



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

ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: TREHALOSE DIHYDRATE 2021

Table 1: Elemental Impurity Risk Assessment	Analytical Method: BSI-ATM-0057, Method Validation Report: BSI-RPT-0541 Manufacturing Process DCN: BSI-PRL-0395 Parenteral Specifications (50g/day MDD)	
Element	Class	Limits 1.0J Target ppm (µg/g)
Cd	1	0.04
Pb	1	0.10
As	1	0.30
Hg	1	0.06
Co	2A	0.10
V	2A	0.20
Ni	2A	0.40
Tl	2B	0.16
Au	2B	2.0
Pd	2B	0.20
Ir	2B	0.20
Os	2B	0.20
Rh	2B	0.20
Ru	2B	0.20
Se	2B	1.6
Ag	2B	0.20
Pt	2B	0.20
Li	3	5.0

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Table 1: Elemental Impurity Risk Assessment	Analytical Method: BSI-ATM-0057, Method Validation Report: BSI-RPT-0541 Manufacturing Process DCN: BSI-PRL-0395 Parenteral Specifications (50g/day MDD)	
Element	Class	Limits 1.0J Target ppm (µg/g)
Sb	3	1.8
Ba	3	14
Mo	3	30
Cu	3	6.0
Sn	3	12
Cr	3	22
¹ Fe	4	2.0

¹Fe is not included within BSI-ATM-0057 analytical method and is for reporting only.

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT			Manufacturing Process DCN: BSI-PRL-0395 Parenteral Specifications (50g/day MDD)		
Element	Class	Limits 1.0J Target ppm (µg/g)	Result Batch 1 Lot: TRED-0121-00002-PV ppm (µg/g)	Result Batch 2 Lot: TRED-0121-00003-PV ppm (µg/g)	Result Batch 3 Lot: TRED-0121-00004-PV ppm (µg/g)
Cd	1	0.04	<0.012	<0.012	<0.012
Pb	1	0.10	<0.03	<0.03	<0.03
As	1	0.30	<0.09	<0.09	<0.09
Hg	1	0.06	<0.018	<0.018	<0.018
Co	2A	0.10	<0.03	<0.03	<0.03
V	2A	0.20	<0.06	<0.06	<0.06
Ni	2A	0.40	<0.12	<0.12	<0.12
Tl	2B	0.16	<0.048	<0.048	<0.048
Au	2B	2.0	<0.60	<0.60	<0.60
Pd	2B	0.20	<0.06	<0.06	<0.06
Ir	2B	0.20	<0.06	<0.06	<0.06
Os	2B	0.20	<0.06	<0.06	<0.06
Rh	2B	0.20	<0.06	<0.06	<0.06
Ru	2B	0.20	<0.06	<0.06	<0.06
Se	2B	1.6	<0.48	<0.48	<0.48
Ag	2B	0.20	<0.06	<0.06	<0.06
Pt	2B	0.20	<0.06	<0.06	<0.06
Li	3	5.0	<1.5	<1.5	<1.5

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Element	Class	Limits 1.0J Target ppm (µg/g)	Result Batch 1 Lot: TRED-0121-00002-PV ppm (µg/g)	Result Batch 2 Lot: TRED-0121-00003-PV ppm (µg/g)	Result Batch 3 Lot: TRED-0121-00004-PV ppm (µg/g)
Sb	3	1.8	<0.54	<0.54	<0.54
Ba	3	14	<4.2	<4.2	<4.2
Mo	3	30	<9.0	<9.0	<9.0
Cu	3	6.0	<1.8	<1.8	<1.8
Sn	3	12	<3.6	<3.6	<3.6
Cr	3	22	<6.6	<6.6	<6.6
¹ Fe	4	2.0	<0.60	<0.60	<0.60

¹Fe is not validated under analytical method BSI-ATM-0057 and is included on monitor basis.

TABLE 3: ELEMENTAL IMPURITY ASSESSMENT				Manufacturing Process DCN: BSI-PRL-0395 Parenteral Specifications (50g/day MDD)		
Element	Class	Limits 1.0J Target ppm (µg/g)	Result RM Lot: OD041 ppm (µg/g)	Result ML Lot: TRED-0121-00002- PV ML ppm (µg/g)	Result WC Lot: TRED-0121-00002- PV WC Basket #1 ppm (µg/g)	Result FG Lot: TRED-0121-00002-PV FG Drum #1 ppm (µg/g)
Cd	1	0.04	<0.012	<0.012	<0.012	<0.012
Pb	1	0.10	<0.03	<0.03	<0.03	<0.03
As	1	0.30	<0.09	<0.09	<0.09	<0.09
Hg	1	0.06	<0.018	<0.018	<0.018	<0.018
Co	2A	0.10	<0.03	<0.03	<0.03	<0.03
V	2A	0.20	<0.06	<0.06	<0.06	<0.06
Ni	2A	0.40	<0.12	<0.12	<0.12	<0.12
Tl	2B	0.16	<0.048	<0.048	<0.048	<0.048
Au	2B	2.0	<0.60	<0.60	<0.60	<0.60
Pd	2B	0.20	<0.06	<0.06	<0.06	<0.06
Ir	2B	0.20	<0.06	<0.06	<0.06	<0.06
Os	2B	0.20	<0.06	<0.06	<0.06	<0.06
Rh	2B	0.20	<0.06	<0.06	<0.06	<0.06
Ru	2B	0.20	<0.06	<0.06	<0.06	<0.06
Se	2B	1.6	<0.48	<0.48	<0.48	<0.48
Ag	3	0.20	<0.06	<0.06	<0.06	<0.06
Pt	3	0.20	<0.06	<0.06	<0.06	<0.06

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Element	Class	Limits 1.0J Target ppm (µg/g)	Result RM Lot: OD041 ppm (µg/g)	Result ML Lot: TRED-0121-00002- PV ML ppm (µg/g)	Result WC Lot: TRED-0121-00002- PV WC Basket #1 ppm (µg/g)	Result FG Lot: TRED-0121-00002-PV FG Drum #1 ppm (µg/g)
Li	3	5.0	<1.5	<1.5	<1.5	<1.5
Sb	3	1.8	<0.54	<0.54	<0.54	<0.54
Ba	3	14	<4.2	<4.2	<4.2	<4.2
Mo	3	30	<9.0	<9.0	<9.0	<9.0
Cu	3	6.0	<1.8	<1.8	<1.8	<1.8
Sn	3	12	<3.6	<3.6	<3.6	<3.6
Cr	3	22	<6.6	<6.6	<6.6	<6.6
¹ Fe	4	2.0	<0.60	<0.60	<0.60	<0.60

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