



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

ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: TRIS HYDROCHLORIDE
M11 VALIDATION 2022

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT				Process Validation Protocol: BSI-PRL-0573 Degradation and Impurity Protocol: BSI-PRL-0574 Degradation and Impurity Report: BSI-RPT-1209 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)	RM Result Lot: RMAT-0622-0027 ppm (µg/g)	RM Result Lot: RMAT-1221-0162 ppm (µg/g)	ML Result Lot: PMAT-0822-01006 ppm (µg/g)	WC Result Lot: THCL-0122-00207-PV 1st Basket ppm (µg/g)	FG Result Lot: THCL-0122-00207-PV Drum 1 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	<0.015	<0.015	<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	<0.005	<0.005	<0.005
V	2A	0.10	0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Ni	2A	0.20	0.02	0.032	3.1	0.11	<0.02	<0.02
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

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT				Process Validation Protocol: BSI-PRL-0573 Degradation and Impurity Protocol: BSI-PRL-0574 Degradation and Impurity Report: BSI-RPT-1209 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)	RM Result Lot: RMAT-0622-0027 ppm (µg/g)	RM Result Lot: RMAT-1221-0162 ppm (µg/g)	ML Result Lot: PMAT-0822-01006 ppm (µg/g)	WC Result Lot: THCL-0122-00207-PV 1st Basket ppm (µg/g)	FG Result Lot: THCL-0122-00207-PV Drum 1 ppm (µg/g)
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	1.0	<0.05	0.40	<0.05	<0.05
¹ Cu	3	0.25	0.025	<0.025	<0.025	<0.025	<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	<0.05	<0.05	<0.05
Al	4	4.0	0.40	5.5	4.7	1.9	1.4	1.5
Fe	4	2.0	0.20	<0.20	0.41	<0.20	<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	1.4	1.5	<0.60	0.75	0.72
Mg	4	Not Applicable	0.60	<0.60	<0.60	<0.60	<0.60	<0.60

¹Specification calculated based on lower internal specification.

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.