

# BIOSPECTRA

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

Effective Date:	3-Feb-2025	3-Feb-2028	: Date of Next Review
Prepared By:	Taylor Yurick	BSI-COA-0299 v.1.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

## CERTIFICATE OF ANALYSIS D-GALACTOSE, PLANT DERIVED BIO EXCIPIENT GRADE / GALP-3350 LOT: GALP-0124-00092

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

Manufacturing Date: 4/2/24 Retest Date: 4/30/26

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	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	≤ 1.0%	<0.05 %
Related Substances	Unspecified Impurities	
	≤ 0.3% each	<0.05 %
	Total Impurities	
	≤ 2.0%	0.05 %
Sulfated Ash	≤ 0.1%	<0.1 %
Water	≤ 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	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	<i>Salmonella species</i>	Absent
Content	<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	Tagatose	≤0.6%
Substances	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°	+80.6°
Water	≤ 1.0%	0.2%

ADDITIONAL ANALYSES		
ANALYSIS	SPECIFICATION	TEST RESULT
Endotoxins	≤ 2.5 EU/g	<1.0 EU/g
Glucose	≤ 0.1%	<0.05%
Lead	≤ 0.5 ppm	<0.005 ppm
Residual Ethanol	≤ 500 ppm	<100 ppm
Residual Isopropanol	≤ 5000 ppm	<2550 ppm
Residual Methanol	≤ 100 ppm	<50 ppm
Residual Methyl Isobutyl Ketone	≤ 500 ppm	<250 ppm

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: Car Allert Date: 2/4/25 Job Title: Senior Quality Manager

Reviewed by: Jason English Date: 2/5/25 Job Title: QA Supervisor

