



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

ELEMENTAL IMPURITY ASSESSMENT

D-GALACTOSE 2023 E06 PROCESS VALIDATION

Table 1: Elemental Impurity Risk Assessment

Analytical Method: BSI-ATM-0069, Method Validation Report: BSI-RPT-0739
Galactose Bio Excipient Grade Batch Record DCN: BSI-MPR-0062
Manufacturing Process DCN: BSI-PRL-0594
Degradation and Impurity Protocol: BSI-PRL-0437
Degradation and Impurity Report: BSI-RPT-1310
Parenteral Specifications (100g/day MDD)

Element	Class	¹ Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)
Cd	1	0.02	0.006
Pb	1	0.05	0.015
As	1	0.15	0.045
Hg	1	0.03	0.009
Co	2A	0.05	0.015
V	2A	0.10	0.03
Ni	2A	0.20	0.06
Tl	2B	0.08	0.024
Au	2B	1.0	0.30
Pd	2B	0.10	0.03
Ir	2B	0.10	0.03
Os	2B	0.10	0.03
Rh	2B	0.10	0.03
Ru	2B	0.10	0.03
Se	2B	0.50	0.15
Ag	2B	0.10	0.03

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Element	Class	¹Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)
Pt	2B	0.10	0.03
Li	3	2.5	0.75
Sb	3	0.90	0.27
Ba	3	7.0	2.1
Mo	3	0.50	0.15
Cu	3	0.25	0.075
Sn	3	6.0	1.8
Cr	3	0.50	0.15
Al	4	4.0	1.2
Fe	4	2.0	0.60
Mn	4	0.25	0.075
Zn	4	2.0	0.60

¹Limits derived from Analytical Method BSI-ATM-0069, Cadmium is the only element in the method that did not meet the criteria at the 0.1J specification.

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT

Analytical Method: BSI-ATM-0069, Method Validation Report: BSI-RPT-0739
 Galactose Bio Excipient Grade Batch Record DCN: BSI-MPR-0062
 Manufacturing Process DCN: BSI-PRL-0594
 Degradation and Impurity Protocol: BSI-PRL-0437
 Degradation and Impurity Report: BSI-RPT-1310
 Parenteral Specifications (100g/day MDD)

Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result FG Lot: GALP-0123-00007-PV Beginning Drum 1 ppm (µg/g)	Result ML Lot: GALP-0123-00007-PV ML ppm (µg/g)	Result WC Lot: GALP-0123-00007-PV WC Basket 1 ppm (µg/g)	Result RM Lot: RMAT-1122-0017 ppm (µg/g)
Cd	1	0.02	0.006	<0.006	<0.006	<0.006	<0.006
Pb	1	0.05	0.015	<0.005	<0.005	<0.005	<0.005
As	1	0.15	0.045	<0.015	<0.015	<0.015	<0.015
Hg	1	0.03	0.009	<0.003	<0.003	<0.003	<0.003
Co	2A	0.05	0.015	<0.005	<0.005	<0.005	<0.005
V	2A	0.10	0.03	<0.01	<0.01	<0.01	<0.01
Ni	2A	0.20	0.06	<0.02	<0.02	<0.02	<0.02
Tl	2B	0.08	0.024	<0.008	<0.008	<0.008	<0.008
Au	2B	1.0	0.30	<0.10	<0.10	<0.10	<0.10
Pd	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01
Ir	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01
Os	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01
Rh	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01
Ru	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01

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Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result FG Lot: GALP-0123-00007-PV Beginning Drum 1 ppm (µg/g)	Result ML Lot: GALP-0123-00007-PV ML ppm (µg/g)	Result WC Lot: GALP-0123-00007-PV WC Basket 1 ppm (µg/g)	Result RM Lot: RMAT-1122-0017 ppm (µg/g)
Se	2B	0.50	0.15	<0.05	<0.05	<0.05	<0.05
Ag	3	0.10	0.03	<0.01	<0.01	<0.01	<0.01
Pt	3	0.10	0.03	<0.01	<0.01	<0.01	<0.01
Li	3	2.5	0.75	<0.25	<0.25	<0.25	<0.25
Sb	3	0.90	0.27	<0.09	<0.09	<0.09	<0.09
Ba	3	7.0	2.1	<0.70	<0.70	<0.70	<0.70
Mo	3	0.50	0.15	<0.05	<0.05	<0.05	<0.05
Cu	3	0.25	0.075	<0.025	<0.025	<0.025	<0.025
Sn	3	6.0	1.8	<0.60	<0.60	<0.60	<0.60
Cr	3	0.50	0.15	<0.05	<0.05	<0.05	<0.05
Al	4	4.0	1.2	<0.40	<0.40	<0.40	<0.40
Fe	4	2.0	0.60	<0.20	<0.20	<0.20	<0.20
Mn	4	0.25	0.075	<0.025	<0.025	<0.025	<0.025
Zn	4	2.0	0.60	<0.20	<0.20	<0.20	<0.20

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