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ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: TRIS HYDROCHLORIDE EXCIPIENT 2021

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TABLE 1: ELEMENTAL IMPURITY RISK ASSESSMENT	Manufacturing Process DCN: 16-000622 Parenteral Specifications 10g/day MDD						
Element	**Class**	**Intentionally Added?**	**Potential Sources?**	**Manufacturing Equipment Risk?**	**Method LOQ ppm (µg/g)**	**Limits 1.0J Target ppm (µg/g)**	**Control Threshold Limits 0.3J Target ppm (µg/g)**
Cd	1	No	No	No	0.002	0.20	0.06
Pb	1	No	No	No	0.005	0.50	0.15
As	1	No	No	No	0.015	1.5	0.45
Hg	1	No	No	No	0.003	0.30	0.09
Co	2A	No	No	No	0.005	0.50	0.15
V	2A	No	No	No	0.01	1.0	0.30
Ni	2A	No	Yes	No	0.02	2.0	0.60
Tl	2B	No	No	No	0.008	0.80	0.24
Au	2B	No	No	No	0.10	10	3.0
Pd	2B	No	No	No	0.01	1.0	0.30
Ir	2B	No	No	No	0.01	1.0	0.30
Os	2B	No	No	No	0.01	1.0	0.30
Rh	2B	No	No	No	0.01	1.0	0.30
Ru	2B	No	No	No	0.01	1.0	0.30
[1]Se	2B	No	No	No	0.05	5	1.5
Ag	2B	No	No	No	0.01	1.0	0.30

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Pt	2B	No	No	No	0.01	1.0	0.30
Li	3	No	No	No	0.25	25	7.5
Sb	3	No	No	No	0.09	9.0	2.7
Ba	3	No	No	No	0.70	70	21
[1]Mo	3	No	No	No	0.05	5.0	1.5
[1]Cu	3	No	No	No	0.025	2.5	0.75
Sn	3	No	No	No	0.60	60	18
[1]Cr	3	No	No	No	0.05	5.0	1.5
[2]Additional Elements							
Al	4	No	Yes	No	0.40	40	12
Fe	4	No	No	No	0.20	20	6.0
Mn	4	No	No	No	0.025	2.5	0.75
Zn	4	No	No	No	0.20	20	6.0

[1]Specification calculated based on lower internal specification
[2]Additional Elements Specifications and Results are For Informational Purposes only.

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT				Manufacturing Process DCN: 16-000622 Parenteral Specifications: 10g/day MDD			
Element	**Class**	**Limits 1.0J Target ppm (µg/g)**	**Control Threshold Limits 0.3J Target ppm (µg/g)**	**Result Batch 1 Lot: TH3200-358-0121 ppm (µg/g)**	**Result Batch 2 Lot: TH3200-359-0221 ppm (µg/g)**	**Result Batch 3 Lot: TH3200-360-0221 ppm (µg/g)**	**Meets Control Threshold (Yes or No)**
Cd	1	0.20	0.06	<0.06	<0.06	<0.06	Yes
Pb	1	0.50	0.15	<0.15	<0.15	<0.15	Yes
As	1	1.5	0.45	<0.45	<0.45	<0.45	Yes
Hg	1	0.30	0.09	<0.09	<0.09	<0.09	Yes
Co	2A	0.50	0.15	<0.15	<0.15	<0.15	Yes
V	2A	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ni	2A	2.0	0.60	0.147	0.198	0.110	Yes
Tl	2B	0.80	0.24	<0.24	<0.24	<0.24	Yes
Au	2B	10	3.0	<3.0	<3.0	<3.0	Yes
Pd	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ir	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Os	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Rh	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ru	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
[1]Se	2B	8.0	2.4	<2.4	<2.4	<2.4	Yes

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Element	**Class**	**Limits 1.0J Target ppm (µg/g)**	**Control Threshold Limits 0.3J Target ppm (µg/g)**	**Result Batch 1 Lot: TH3200-358-0121 ppm (µg/g)**	**Result Batch 2 Lot: TH3200-359-0221 ppm (µg/g)**	**Result Batch 3 Lot: TH3200-360-0221 ppm (µg/g)**	**Meets Control Threshold (Yes or No)**
Ag	3	1.0	0.30	<0.30	<0.30	<0.30	Yes
Pt	3	1.0	0.30	<0.30	<0.30	<0.30	Yes
Li	3	25	7.5	<7.5	<7.5	<7.5	Yes
Sb	3	9.0	2.7	<2.7	<2.7	<2.7	Yes
Ba	3	70	21	<21	<21	<21	Yes
[1]Mo	3	15	4.5	0.051	0.051	<0.05	Yes
[1]Cu	3	5.0	1.5	<1.5	<1.5	<1.5	Yes
Sn	3	60	18	<18	<18	<18	Yes
[1]Cr	3	5.0	1.5	<1.5	<1.5	<1.5	Yes
[1]Additional Elements							
Al	4	40	12	0.494	0.529	0.356	Yes
Fe	4	20	6.0	<6.0	<6.0	<6.0	Yes
Mn	4	2.5	0.75	<0.75	<0.75	<0.75	Yes
Zn	4	20	6.0	<6.0	<6.0	<6.0	Yes

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