

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://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-3250-10

### (HISTORICAL CODE GA3250-K010)

LOT: GALP-0123-00096

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

Manufacturing Date: 09/07/23 Retest Date: 09/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 10/31/23 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%	99.4%
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 $\leq 100$ CFU/g	$< 10$ CFU/g
Proteins	$\leq 0.1$ 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	$\leq 2.0\%$	0.07%
Sulfated Ash	$\leq 0.1\%$	$< 0.1\%$
Water	$\leq 1.0\%$	0.3%

## NF COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Acidity	Passes Test	Passes Test
Appearance of Solution	Passes Test	Passes Test
Assay	98.0 - 102.0%	99.4%
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°	+80.7°
Water	≤ 1.0%	0.3%

## ADDITIONAL ANALYSES

ANALYSIS	SPECIFICATION	TEST RESULT
Endotoxins	$\leq 2.5$ EU/g	< 1.2 EU/g
Glucose	$\leq 0.1\%$	< 0.05%
Lead	$\leq 0.5$ ppm	< 0.005 ppm
Residual Ethanol	$\leq 500$ ppm	< 240 ppm
Residual Isopropanol	$\leq 5000$ ppm	< 2510 ppm
Residual Methanol	$\leq 100$ ppm	< 80 ppm
Residual Methyl Isobutyl Ketone	$\leq 500$ 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: M. Shafer Date: 11/09/23 Job Title: QA Mater. Disp. Tech. III

Reviewed by: [Signature] Date: 11/9/23 Job Title: QA Mater. Disp. Supervisor

