

BIO SPECTRA

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

Effective Date:	02-Apr-2025	02-Apr-2028	: Date of Next Review
Prepared By:	Amy Yenko	BSI-COA-0098 v.4.1	: Supersedes
QA/QC Approval:	Carissa Albert	Krista Rehrig	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

CERTIFICATE OF ANALYSIS

D-GALACTOSE, PLANT DERIVED

BIO EXCIPIENT GRADE / GALP-3250

LOT: GALP-N02-0126-0002

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

Manufacturing Date: 01/22/26 Retest Date: 01/31/28

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds EP and NF Specifications

EP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Acidity or Alkalinity	Passes Test	Passes Test
Appearance	White to almost white, crystalline powder	White to almost white, crystalline powder
Appearance of Solution	Passes Test	Passes Test
Assay, Anhydrous Basis	97.0 – 102.0%	99.8 %
Barium	Passes Test	Passes Test
Identification A	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
Identification C	Passes Test	Passes Test
Microbial Content TAMC	≤ 100 CFU/g	< 10 CFU/g
Proteins	≤ 0.1 mg/mL	< 0.1 mg/ml
Impurities A and B	$\leq 1.0\%$	0.05 %
Related Substances Unspecified Impurities	$\leq 0.3\%$ each	< 0.05 %
Total Impurities	$\leq 2.0\%$	0.26 %
Sulfated Ash	$\leq 0.1\%$	< 0.1 %
Water	$\leq 1.0\%$	0.2 %

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NF COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Acidity	Passes Test	Passes Test
Appearance of Solution	Passes Test	Passes Test
Assay, Anhydrous Basis	98.0-102.0%	99.8%
Barium	Passes Test	Passes Test
Identification A	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
Identification C	Passes Test	Passes Test
Limit of Lead	≤ 0.5 ppm	< 0.005 ppm
	<i>Escherichia coli</i>	Absent
	<i>Pseudomonas aeruginosa</i>	Absent
Microbial Content	<i>Salmonella species</i>	Absent
	<i>Staphylococcus aureus</i>	Absent
	TAMC	≤ 1000 CFU/g
	TYMC	≤ 100 CFU/g
	Lactose and 1,6-galactosyl-galactose	≤0.6%
	Galacturonic acid	≤0.6%
	Dextrose	≤0.6%
Related Substances	Tagatose	≤0.6%
	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	+78.0° to +81.5°	+80.8°
Water	≤ 1.0%	0.2%

ADDITIONAL ANALYSES		
ANALYSIS	SPECIFICATION	TEST RESULT
Endotoxins	≤ 2.5 EU/g	< 1.1 EU/g
Glucose	$\leq 0.1\%$	< 0.05%
Lead	≤ 0.5 ppm	< 0.005 ppm
Residual Ethanol	≤ 500 ppm	< 100 ppm
Residual Isopropanol	≤ 5000 ppm	< 2520 ppm
Residual Methanol	≤ 100 ppm	< 50 ppm
Residual Methyl Isobutyl Ketone	≤ 500 ppm	< 250 ppm

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0026

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: 2/24/26 Job Title: QA Tech III

Reviewed by: Jan Bingham Date: 2/24/26 Job Title: QA Supervisor

