

BIO SPECTRA

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-0123-00084

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

Manufacturing Date: 08/29/23 Retest Date: 08/31/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 10/21/23 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% | 99.3% |
| 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 | $\leq 1.0\%$ | $< 0.05\%$ |
| Related Substances | Unspecified Impurities $\leq 0.3\%$ each | $< 0.05\%$ |
| Total Impurities | $\leq 2.0\%$ | 0.06% |
| Sulfated Ash | $\leq 0.1\%$ | $< 0.1\%$ |
| Water | $\leq 1.0\%$ | 0.1% |

NF COMPENDIA

| ANALYSIS | SPECIFICATION | TEST RESULT |
|-------------------------------------|--------------------------------------|-------------------|
| Acidity | Passes Test | Passes Test |
| Appearance of Solution | Passes Test | Passes Test |
| Assay | 98.0 - 102.0% | 99.3% |
| 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 | $\leq 0.6\%$ |
| | Galacturonic acid | $\leq 0.6\%$ |
| | Dextrose | $\leq 0.6\%$ |
| Related | Tagatose | $\leq 0.6\%$ |
| Substances | Dulcitol | $\leq 0.6\%$ |
| | Arabinose | $\leq 0.6\%$ |
| | Any unspecified impurity | $\leq 0.2\%$ |
| | Total Impurities | $\leq 1.0\%$ |
| Residue on Ignition | $\leq 0.1\%$ | $< 0.1\%$ |
| Optical Rotation, Specific Rotation | $+78.0^\circ$ to $+81.5^\circ$ | $+80.6^\circ$ |
| Water | $\leq 1.0\%$ | 0.1% |

ADDITIONAL ANALYSES

| ANALYSIS | SPECIFICATION | TEST RESULT |
|---------------------------------|-----------------|-------------|
| Endotoxins | ≤ 2.5 EU/g | < 1.0 EU/g |
| Glucose | $\leq 0.1\%$ | < 0.05% |
| Lead | ≤ 0.5 ppm | < 0.005 ppm |
| Residual Ethanol | ≤ 500 ppm | < 240 ppm |
| Residual Isopropanol | ≤ 5000 ppm | < 2510 ppm |
| Residual Methanol | ≤ 100 ppm | < 80 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: M. Masfuz Date: 11/08/23 Job Title: QA Mater. Disp. Tech. III

Reviewed by: Jaron Stephen Date: 11/9/23 Job Title: QA Mater. Disp. Supervisor

