



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

|                      |                                        |                    |                       |
|----------------------|----------------------------------------|--------------------|-----------------------|
| Effective Date:      | 15-Jul-2025                            | 15-Jul-2028        | : Date of Next Review |
| Prepared By:         | Amy Yencho                             | BSI-COA-0303 v.1.2 | : Supersedes          |
| QA/QC Approval:      | Emily Gibbons                          | Carissa Albert     | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. |                    |                       |

**CERTIFICATE OF ANALYSIS**  
**D-GALACTOSE, PLANT DERIVED**  
**LBLE, ULTRA LOW LEI, GMP**  
**BIO EXCIPIENT GRADE / GALP-3252**  
**LOT: GALP-0124-00038**

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

Manufacturing Date: 04/02/24      Retest Date: 04/30/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets EP and NF Specifications

| ANALYSIS                            | SPECIFICATION                                                  | TEST RESULT                                |
|-------------------------------------|----------------------------------------------------------------|--------------------------------------------|
| Acidity or Alkalinity               | Acidity or Alkalinity (EP)                                     | Passes Test                                |
|                                     | Acidity (NF)                                                   | Passes Test                                |
| Appearance                          | White to almost white, crystalline or finely granulated powder | White finely granulated crystalline powder |
| Appearance of Solution (EP/NF)      | Passes Test                                                    | Passes Test                                |
| Assay, Anhydrous Basis HPLC (EP/NF) | 98.0 - 102.0%                                                  | 99.8%                                      |
| Endotoxins                          | $\leq 1.0$ EU/g                                                | $< 1.0$ EU/g                               |
| Glucose                             | $\leq 0.2\%$                                                   | $< 0.05\%$                                 |
| Identification A (EP/NF)            | Conforms to Reference                                          | Conforms to Reference                      |
| Identification B (EP/NF)            | Passes Test                                                    | Passes Test                                |
| Identification C (EP/NF)            | Passes Test                                                    | Passes Test                                |
|                                     | TAMC (EP/NF)                                                   | $\leq 50$ CFU/g                            |
|                                     | TYMC (NF)                                                      | $\leq 50$ CFU/g                            |
|                                     | <i>Escherichia coli</i> (NF)                                   | Absent                                     |
| Microbial Content                   | <i>Pseudomonas aeruginosa</i> (NF)                             | Absent                                     |
|                                     | <i>Salmonella species</i> (NF)                                 | Absent                                     |
|                                     | <i>Staphylococcus aureus</i> (NF)                              | Absent                                     |

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| ANALYSIS                                        |                                           | SPECIFICATION    | TEST RESULT |
|-------------------------------------------------|-------------------------------------------|------------------|-------------|
| Proteins (EP)                                   |                                           | ≤ 0.1 mg/mL      | < 0.1 mg/mL |
|                                                 | Lactose and 1,6-galactosyl-galactose (NF) | ≤ 0.3%           | < 0.05%     |
|                                                 | Galacturonic acid (NF)                    | ≤ 0.2%           | < 0.05%     |
|                                                 | Dextrose (NF)                             | ≤ 0.2%           | < 0.05%     |
|                                                 | Tagatose (NF)                             | ≤ 0.2%           | < 0.05%     |
| Related Substances                              | Dulcitol (NF)                             | ≤ 0.2%           | < 0.05%     |
|                                                 | Arabinose (NF)                            | ≤ 0.3%           | < 0.05%     |
|                                                 | Any Unspecified Impurity (EP/NF)          | ≤ 0.2%           | < 0.05%     |
|                                                 | Sum of Impurities A and B (EP)            | ≤ 1.0%           | < 0.05%     |
|                                                 | Total Impurities (EP/NF)                  | ≤ 0.8%           | < 0.05%     |
| Optical Rotation, Specific Rotation @ 20°C (NF) |                                           | +78.0° to +81.5° | + 80.7°     |
| Purity                                          |                                           | ≥ 99 %           | 100%        |
| Residue on Ignition (NF)                        |                                           | ≤ 0.05%          | < 0.01%     |
| Sulfated Ash (EP)                               |                                           | ≤ 0.1%           | < 0.1%      |
| Water (EP/NF)                                   |                                           | ≤ 1.0%           | 0.2%        |
|                                                 | Aluminum (Al)                             | ≤ 63 ppb         | < 25 ppb    |
|                                                 | Arsenic (As)                              | ≤ 50 ppb         | < 15 ppb    |
|                                                 | Barium (Ba)                               | ≤ 63 ppb         | < 25 ppb    |
|                                                 | Cadmium (Cd)                              | ≤ 50 ppb         | < 2 ppb     |
|                                                 | Cobalt (Co)                               | ≤ 50 ppb         | < 5 ppb     |
|                                                 | Chromium (Cr)                             | ≤ 250 ppb        | < 50 ppb    |
|                                                 | Copper (Cu)                               | ≤ 63 ppb         | < 25 ppb    |
| Trace Metals                                    | Iron (Fe)                                 | ≤ 250 ppb        | < 20 ppb    |
|                                                 | Lead (Pb)                                 | ≤ 50 ppb         | < 5 ppb     |
|                                                 | Manganese (Mn)                            | ≤ 63 ppb         | < 25 ppb    |
|                                                 | Molybdenum (Mo)                           | ≤ 50 ppb         | < 50 ppb    |
|                                                 | Nickel (Ni)                               | ≤ 50 ppb         | < 20 ppb    |
|                                                 | Selenium (Se)                             | ≤ 50 ppb         | < 50 ppb    |
|                                                 | Vanadium (V)                              | ≤ 63 ppb         | < 10 ppb    |
|                                                 | Zinc (Zn)                                 | ≤ 250 ppb        | < 200 ppb   |

| ANALYSIS                        | SPECIFICATION   | TEST RESULT |
|---------------------------------|-----------------|-------------|
| Residual Ethanol                | $\leq 200$ ppm  | < 100 ppm   |
| Residual Isopropanol            | $\leq 5000$ ppm | < 2520 ppm  |
| Residual Methanol               | $\leq 200$ ppm  | < 50 ppm    |
| Residual Methyl Isobutyl Ketone | $\leq 500$ ppm  | < 250 ppm   |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0026

SPECIFICATION STATEMENT: When applicable, the most stringent monograph specification will be referenced as the specification.

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: Julie McCall Date: 7/23/25 Job Title: QA Technician

Reviewed by: Carla Albert Date: 7/24/25 Job Title: Senior Quality Manager