	<0.70	<0.70	<0.70
Mo	3	0.50	0.05	<0.05	0.075	<0.05	<0.05
Cu	3	0.25	0.025	<0.025	<0.025	<0.025	<0.025
Sn	3	6.0	0.60	<0.60	<0.60	<0.60	<0.60
Cr	3	0.50	0.05	<0.05	<0.05	<0.05	<0.05
Al	4	4.0	0.40	5.6	3.9	<0.40	<0.40
Fe	4	2.0	0.20	<0.20	<0.20	<0.20	<0.20
Mn	4	0.25	0.025	<0.025	<0.025	<0.025	<0.025
Zn	4	2.0	0.20	<0.20	<0.20	<0.20	<0.20
Ca	4	2.0	0.60	1.1	1.0	0.79	0.63
Mg	4	2.0	0.60	<0.60	<0.60	<0.60	<0.60

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT Analytical Method: BSI-ATM-0058, BSI-ATM-0059 Tris Hydrochloride Batch Record: MT-0001 Tris Hydrochloride Process Validation Protocol: BSI-PRL-0802 Degradation and Impurity Protocol: BSI-PRL-0500 v1.1 Degradation and Impurity Report: BSI-RPT-1843 Parenteral Specifications: 100 g/day MDD							
Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	ML Result Lot: PMAT-0524-00452 ppm (µg/g)	ML Result Lot: PMAT-0524-00454-PV ppm (µg/g)	WC Result Lot: THCL-0224-00048-PV WC Middle Basket ppm (µg/g)	FG Result Lot: THCL-0224-00048-PV FG Middle Drum ppm (µg/g)
Cd	1	0.02	0.002	<0.002	<0.002	<0.002	<0.002
Pb	1	0.05	0.005	<0.005	<0.005	<0.005	<0.005
As	1	0.15	0.015	<0.015	<0.015	0.021	0.017
Hg	1	0.03	0.003	<0.003	<0.003	<0.003	<0.003
Co	2A	0.05	0.005	<0.005	<0.005	<0.005	<0.005
V	2A	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Ni	2A	0.20	0.02	0.025	0.48	<0.02	<0.02
Tl	2B	0.08	0.008	<0.008	<0.008	<0.008	<0.008
Au	2B	1.0	0.10	<0.10	<0.10	<0.10	<0.10
Pd	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Ir	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Os	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Rh	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Ru	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Se	2B	0.50	0.05	<0.05	<0.05	<0.05	<0.05

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Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	ML Result Lot: PMAT-0524-00452 ppm (µg/g)	ML Result Lot: PMAT-0524-00454-PV ppm (µg/g)	WC Result Lot: THCL-0224-00048-PV WC Middle Basket ppm (µg/g)	FG Result Lot: THCL-0224-00048-PV FG Middle Drum ppm (µg/g)
Ag	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Pt	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01
Li	3	2.5	0.25	<0.25	<0.25	<0.25	<0.25
Sb	3	0.90	0.09	<0.09	<0.09	<0.09	<0.09
Ba	3	7.0	0.70	<0.70	<0.70	<0.70	<0.70
Mo	3	0.50	0.05	<0.05	<0.05	<0.05	<0.05
Cu	3	0.25	0.025	<0.025	<0.025	<0.025	<0.025
Sn	3	6.0	0.60	<0.60	<0.60	<0.60	<0.60
Cr	3	0.50	0.05	<0.05	0.13	<0.05	<0.05
Al	4	4.0	0.40	0.78	0.69	1.0	1.2
Fe	4	2.0	0.20	<0.20	1.3	0.23	<0.20
Mn	4	0.25	0.025	<0.025	0.039	<0.025	<0.025
Zn	4	2.0	0.20	<0.20	<0.20	<0.20	<0.20
Ca	4	2.0	0.60	<0.60	<0.60	0.73	0.98
Mg	4	2.0	0.60	<0.60	<0.60	<0.60	<0.60

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