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## ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: TREHALOSE DIHYDRATE

<b>Table 1: Elemental Impurity Risk Assessment</b>			Method Validation Protocol: BSI-PRL-0509, Method Validation Report: BSI-RPT-0541 Manufacturing Process DCN: 18-001765 v.2.0 Parenteral Specifications (50 g/day MDD)			
<b>Element</b>	<b>Class</b>	<b>Intentionally Added?</b>	<b>Potential Sources?</b>	<b>Manufacturing Equipment Risk?</b>	<b>Limits 1.0J Target ppm (µg/g)</b>	<b>Control Threshold Limits 0.3J Target ppm (µg/g)</b>
Cd	1	No	No	No	0.04	0.012
Pb	1	No	'Yes	No	0.10	0.030
As	1	No	'Yes	No	0.30	0.09
Hg	1	No	No	No	0.06	0.018
Co	2A	No	No	No	0.10	0.030
V	2A	No	No	No	0.20	0.06
Ni	2A	No	No	No	0.40	0.12
Tl	2B	No	No	No	0.16	0.08
Au	2B	No	No	No	2.0	0.60
Pd	2B	No	No	No	0.20	0.06
Ir	2B	No	No	No	0.20	0.06
Os	2B	No	No	No	0.20	0.06
Rh	2B	No	No	No	0.20	0.06
Ru	2B	No	No	No	0.20	0.06
Se	2B	No	No	No	1.6	0.48
Ag	2B	No	No	No	0.20	0.06

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<b>Element</b>	<b>Class</b>	<b>Intentionally Added?</b>	<b>Potential Sources?</b>	<b>Manufacturing Equipment Risk?</b>	<b>Limits 1.0J Target ppm (µg/g)</b>	<b>Control Threshold Limits 0.3J Target ppm (µg/g)</b>
Pt	2B	No	No	No	0.20	0.06
Li	3	No	No	No	5.0	1.5
Sb	3	No	No	No	1.8	0.54
Ba	3	No	No	No	14	4.2
Mo	3	No	No	No	30	9.0
Cu	3	No	No	No	6.0	1.8
Sn	3	No	No	No	12	3.6
Cr	3	No	No	No	22	6.6

<sup>1</sup>Manufacturer provided information

<b>TABLE 2: ELEMENTAL IMPURITY ASSESSMENT</b>				Manufacturing Process DCN: 18-001765 v.2.0 Parenteral Specifications (50 g/day MDD)	
<b>Element</b>	<b>Class</b>	<b>Limits 1.0J Target ppm (µg/g)</b>	<b>Control ThresholdLimits 0.3J Target ppm (µg/g)</b>	<b>Result Batch 1 Lot: TE3200-001-0219-PV Composite Validation Protocol: BSI-PRL-0206, ppm (µg/g)</b>	<b>Meets ControlThreshold Yes or No</b>
Cd	1	0.04	0.012	<0.012	Yes
Pb	1	0.10	0.03	<0.03	Yes
As	1	0.30	0.09	<0.09	Yes
Hg	1	0.06	0.018	<0.018	Yes
Co	2A	0.10	0.03	<0.03	Yes
V	2A	0.20	0.06	<0.06	Yes
Ni	2A	0.40	0.12	<0.12	Yes
Tl	2B	0.16	0.048	<0.048	Yes
Au	2B	2.0	0.60	<0.06	Yes
Pd	2B	0.20	0.06	<0.06	Yes
Ir	2B	0.20	0.06	<0.06	Yes
Os	2B	0.20	0.06	<0.06	Yes
Rh	2B	0.20	0.06	<0.06	Yes
Ru	2B	0.20	0.06	<0.06	Yes
Se	2B	1.6	0.48	<0.48	Yes
Ag	2B	0.20	0.06	<0.06	Yes

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<b>TABLE 2: ELEMENTAL IMPURITY ASSESSMENT</b>				Manufacturing Process DCN: 18-001765 v.2.0 Parenteral Specifications (50 g/day MDD)	
<b>Element</b>	<b>Class</b>	<b>Limits 1.0J Target ppm (µg/g)</b>	<b>Control Threshold Limits 0.3J Target ppm (µg/g)</b>	<b>Result Batch 1 Lot: TE3200-001-0219-PV Composite Validation Protocol: BSI-PRL-0206, ppm (µg/g)</b>	<b>Meets Control Threshold Yes or No</b>
Pt	2B	0.20	0.06	<0.06	Yes
Li	3	5.0	1.5	<1.5	Yes
Sb	3	1.8	0.54	<0.54	Yes
Ba	3	14	4.2	<4.2	Yes
Mo	3	30	9.0	<9.0	Yes
Cu	3	6.0	1.8	<1.8	Yes
Sn	3	12	3.6	<3.6	Yes
Cr	3	22	6.6	<6.6	Yes

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