



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

ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: DEXTRAN SULFATE 8000
G13 2023 VALIDATION

TABLE 1: ELEMENTAL IMPURITY ASSESSMENT		Analytical Methods: BSI-ATM-0093, BSI-ATM-0100 Method Validation Reports: BSI-RPT-0988, BSI-RPT-1097 Dextran Sulfate 8000 Batch Record: BSI-MPR-0063 Manufacturing Process Validation: BSI-PRL-0692 Degradation and Impurity Protocol: BSI-PRL-0685 Degradation and Impurity Report: BSI-RPT-1391 Parenteral Specifications (10 g/day MDD)	
Element	Class	¹Limits 1.0J Target (µg/g)	Method Limit of Quantitation (µg/g)
Cadmium (Cd)	1	0.20	0.06
Lead (Pb)	1	0.50	0.15
Arsenic (As)	1	1.5	0.45
Mercury (Hg)	1	0.30	0.09
Cobalt (Co)	2A	0.50	0.15
Vanadium (V)	2A	1.0	0.30
Nickel (Ni)	2A	2.0	0.60
Thallium (Tl)	2B	0.80	0.24
Gold (Au)	2B	10	3.0
Palladium (Pd)	2B	1.0	0.30
Iridium (Ir)	2B	1.0	0.30
Osmium (Os)	2B	1.0	0.30
Rhodium (Rh)	2B	1.0	0.30
Ruthenium (Ru)	2B	1.0	0.30
Selenium (Se)	2B	8.0	2.4
Silver (Ag)	2B	1.0	0.30

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Element	Class	¹Limits 1.0J Target (µg/g)	Method Limit of Quantitation (µg/g)
Platinum (Pt)	2B	1.0	0.30
Lithium (Li)	3	25	7.5
Antimony (Sb)	3	9.0	2.7
Barium (Ba)	3	70	21
Molybdenum (Mo)	3	150	45
Copper (Cu)	3	30	9.0
Tin (Sn)	3	60	18
Chromium (Cr)	3	110	33
Iron (Fe)	4	15	4.5
Manganese (Mn)	4	0.50	0.05

¹Limits derived from Analytical Method BSI-ATM-0093 and BSI-ATM-0100.

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT			Analytical Methods: BSI-ATM-0093; BSI-ATM-0100 Degradation and Impurity Protocol: BSI-PRL-0685 Degradation and Impurity Report: BSI-RPT-1391 Parenteral Specifications (10 g/day MDD)			
Element	Class	Limits 1.0J Target ppm (µg/g)	Sample Lot: DXSE-0123-00004-PV			
			FG Composite Results: ppm (µg/g)	FG 1 st 10 Gallons Results: ppm (µg/g)	IP Post-Adjustment, Pre-Filtration Results: ppm (µg/g)	IP Post-Filtration Results: ppm (µg/g)
Cd	1	0.20	<0.06	<0.06	<0.06	<0.06
Pb	1	0.50	<0.15	<0.15	<0.15	<0.15
As	1	1.5	<0.45	<0.45	<0.45	<0.45
Hg	1	0.30	<0.09	<0.09	<0.09	<0.09
Co	2A	0.50	<0.15	<0.15	<0.15	<0.15
V	2A	1.0	<0.30	<0.30	<0.30	<0.30
Ni	2A	2.0	<0.60	<0.60	<0.60	<0.60
Tl	2B	0.80	<0.24	<0.24	<0.24	<0.24
Au	2B	10	<3.0	<3.0	<3.0	<3.0
Pd	2B	1.0	<0.30	<0.30	<0.30	<0.30
Ir	2B	1.0	<0.30	<0.30	<0.30	<0.30
Os	2B	1.0	<0.30	<0.30	<0.30	<0.30
Rh	2B	1.0	<0.30	<0.30	<0.30	<0.30
Ru	2B	1.0	<0.30	<0.30	<0.30	<0.30
Se	2B	8.0	<2.4	<2.4	<2.4	<2.4
Ag	2B	1.0	<0.30	<0.30	<0.30	<0.30

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT			Analytical Methods: BSI-ATM-0093; BSI-ATM-0100 Degradation and Impurity Protocol: BSI-PRL-0685 Degradation and Impurity Report: BSI-RPT-1391 Parenteral Specifications (10 g/day MDD)			
Element	Class	Limits 1.0J Target ppm (µg/g)	Sample Lot: DXSE-0123-00004-PV			
			FG Composite Results: ppm (µg/g)	FG 1 st 10 Gallons Results: ppm (µg/g)	IP Post-Adjustment, Pre-Filtration Results: ppm (µg/g)	IP Post-Filtration Results: ppm (µg/g)
Pt	2B	1.0	<0.30	<0.30	<0.30	<0.30
Li	3	25	<7.5	<7.5	<7.5	<7.5
Sb	3	9.0	<2.7	<2.7	<2.7	<2.7
Ba	3	70	<21	<21	<21	<21
Mo	3	150	<45	<45	<45	<45
Cu	3	30	<9.0	<9.0	<9.0	<9.0
Sn	3	60	<18	<18	<18	<18
Cr	3	110	<33	<33	<33	<33
Fe	4	15	<4.5	<4.5	<4.5	<4.5
Mn	4	0.50	0.075	0.084	<0.05	<0.05

TABLE 3: ELEMENTAL IMPURITY ASSESSMENT			Analytical Methods: BSI-ATM-0093; BSI-ATM-0100 Degradation and Impurity Protocol: BSI-PRL-0685 Degradation and Impurity Report: BSI-RPT-1391 Parenteral Specifications (10 g/day MDD)			
Element	Class	Limits 1.0J Target ppm (µg/g)	Sample Lot: DXSE-0123-00006-PV			
			FG Composite Results: ppm (µg/g)	FG 1 st 10 Gallons Results: ppm (µg/g)	IP Post-Adjustment, Pre-Filtration Results: ppm (µg/g)	IP Post-Filtration Results: ppm (µg/g)
Cd	1	0.20	<0.06	<0.06	<0.06	<0.06
Pb	1	0.50	<0.15	<0.15	<0.15	<0.15
As	1	1.5	<0.45	<0.45	<0.45	<0.45
Hg	1	0.30	<0.09	<0.09	<0.09	<0.09
Co	2A	0.50	<0.15	<0.15	<0.15	<0.15
V	2A	1.0	<0.30	<0.30	<0.30	<0.30
Ni	2A	2.0	<0.60	<0.60	<0.60	<0.60
Tl	2B	0.80	<0.24	<0.24	<0.24	<0.24
Au	2B	10	<3.0	<3.0	<3.0	<3.0
Pd	2B	1.0	<0.30	<0.30	<0.30	<0.30
Ir	2B	1.0	<0.30	<0.30	<0.30	<0.30
Os	2B	1.0	<0.30	<0.30	<0.30	<0.30
Rh	2B	1.0	<0.30	<0.30	<0.30	<0.30
Ru	2B	1.0	<0.30	<0.30	<0.30	<0.30
Se	2B	8.0	<2.4	<2.4	<2.4	<2.4
Ag	2B	1.0	<0.30	<0.30	<0.30	<0.30

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TABLE 3: ELEMENTAL IMPURITY ASSESSMENT			Analytical Methods: BSI-ATM-0093; BSI-ATM-0100 Degradation and Impurity Protocol: BSI-PRL-0685 Degradation and Impurity Report: BSI-RPT-1391 Parenteral Specifications (10 g/day MDD)			
Element	Class	Limits 1.0J Target ppm (µg/g)	Sample Lot: DXSE-0123-00006-PV			
			FG Composite Results: ppm (µg/g)	FG 1 st 10 Gallons Results: ppm (µg/g)	IP Post-Adjustment, Pre-Filtration Results: ppm (µg/g)	IP Post-Filtration Results: ppm (µg/g)
Pt	2B	1.0	<0.30	<0.30	<0.30	<0.30
Li	3	25	<7.5	<7.5	<7.5	<7.5
Sb	3	9.0	<2.7	<2.7	<2.7	<2.7
Ba	3	70	<21	<21	<21	<21
Mo	3	150	<45	<45	<45	<45
Cu	3	30	<9.0	<9.0	<9.0	<9.0
Sn	3	60	<18	<18	<18	<18
Cr	3	110	<33	<33	<33	<33
Fe	4	15	<4.5	<4.5	<4.5	<4.5
Mn	4	0.50	<0.05	<0.05	<0.05	<0.05

TABLE 4: ELEMENTAL IMPURITY ASSESSMENT			Analytical Methods: BSI-ATM-0093; BSI-ATM-0100 Degradation and Impurity Protocol: BSI-PRL-0685 Degradation and Impurity Report: BSI-RPT-1391 Parenteral Specifications (10 g/day MDD)			
Element	Class	Limits 1.0J Target ppm (µg/g)	Sample Lot: DXSE-0123-00007-PV			
			FG Composite Results: ppm (µg/g)	FG 1 st 10 Gallons Results: ppm (µg/g)	IP Post-Adjustment, Pre-Filtration Results: ppm (µg/g)	IP Post-Filtration Results: ppm (µg/g)
Cd	1	0.20	<0.06	<0.06	<0.06	<0.06
Pb	1	0.50	<0.15	<0.15	<0.15	<0.15
As	1	1.5	<0.45	<0.45	<0.45	<0.45
Hg	1	0.30	<0.09	<0.09	<0.09	<0.09
Co	2A	0.50	<0.15	<0.15	<0.15	<0.15
V	2A	1.0	<0.30	<0.30	<0.30	<0.30
Ni	2A	2.0	<0.60	<0.60	<0.60	<0.60
Tl	2B	0.80	<0.24	<0.24	<0.24	<0.24
Au	2B	10	<3.0	<3.0	<3.0	<3.0
Pd	2B	1.0	<0.30	<0.30	<0.30	<0.30
Ir	2B	1.0	<0.30	<0.30	<0.30	<0.30
Os	2B	1.0	<0.30	<0.30	<0.30	<0.30
Rh	2B	1.0	<0.30	<0.30	<0.30	<0.30
Ru	2B	1.0	<0.30	<0.30	<0.30	<0.30
Se	2B	8.0	<2.4	<2.4	<2.4	<2.4
Ag	2B	1.0	<0.30	<0.30	<0.30	<0.30

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TABLE 4: ELEMENTAL IMPURITY ASSESSMENT			Analytical Methods: BSI-ATM-0093; BSI-ATM-0100 Degradation and Impurity Protocol: BSI-PRL-0685 Degradation and Impurity Report: BSI-RPT-1391 Parenteral Specifications (10 g/day MDD)			
Element	Class	Limits 1.0J Target ppm (µg/g)	Sample Lot: DXSE-0123-00007-PV			
			FG Composite Results: ppm (µg/g)	FG 1 st 10 Gallons Results: ppm (µg/g)	IP Post-Adjustment, Pre-Filtration Results: ppm (µg/g)	IP Post-Filtration Results: ppm (µg/g)
Pt	2B	1.0	<0.30	<0.30	<0.30	<0.30
Li	3	25	<7.5	<7.5	<7.5	<7.5
Sb	3	9.0	<2.7	<2.7	<2.7	<2.7
Ba	3	70	<21	<21	<21	<21
Mo	3	150	<45	<45	<45	<45
Cu	3	30	<9.0	<9.0	<9.0	<9.0
Sn	3	60	<18	<18	<18	<18
Cr	3	110	<33	<33	<33	<33
Fe	4	15	<4.5	<4.5	<4.5	<4.5
Mn	4	0.50	0.086	0.079	<0.05	<0.05