



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

Effective Date:	21-Jan-2025	21-Jan-2028	: Date of Next Review
Prepared By:	Amy Yenko	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-0124-00067

C₆H₁₂O₆ ★ F.W. 180.16 g/mol. ★ CAS# 59-23-4

Manufacturing Date: 05/18/24 Retest Date: 05/31/26

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
	Acidity (NF)	Passes Test
Appearance	White to almost white crystalline powder	White to almost white crystalline powder
Appearance of Solution (EP/NF)	Passes Test	Passes Test
Assay, Anhydrous Basis (EP/NF)	98.0 - 102.0%	99.6 %
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
	TAMC (EP/NF)	≤ 100 CFU/g
	TYMC (NF)	≤ 100 CFU/g
	<i>Escherichia coli</i> (NF)	Absent
Microbial Content	<i>Pseudomonas aeruginosa</i> (NF)	Absent
	<i>Salmonella species</i> (NF)	Absent
	<i>Staphylococcus aureus</i> (NF)	Absent

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ANALYSIS	SPECIFICATION	TEST RESULT
Proteins (EP)	$\leq 0.1 \text{ mg/mL}$	$< 0.1 \text{ mg/mL}$
Lactose and 1,6-galactosyl-galactose (NF)	$\leq 0.6 \%$	0.05 %
Galacturonic acid (NF)	$\leq 0.6 \%$	$< 0.05 \%$
Dextrose (NF)	$\leq 0.6 \%$	$< 0.05 \%$
Tagatose (NF)	$\leq 0.6 \%$	$< 0.05 \%$
Related Substances Dulcitol (NF)	$\leq 0.6 \%$	$< 0.05 \%$
Arabinose (NF)	$\leq 0.6 \%$	0.07 %
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)	$\leq 1.0 \%$	0.12 %
Optical Rotation, Specific Rotation (NF)	$+78.0^\circ \text{ to } +81.5^\circ$	$+80.4^\circ$
Residue on Ignition (NF)	$\leq 0.1 \%$	$< 0.1 \%$
Sulfated Ash (EP)	$\leq 0.1 \%$	$< 0.1 \%$
Residual Ethanol	$\leq 500 \text{ ppm}$	$< 240 \text{ ppm}$
Residual Isopropanol	$\leq 5000 \text{ ppm}$	$< 2520 \text{ ppm}$
Residual Methanol	$\leq 100 \text{ ppm}$	$< 80 \text{ ppm}$
Residual Methyl Isobutyl Ketone	$\leq 500 \text{ ppm}$	$< 250 \text{ ppm}$
Water, KF (EP/NF)	$\leq 1.0 \%$	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: Anil McCall Date: 1/31/25 Job Title: QA Tech III

Reviewed by: Car Allert Date: 1/31/25 Job Title: Senior Quality Manager