



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

Effective Date:	15-Jul-2025	15-Jul-2028	: Date of Next Review
Prepared By:	Amy Yenko	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**  
**LBL, ULTRA LOW LEI, GMP**  
**BIO EXCIPIENT GRADE / GALP-3252**  
**LOT: GALP-N02-1225-0057**

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

Manufacturing Date: 12/11/25      Retest Date: 12/31/27

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%	99.2%
Endotoxins		$\leq 1.0$ EU/g	$< 1.0$ EU/g
Glucose		$\leq 0.2\%$	$< 0.05\%$
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
	TAMC (EP/NF)	$\leq 50$ CFU/g	$< 10$ CFU/g
	TYMC (NF)	$\leq 50$ CFU/g	10 CFU/g
	<i>Escherichia coli</i> (NF)	Absent	Absent
Microbial Content	<i>Pseudomonas aeruginosa</i> (NF)	Absent	Absent
	<i>Salmonella species</i> (NF)	Absent	Absent
	<i>Staphylococcus aureus</i> (NF)	Absent	Absent

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ANALYSIS		SPECIFICATION	TEST RESULT
Proteins (EP)		$\leq 0.1$ mg/mL	$< 0.1$ mg/mL
	Lactose and 1,6-galactosyl-galactose (NF)	$\leq 0.3\%$	$< 0.05\%$
	Galacturonic acid (NF)	$\leq 0.2\%$	$< 0.05\%$
	Dextrose (NF)	$\leq 0.2\%$	$< 0.05\%$
	Tagatose (NF)	$\leq 0.2\%$	$< 0.05\%$
Related Substances	Dulcitol (NF)	$\leq 0.2\%$	$< 0.05\%$
	Arabinose (NF)	$\leq 0.3\%$	0.20%
	Any Unspecified Impurity (EP/NF)	$\leq 0.2\%$	$< 0.05\%$
	Sum of Impurities A and B (EP)	$\leq 1.0\%$	$< 0.05\%$
	Total Impurities (EP/NF)	$\leq 0.8\%$	0.20%
Optical Rotation, Specific Rotation @ 20°C (NF)		+78.0° to +81.5°	+80.8°
Purity		$\geq 99\%$	100%
Residue on Ignition (NF)		$\leq 0.05\%$	$< 0.01\%$
Sulfated Ash (EP)		$\leq 0.1\%$	$< 0.1\%$
Water (EP/NF)		$\leq 1.0\%$	0.2%
Trace Metals	Aluminum (Al)	$\leq 63$ ppb	$< 25$ ppb
	Arsenic (As)	$\leq 50$ ppb	$< 15$ ppb
	Barium (Ba)	$\leq 63$ ppb	$< 25$ ppb
	Cadmium (Cd)	$\leq 50$ ppb	$< 2$ ppb
	Cobalt (Co)	$\leq 50$ ppb	$< 5$ ppb
	Chromium (Cr)	$\leq 250$ ppb	$< 50$ ppb
	Copper (Cu)	$\leq 63$ ppb	$< 25$ ppb
	Iron (Fe)	$\leq 250$ ppb	$< 200$ ppb
	Lead (Pb)	$\leq 50$ ppb	$< 5$ ppb
	Manganese (Mn)	$\leq 63$ ppb	$< 25$ ppb
	Molybdenum (Mo)	$\leq 50$ ppb	$< 50$ ppb
	Nickel (Ni)	$\leq 50$ ppb	$< 20$ ppb
	Selenium (Se)	$\leq 50$ ppb	$< 50$ ppb
	Vanadium (V)	$\leq 63$ ppb	$< 10$ ppb
	Zinc (Zn)	$\leq 250$ ppb	$< 200$ ppb

ANALYSIS	SPECIFICATION	TEST RESULT
Residual Ethanol	$\leq 200$ ppm	< 100 ppm
Residual Isopropanol	$\leq 5000$ ppm	< 2550 ppm
Residual Methanol	$\leq 200$ ppm	< 50 ppm
Residual Methyl Isobutyl Ketone	$\leq 500$ 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: Anil McCall Date: 1/14/26 Job Title: QA Tech III

Reviewed by: Car Aleut Date: 1/14/26 Job Title: Senior Quality Manager