

DCN: BSI-RPT-1356 , , Revision: 1.0 , Effective Date: 19 Sep 2023 .



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

ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: TRIS HYDROCHLORIDE
S03 PROCESS VALIDATION 2023

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT					Process Validation Protocol: BSI-PRL-0666 Degradation and Impurity Protocol: BSI-PRL-0500 Degradation and Impurity Report: BSI-RPT-1388 Analytical Method: BSI-ATM-0058, BSI-ATM-0059 Parenteral Specifications: 100 g/day MDD			
Element	Class	Limits 1.0J Target ppm (µg/g)	Method Limit of Quantitation ppm (µg/g)	FG Result Lot: THCL-0223-00135-PV Beginning Drum ppm (µg/g)	WC Result Lot: THCL-0223-00135-PV WC Basket 1 ppm (µg/g)	ML Result Lot: PMAT-0423-00526 ppm (µg/g)	RM Result Lot: PMAT-0423-00527 ppm (µg/g)	RM Result Lot: RMAT-0323-0092 ppm (µg/g)
Cd	1	0.02	0.002	<0.002	<0.002	<0.002	<0.002	<0.002
Pb	1	0.05	0.005	<0.005	<0.005	<0.005	<0.005	<0.005
As	1	0.15	0.015	<0.015	<0.015	0.017	0.016	<0.015
Hg	1	0.03	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Co	2A	0.05	0.005	<0.005	<0.005	0.012	<0.005	<0.005
V	2A	0.10	0.01	<0.01	<0.01	0.010	<0.01	<0.01
Ni	2A	0.20	0.02	0.068	0.045	9.5	0.068	1.9
Tl	2B	0.08	0.008	<0.008	<0.008	<0.008	<0.008	<0.008
Au	2B	1.0	0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Pd	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Ir	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Os	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Rh	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Ru	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01	<0.01
¹ Se	2B	0.50	0.05	<0.05	<0.05	<0.05	<0.05	<0.05

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Ag	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Pt	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Li	3	2.5	0.25	<0.25	<0.25	<0.25	<0.25	<0.25
Sb	3	0.90	0.09	<0.09	<0.09	<0.09	<0.09	<0.09
Ba	3	7.0	0.70	<0.70	<0.70	<0.70	<0.70	<0.70
¹ Mo	3	0.50	0.05	<0.05	<0.05	0.20	<0.05	<0.05
¹ Cu	3	0.25	0.025	<0.025	<0.025	0.063	<0.025	<0.025
Sn	3	6.0	0.60	<0.60	<0.60	<0.60	<0.60	<0.60
¹ Cr	3	0.50	0.05	<0.05	<0.05	0.10	<0.05	<0.05
Al	4	4.0	0.40	<0.40	<0.40	4.5	<0.40	1.4
Fe	4	2.0	0.20	<0.20	<0.20	1.2	<0.20	<0.20
Mn	4	0.25	0.025	<0.025	<0.025	<0.025	<0.025	<0.025
Zn	4	2.0	0.20	<0.20	<0.20	<0.20	<0.20	<0.20
Ca	4	Not Applicable	0.60	<0.60	0.78	1.8	0.77	0.85
Mg	4	Not Applicable	0.60	<0.60	<0.60	<0.60	<0.60	<0.60

¹Specification calculated based on lower internal specification.

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