BIOSPECTRA

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

Effective Date:	15-Nov-2021	15-Nov-2024	: Date of Next Review
Prepared By:	Amy Hosein	18-002615 v.3.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Carissa McCollian	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

D-GALACTOSE, PLANT DERIVED

BIO EXCIPIENT GRADE / NEW CODE GALP-3250-10

(HISTORICAL CODE GA3250-K010)

LOT: GALP-0122-00019

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

Manufacturing Date: 10/7/21 Retest Date: 10/31/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 5/14/22 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%	98.9 %
Barium		Passes Test	Passes Test
Identification A		Passes Test	Passes Test
Identification B		Passes Test	Passes Test
Identification C		Passes Test	Passes Test
Impurities A and B		≤ 1.0%	0.2 %
Lead		≤ 0.5 ppm	< 0.5 ppm
Microbial Content	TAMC	≤ 100 CFU/g	< 10 CFU/g
Proteins		≤ 0.1 mg/ml	< 0.1 mg/ml
Sulfated Ash		≤ 0.1%	< 0.1 %
Total Impurities		≤ 2.0%	0.2 %
Unspecified Impurities		≤ 0.3% each	< 0.3 %
Water		≤ 1.0%	0.3 %

NF COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
Acidity		Passes Test	Passes Test
Appearance of Solution		Passes Test	Passes Test
Barium		Passes Test	Passes Test
Identification A		Passes Test	Passes Test
Identification B		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
Residue on Ignition		≤ 0.1%	< 0.1%
Optical Rotation, Specific Rotation		+78.0° to +81.5°	+80.4°
Water		≤ 1.0%	0.3%

ANALYSIS	SPECIFICATION	TEST RESULT
Endotoxins	≤ 2.5 EU/g	< 0.7 EU/g
Glucose	≤ 0.1%	< 0.1%
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: 18-002374

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: 5/19/22 Job Title: QA Specialist

Reviewed by: _____ Date: 5/20/22 Job Title: QA Manager