BIOSPECTRA

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

Effective Date:	21-Jun-2022	21-Jun-2025	: Date of Next Review
Prepared By:	Crystal Hamelburg	BSI-COA-0098 v.4.0	: Supersedes
QA/QC Approval:	Wendy Santay	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

CERTIFICATE OF ANALYSIS

D-GALACTOSE, PLANT DERIVED

BIO EXCIPIENT GRADE / NEW CODE GALP-3250-27

(HISTORICAL CODE GA3250-K025)

LOT: GALP-0122-00026

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

Manufacturing Date: 9/12/21 Retest Date: 9/30/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 10/11/22 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%	100.0 %
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
Related Substances	Impurities A and B	≤ 1.0%	0.1 %
	Unspecified Impurities	≤ 0.3% each	<0.3 %
	Total Impurities	≤ 2.0%	0.2 %
Sulfated Ash		≤ 0.1%	<0.1 %
Water		≤ 1.0%	0.2 %

NF COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
Acidity		Passes Test	Passes Test
Appearance of Solution		Passes Test	Passes Test
Assay		98.0-102.0%	100.0%
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	<0.5 ppm
Microbial Content	*Escherichia coli*	Absent	Absent
	Pseudomonas aeruginosa	Absent	Absent
	Salmonella species	Absent	Absent
	Staphylococcus aureus	Absent	Absent
	TAMC	≤ 1000 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
Related Substances	Lactose and 1,6-galactosyl-galactose	≤0.6%	0.1%
	Galacturonic acid	≤0.6%	<0.6%
	Dextrose	≤0.6%	<0.6%
	Tagatose	≤0.6%	<0.6%
	Dulcitol	≤0.6%	<0.6%
	Arabinose	≤0.6%	0.1%
	Any unspecified impurity	≤0.2%	<0.2%
	Total Impurities	≤1.0%	0.2%
Residue on Ignition		≤ 0.1%	<0.1%
Optical Rotation, Specific Rotation		+78.0° to +81.5°	+80.4°
Water		≤ 1.0%	0.2%

ADDITIONAL ANALYSES

ANALYSIS	SPECIFICATION	TEST RESULT
Endotoxins	≤ 2.5 EU/g	<1.0 EU/g
Glucose	≤ 0.1%	<0.1%
Lead	≤ 0.5 ppm	<0.5 ppm
Residual Ethanol	≤ 500 ppm	<500 ppm
Residual Isopropanol	≤ 5000 ppm	<5000 ppm
Residual Methanol	≤ 100 ppm	<100 ppm
Residual Methyl Isobutyl Ketone	≤ 500 ppm	<500 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: _____ Date: 10/17/22 Job Title: QA Specialist

Reviewed by: _____ Date: 10/18/22 Job Title: Assoc. Director of Quality