BIOSPECTRA

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

Effective Date:	21-Jan-2025	21-Jan-2028	: Date of Next Review
Prepared By:	Amy Yencho	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

CERTIFICATE OF ANALYSIS

D-GALACTOSE, PLANT DERIVED

BIOTECH, MEETS EP, NF, LBLE, GMP

BIO PHARMA GRADE / GALP-4250

LOT: GALP-E06-0525-0021

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

Manufacturing Date: 05/09/25 Retest Date: 05/31/27

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

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 powder	White Crystalline Powder
Appearance of Solution (EP/NF)		Passes Test	Passes Test
Assay, Anhydrous Basis (EP/NF)		98.0 - 102.0%	99.9 %
Barium (NF)		Passes Test	Passes Test
Endotoxins		≤ 2.5 EU/g	< 1.0 EU/g
Glucose		≤ 0.1 %	< 0.05 %
Identification A (EP/NF)		Conforms to Reference Standard	Conforms to Reference Standard
Identification B (EP/NF)		Passes Test	Passes Test
Identification C (EP/NF)		Passes Test	Passes Test
Limit of Lead (NF)		≤ 0.5 ppm	< 0.005 ppm
Microbial Content	TAMC (EP/NF)	≤ 100 CFU/g	< 10 CFU/g
	TYMC (NF)	≤ 100 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)	≤ 0.6 %	< 0.05 %
	Galacturonic acid (NF)	≤ 0.6 %	< 0.05 %
	Dextrose (NF)	≤ 0.6 %	< 0.05 %
	Tagatose (NF)	≤ 0.6 %	< 0.05 %
	Dulcitol (NF)	≤ 0.6 %	< 0.05 %
	Arabinose (NF)	≤ 0.6 %	< 0.05 %
	Any Unspecified Impurity (EP/NF)	≤ 0.2 %	< 0.05 %
	Sum of Impurities A and B (EP)	≤ 1.0 %	< 0.05 %
	Total Impurities (EP/NF)	≤ 1.0 %	< 0.05 %
Optical Rotation, Specific Rotation (NF)		+78.0° to +81.5°	+80.2 °
Residue on Ignition (NF)		≤ 0.1 %	< 0.1 %
Sulfated Ash (EP)		≤ 0.1 %	< 0.1 %
Residual Ethanol		≤ 500 ppm	< 100 ppm
Residual Isopropanol		≤ 5000 ppm	< 2540 ppm
Residual Methanol		≤ 100 ppm	< 50 ppm
Residual Methyl Isobutyl Ketone		≤ 500 ppm	< 250 ppm
Water, KF (EP/NF)		≤ 1.0 %	0.2 %

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 a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Prepared by: Amil McCall Date: 10/30/25 Job Title: QA Tech III

Reviewed by: Jason Bingham Date: 10/30/25 Job Title: QA Supervisor