

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

Effective Date:	06 Apr 2021	06 Apr 2024	: Date of Next Review
Prepared By:	Jared L Lobb	19-002872 v.3.0	: Supersedes
QA/QC Approval:	Carissa McCollan	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

## CERTIFICATE OF ANALYSIS

### D-GALACTOSE, PLANT DERIVED

### BIO EXCIPIENT GRADE / GALP-3251-27

(HISTORICAL CODE GA3251-K025)

LOT: GALP-0123-00061

 $C_6H_{12}O_6$   $\Delta$  F.W. 180.16 g/mol.  $\Delta$  CAS# 59-23-4

Manufacturing Date: 6/3/23 Retest Date: 6/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 8/30/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

#### EP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
<sup>2</sup> Acidity or Alkalinity	Passes Test	Passes Test
Appearance	White to almost white, crystalline or finely granulated powder	White to almost white, crystalline or finely granulated powder
<sup>2</sup> Appearance of Solution	Passes Test	Passes Test
<sup>1</sup> Assay	<sup>3</sup> 98.0%-102.0%	99.6%
<sup>2</sup> Identification A	Conforms to Reference	Conforms to Reference
<sup>1</sup> Identification B	Passes Test	Passes Test
<sup>2</sup> Identification C	Passes Test	Passes Test
<sup>2</sup> Microbial Content	TAMC $\leq 100$ CFU/g	$<10$ CFU/g
Proteins	$\leq 0.1$ mg/mL	$<0.1$ mg/mL
	Sum of Impurities A and B	$\leq 1.0\%$ $<0.05\%$
<sup>1</sup> Related Substances	Unspecified Impurities	$\leq 0.3\%$ $<0.05\%$
	Total Impurities	$\leq 2.0\%$ 0.07%
Sulfated Ash	$\leq 0.1\%$	$<0.1\%$
<sup>2</sup> Water	$\leq 1.0\%$	0.2%

## NF COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
<sup>2</sup> Acidity	Passes Test	Passes Test
<sup>2</sup> Appearance of Solution	Passes Test	Passes Test
<sup>1</sup> Assay	98.0 – 102.0%	99.6%
Barium	Passes Test	Passes Test
<sup>2</sup> Identification A	Conforms to Reference	Conforms to Reference
<sup>1</sup> Identification B	Passes Test	Passes Test
<sup>2</sup> Identification C	Passes Test	Passes Test
<sup>1</sup> Limit of Lead	≤ 0.5 ppm	<0.005 ppm
	<i>Escherichia coli</i>	Absent
	<i>Pseudomonas aeruginosa</i>	Absent
<sup>2</sup> Microbial	<i>Salmonella species</i>	Absent
Content	<i>Staphylococcus aureus</i>	Absent
	TAMC	<sup>3</sup> ≤ 100 CFU/g
	TYMC	≤ 100 CFU/g
	Lactose and 1,6-galactosyl-galactose	≤ 0.6%
	Galacturonic Acid	≤ 0.6%
	Dextrose	≤ 0.6%
<sup>1</sup> Related	Tagatose	≤ 0.6%
Substances	Dulcitol	≤ 0.6%
	Arabinose	≤ 0.6%
	Any Unspecified Impurity	≤ 0.2%
	Total Impurities	≤ 1.0%
Residue on Ignition	≤ 0.1%	<0.1 %
Optical Rotation, Specific Rotation @ 20°C	+78.0° to +81.5°	+80.7°
<sup>2</sup> Water	≤ 1.0%	0.2%

## ADDITIONAL ANALYSES

ANALYSIS	SPECIFICATION	TEST RESULT
Endotoxins	≤ 2.5 EU/g	<1.0 EU/g
<sup>1</sup> Glucose	≤ 0.1%	<0.05%
Aluminum (Al)	≤ 400 ppb	<400 ppb
Cadmium (Cd)	≤ 10 ppb	<6 ppb
Cobalt (Co)	≤ 50 ppb	<5 ppb
Chromium (Cr)	≤ 50 ppb	<50 ppb
Copper (Cu)	≤ 25 ppb	<25 ppb
Trace Metals		
Iron (Fe)	≤ 200 ppb	<200 ppb
Manganese (Mn)	≤ 25 ppb	<25 ppb
Molybdenum (Mo)	≤ 50 ppb	<50 ppb
Nickel (Ni)	≤ 50 ppb	<20 ppb
Selenium (Se)	≤ 50 ppb	<50 ppb
Vanadium (V)	≤ 50 ppb	<10 ppb
Zinc (Zn)	≤ 200 ppb	<200 ppb
<sup>1</sup> Residual Ethanol	≤ 500 ppm	<240 ppm
<sup>1</sup> Residual Isopropanol	≤ 5000 ppm	<2530 ppm
<sup>1</sup> Residual Methanol	≤ 100 ppm	<80 ppm
<sup>1</sup> Residual Methyl Isobutyl Ketone	≤ 500 ppm	<250 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 18-002374

<sup>1</sup>Alternate Validated Method<sup>2</sup>Analyses are Harmonized<sup>3</sup>Specification is more stringent than Compendia Monograph

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Prepared by: David McLaughlin Date: 10/4/23 Job Title: QA Tech IReviewed by: John Beigh Date: 10/4/23 Job Title: QA Mater. Disp. Supervisor

