

DCN: BSI-RPT-0844 , , Revision: 1.1 , Effective Date: 31 Jul 2023 .



ELEMENTAL IMPURITY ASSESSMENT

MATERIAL NAME: D-GALACTOSE 2021

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

Table 1: Elemental Impurity Risk Assessment		Analytical Method: BSI-ATM-0069, Method Validation Report: BSI-RPT-0739 Galactose Bio Excipient Grade Batch Record: BSI-MPR-0049 Manufacturing Process: BSI-PRL-0398 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
Pt	2B	0.10	0.03

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

Table 1: Elemental Impurity Risk Assessment		Analytical Method: BSI-ATM-0069, Method Validation Report: BSI-RPT-0739 Galactose Bio Excipient Grade Batch Record: BSI-MPR-0049 Manufacturing Process: BSI-PRL-0398 Parenteral Specifications (100g/day MDD)	
Element	Class	¹ Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)
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: BSI-MPR-0049 Manufacturing Process: BSI-PRL-0398 Parenteral Specifications (100g/day MDD)			
Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: GALP-0121-00004-PV ppm (µg/g)	Result Batch 2 Lot: GALP-0121-00005-PV ppm (µg/g)	Result Batch 3 Lot: GALP-0121-00006-PV ppm (µg/g)	Result Batch 4 Lot: GALP-0121-00007-PV ppm (µg/g)	Meets Control Threshold Yes or No
Cd	1	0.02	0.006	<0.006	<0.006	<0.006	<0.006	Yes
Pb	1	0.05	0.015	0.0095	<0.005	<0.005	<0.005	Yes
As	1	0.15	0.045	<0.015	<0.015	<0.015	<0.015	Yes
Hg	1	0.03	0.009	<0.003	<0.003	<0.003	<0.003	Yes
Co	2A	0.05	0.015	<0.005	<0.005	<0.005	<0.005	Yes
V	2A	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Ni	2A	0.20	0.06	<0.02	0.02	<0.02	<0.02	Yes
Tl	2B	0.08	0.024	<0.008	<0.008	<0.008	<0.008	Yes
Au	2B	1.0	0.30	<0.10	<0.10	<0.10	<0.10	Yes
Pd	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Ir	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Os	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Rh	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Ru	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Se	2B	0.50	0.15	<0.05	<0.05	<0.05	<0.05	Yes
Ag	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0069, Method Validation Report: BSI-RPT-0739 Galactose Bio Excipient Grade Batch Record: BSI-MPR-0049 Manufacturing Process: BSI-PRL-0398 Parenteral Specifications (100g/day MDD)			
Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: GALP-0121- 00004-PV ppm (µg/g)	Result Batch 2 Lot: GALP-0121- 00005-PV ppm (µg/g)	Result Batch 3 Lot: GALP-0121- 00006-PV ppm (µg/g)	Result Batch 4 Lot: GALP-0121- 00007-PV ppm (µg/g)	Meets Control Threshold Yes or No
Pt	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Li	3	2.5	0.75	<0.25	<0.25	<0.25	<0.25	Yes
Sb	3	0.90	0.27	<0.09	<0.09	<0.09	<0.09	Yes
Ba	3	7.0	2.1	<0.70	<0.70	<0.70	<0.70	Yes
Mo	3	0.50	0.15	<0.05	<0.05	<0.05	<0.05	Yes
Cu	3	0.25	0.075	<0.025	<0.025	<0.025	<0.025	Yes
Sn	3	6.0	1.8	<0.60	<0.60	<0.60	<0.60	Yes
Cr	3	0.50	0.15	<0.05	<0.05	<0.05	<0.05	Yes
Al	4	4.0	1.2	<0.40	<0.40	<0.40	<0.40	Yes
Fe	4	2.0	0.60	<0.20	<0.20	<0.20	<0.20	Yes
Mn	4	0.25	0.075	<0.025	<0.025	<0.025	<0.025	Yes
Zn	4	2.0	0.60	<0.20	<0.20	<0.20	<0.20	Yes

TABLE 3: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0069, Method Validation Report: BSI-RPT-0739 Galactose Bio Excipient Grade Batch Record: BSI-MPR-0049 Manufacturing Process: BSI-PRL-0398 Parenteral Specifications (100g/day MDD)			
Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result RM Lot: PG-19-092 ppm (µg/g)	Result ML Lot: GALP-0121- 00004-PV ML ppm (µg/g)	Result WC Lot: GALP-0121- 00004-PV WC ppm (µg/g)	Result FG Lot: GALP-0121- 00004-PV Beginning ppm (µg/g)	Meets Control Threshold Yes or No
Cd	1	0.02	0.006	<0.006	<0.006	<0.006	<0.006	Yes
Pb	1	0.05	0.015	<0.005	<0.005	<0.005	0.008	Yes
As	1	0.15	0.045	<0.015	<0.015	<0.015	<0.015	Yes
Hg	1	0.03	0.009	<0.003	<0.003	<0.003	<0.003	Yes
Co	2A	0.05	0.015	<0.005	<0.005	<0.005	<0.005	Yes
V	2A	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Ni	2A	0.20	0.06	<0.02	<0.02	<0.02	<0.02	Yes
Tl	2B	0.08	0.024	<0.008	<0.008	<0.008	<0.008	Yes
Au	2B	1.0	0.30	<0.10	<0.10	<0.10	<0.10	Yes
Pd	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Ir	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Os	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Rh	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Ru	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Se	2B	0.50	0.15	<0.05	<0.05	<0.05	<0.05	Yes
Ag	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

TABLE 3: ELEMENTAL IMPURITY ASSESSMENT				Analytical Method: BSI-ATM-0069, Method Validation Report: BSI-RPT-0739 Galactose Bio Excipient Grade Batch Record: BSI-MPR-0049 Manufacturing Process: BSI-PRL-0398 Parenteral Specifications (100g/day MDD)				
Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result RM Lot: PG-19-092 ppm (µg/g)	Result ML Lot: GALP-0121-00004-PV ML ppm (µg/g)	Result WC Lot: GALP-0121-00004-PV WC ppm (µg/g)	Result FG Lot: GALP-0121-00004-PV Beginning ppm (µg/g)	Meets Control Threshold Yes or No
Pt	2B	0.10	0.03	<0.01	<0.01	<0.01	<0.01	Yes
Li	3	2.5	0.75	<0.25	<0.25	<0.25	<0.25	Yes
Sb	3	0.90	0.27	<0.09	<0.09	<0.09	<0.09	Yes
Ba	3	7.0	2.1	<0.70	<0.70	<0.70	<0.70	Yes
Mo	3	0.50	0.15	<0.05	<0.05	<0.05	<0.05	Yes
Cu	3	0.25	0.075	<0.025	<0.025	<0.025	<0.025	Yes
Sn	3	6.0	1.8	<0.60	<0.60	<0.60	<0.60	Yes
Cr	3	0.50	0.15	<0.05	<0.05	<0.05	<0.05	Yes
Al	4	4.0	1.2	<0.40	<0.40	<0.40	<0.40	Yes
Fe	4	2.0	0.60	<0.20	<0.20	<0.20	<0.20	Yes
Mn	4	0.25	0.075	<0.025	<0.025	<0.025	<0.025	Yes
Zn	4	2.0	0.60	<0.20	<0.20	<0.20	<0.20	Yes