BIOSPECTRA

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

Effective Date:	06 Apr 2021	06 Apr 2024	: Date of Next Review
Prepared By:	Jared L Lobb	19-002872 v.3.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

D-GALACTOSE, PLANT DERIVED

BIO EXCIPIENT GRADE / GALP-3251-21

(HISTORICAL CODE GA3251-K020)

LOT: GALP-0124-00025

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

Manufacturing Date: 01/07/24 Retest Date: 01/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 03/02/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

EP COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
[2]Acidity or Alkalinity		Passes Test	Passes Test
Appearance		White to almost white, crystalline or finely granulated powder	White to almost white, crystalline or finely granulated powder
[2]Appearance of Solution		Passes Test	Passes Test
[1]Assay		[3]98.0%-102.0%	99.2%
[2]Identification A		Conforms to Reference	Conforms to Reference
[1]Identification B		Passes Test	Passes Test
[2]Identification C		Passes Test	Passes Test
[2]Microbial Content	TAMC	≤ 100 CFU/g	<10 CFU/g
Proteins		≤ 0.1 mg/mL	<0.1 mg/mL
[1]Related Substances	Sum of Impurities A and B	≤ 1.0%	<0.05%
	Unspecified Impurities	≤ 0.3%	<0.05%
	Total Impurities	≤ 2.0%	0.06%
Sulfated Ash		≤ 0.1%	<0.1%
[2]Water		≤ 1.0%	0.3%

NF COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
[2]Acidity		Passes Test	Passes Test
[2]Appearance of Solution		Passes Test	Passes Test
[1]Assay		98.0 – 102.0%	99.2%
Barium		Passes Test	Passes Test
[2]Identification A		Conforms to Reference	Conforms to Reference
[1]Identification B		Passes Test	Passes Test
[2]Identification C		Passes Test	Passes Test
[1]Limit of Lead		≤ 0.5 ppm	<0.005 ppm
[2]Microbial Content	*Escherichia coli*	Absent	Absent
	Pseudomonas aeruginosa	Absent	Absent
	Salmonella species	Absent	Absent
	Staphylococcus aureus	Absent	Absent
	TAMC	[3]≤ 100 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
[1]Related Substances	Lactose and 1,6-galactosyl-galactose	≤ 0.6%	<0.05%
	Galacturonic Acid	≤ 0.6%	<0.05%
	Dextrose	≤ 0.6%	<0.05%
	Tagatose	≤ 0.6%	<0.05%
	Dulcitol	≤ 0.6%	<0.05%
	Arabinose	≤ 0.6%	0.06%
	Any Unspecified Impurity	≤ 0.2%	<0.05%
	Total Impurities	≤ 1.0%	0.06%
Residue on Ignition		≤ 0.1%	<0.1 %
Optical Rotation, Specific Rotation @ 20°C		+78.0° to +81.5°	+80.6°
[2]Water		≤ 1.0%	0.3%

ADDITIONAL ANALYSES

ANALYSIS		SPECIFICATION	TEST RESULT
Endotoxins		≤ 2.5 EU/g	<1.0 EU/g
[1]Glucose		≤ 0.1%	<0.05%
Trace Metals	Aluminum (Al)	≤ 400 ppb	<400 ppb
	Cadmium (Cd)	≤ 10 ppb	<6 ppb
	Cobalt (Co)	≤ 50 ppb	<5 ppb
	Chromium (Cr)	≤ 50 ppb	<50 ppb
	Copper (Cu)	≤ 25 ppb	<25 ppb
	Iron (Fe)	≤ 200 ppb	<200 ppb
	Manganese (Mn)	≤ 25 ppb	<25 ppb
	Molybdenum (Mo)	≤ 50 ppb	<50 ppb
	Nickel (Ni)	≤ 50 ppb	<20 ppb
	Selenium (Se)	≤ 50 ppb	<50 ppb
	Vanadium (V)	≤ 50 ppb	<10 ppb
	Zinc (Zn)	≤ 200 ppb	<200 ppb
[1]Residual Ethanol		≤ 500 ppm	<240 ppm
[1]Residual Isopropanol		≤ 5000 ppm	<2500 ppm
[1]Residual Methanol		≤ 100 ppm	<80 ppm
[1]Residual Methyl Isobutyl Ketone		≤ 500 ppm	<250 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 18-002374

[1]Alternate Validated Method
[2]Analyses are Harmonized
[3]Specification is more stringent than Compendia Monograph

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: Amil McCall Date: 3/11/24 Job Title: QA Tech I

Reviewed by: Jason Bright Date: 3/11/24 Job Title: QA Supervisor