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ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: TRIS HYDROCHLORIDE
THCL-3200 VALIDATION 2022

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT					Process Validation Protocol: BSI-PRL-0499 Degradation and Impurity Protocol: BSI-PRL-0500 Degradation and Impurity Report: BSI-RPT-1069 Analytical Method: BSI-ATM-0059, BSI-ATM-0089 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-0122-0084 ppm (µg/g)**	**RM Result Lot: PMAT-0222-00189 ppm (µg/g)**	**ML Result Lot: PMAT-0222-00241 ppm (µg/g)**	**WC Result Lot: THCL-0222-00054-PV 1st Basket ppm (µg/g)**	**FG Result Lot: THCL-0222-00054-PV Re-dried Bin 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	0.02	<0.005	<0.005
V	2A	0.10	0.01	<0.01	<0.01	0.02	<0.01	<0.01
Ni	2A	0.20	0.02	0.03	0.10	11	0.16	0.22
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
Ag	2B	0.10	0.01	<0.01	<0.01	<0.01	<0.01	<0.01

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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	2.4	<0.05	0.05
[1]Cu	3	0.25	0.025	<0.025	<0.025	0.04	<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	0.42	<0.05	<0.05
Al	4	4.0	0.40	13	<0.40	25	3.1	3.3
Fe	4	2.0	0.20	<0.20	<0.20	2.8	<0.20	<0.20
Mn	4	0.25	0.025	<0.025	<0.025	0.10	<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	<0.60	3.0	<0.60	<0.60
Mg	4	Not Applicable	0.60	<0.60	<0.60	1.1	<0.60	<0.60

[1]Specification calculated based on lower internal specification.