BIOSPECTRA

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

Effective Date:	15-Jul-2025	15-Jul-2028	: Date of Next Review
Prepared By:	Amy Yencho	BSI-COA-0303 v.1.2	: Supersedes
QA/QC Approval:	Emily Gibbons	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS
D-GALACTOSE, PLANT DERIVED
LBLE, ULTRA LOW LEI, GMP
BIO EXCIPIENT GRADE / GALP-3252
LOT: GALP-N02-0526-0013

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

Manufacturing Date: 05/07/26 Retest Date: 05/31/28

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets EP and NF Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Acidity or Alkalinity	Acidity or Alkalinity (EP)	Passes Test	Passes Test
	Acidity (NF)	Passes Test	Passes Test
Appearance		White to almost white, crystalline or finely granulated powder	White Crystalline Powder
Appearance of Solution (EP/NF)		Passes Test	Passes Test
Assay, Anhydrous Basis HPLC (EP/NF)		98.0 - 102.0%	100.3%
Endotoxins		≤ 1.0 EU/g	< 1.0 EU/g
Glucose		≤ 0.2%	< 0.05%
Identification A (EP/NF)		Conforms to Reference	Conforms to Reference
Identification B (EP/NF)		Passes Test	Passes Test
Identification C (EP/NF)		Passes Test	Passes Test
Microbial Content	TAMC (EP/NF)	≤ 50 CFU/g	< 10 CFU/g
	TYMC (NF)	≤ 50 CFU/g	< 10 CFU/g
	Escherichia coli (NF)	Absent	Absent
	Pseudomonas aeruginosa (NF)	Absent	Absent
	Salmonella species (NF)	Absent	Absent
	Staphylococcus aureus (NF)	Absent	Absent

ANALYSIS		SPECIFICATION	TEST RESULT
Proteins (EP)		≤ 0.1 mg/mL	< 0.1 mg/mL
Related Substances	Lactose and 1,6-galactosyl-galactose (NF)	≤ 0.3%	< 0.05%
	Galacturonic acid (NF)	≤ 0.2%	< 0.05%
	Dextrose (NF)	≤ 0.2%	< 0.05%
	Tagatose (NF)	≤ 0.2%	< 0.05%
	Dulcitol (NF)	≤ 0.2%	< 0.05%
	Arabinose (NF)	≤ 0.3%	0.10%
	Any Unspecified Impurity (EP/NF)	≤ 0.2%	< 0.05%
	Sum of Impurities A and B (EP)	≤ 1.0%	< 0.05%
	Total Impurities (EP/NF)	≤ 0.8%	0.10%
Optical Rotation, Specific Rotation @ 20°C (NF)		+78.0° to +81.5°	+80.6°
Purity		≥ 99 %	100%
Residue on Ignition (NF)		≤ 0.05%	< 0.01%
Sulfated Ash (EP)		≤ 0.1%	< 0.1%
Water (EP/NF)		≤ 1.0%	0.3%
Trace Metals	Aluminum (Al)	≤ 63 ppb	< 25 ppb
	Arsenic (As)	≤ 50 ppb	< 15 ppb
	Barium (Ba)	≤ 63 ppb	< 25 ppb
	Cadmium (Cd)	≤ 50 ppb	< 2 ppb
	Cobalt (Co)	≤ 50 ppb	< 5 ppb
	Chromium (Cr)	≤ 250 ppb	< 50 ppb
	Copper (Cu)	≤ 63 ppb	< 25 ppb
	Iron (Fe)	≤ 250 ppb	< 200 ppb
	Lead (Pb)	≤ 50 ppb	< 5 ppb
	Manganese (Mn)	≤ 63 ppb	< 25 ppb
	Molybdenum (Mo)	≤ 50 ppb	< 50 ppb
	Nickel (Ni)	≤ 50 ppb	< 20 ppb
	Selenium (Se)	≤ 50 ppb	< 50 ppb
	Vanadium (V)	≤ 63 ppb	< 10 ppb
	Zinc (Zn)	≤ 250 ppb	< 200 ppb

ANALYSIS	SPECIFICATION	TEST RESULT
Residual Ethanol	≤ 200 ppm	< 100 ppm
Residual Isopropanol	≤ 5000 ppm	< 2530 ppm
Residual Methanol	≤ 200 ppm	< 50 ppm
Residual Methyl Isobutyl Ketone	≤ 500 ppm	< 250 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0026

SPECIFICATION STATEMENT: When applicable, the most stringent monograph specification will be referenced as the specification.

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: Chris McCall Date: 5/27/26 Job Title: QA Tech III

Reviewed by: Jason Bryan Date: 5/28/26 Job Title: QA Supervisor