

# BIOSPECTRA

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

|                      |                                        |                     |                       |
|----------------------|----------------------------------------|---------------------|-----------------------|
| Effective Date:      | 13-May-2025                            | 13-May-2028         | : Date of Next Review |
| Prepared By:         | Carissa Albert                         | BSI-COA-0128 v. 4.3 | : Supersedes          |
| QA/QC Approval:      | Jaron Hughes                           | Krista Rehrig       | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. |                     |                       |

## CERTIFICATE OF ANALYSIS

### D-GALACTOSE, PLANT DERIVED

### BIO EXCIPIENT GRADE / GALP-3251

### LOT: GALP-N02-0526-0014

C<sub>6</sub>H<sub>12</sub>O<sub>6</sub> ▲ F.W. 180.16 g/mol. ▲ CAS# 59-23-4

Manufacturing Date: 05/12/26      Retest Date: 05/31/28

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

#### EP COMPENDIA

| ANALYSIS                            |                           | SPECIFICATION                                                  | TEST RESULT                                                    |
|-------------------------------------|---------------------------|----------------------------------------------------------------|----------------------------------------------------------------|
| <sup>2</sup> 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 |
| <sup>2</sup> Appearance of Solution |                           | Passes Test                                                    | Passes Test                                                    |
| <sup>1</sup> Assay, Anhydrous Basis |                           | <sup>3</sup> 98.0%-102.0%                                      | 99.8%                                                          |
| <sup>2</sup> Identification A       |                           | Conforms to Reference                                          | Conforms to Reference                                          |
| <sup>1</sup> Identification B       |                           | Passes Test                                                    | Passes Test                                                    |
| <sup>2</sup> Identification C       |                           | Passes Test                                                    | Passes Test                                                    |
| <sup>2</sup> Microbial Content      | TAMC                      | ≤ 100 CFU/g                                                    | < 10 CFU/g                                                     |
| Proteins                            |                           | ≤ 0.1 mg/mL                                                    | < 0.1 mg/mL                                                    |
|                                     | Sum of Impurities A and B | ≤ 1.0%                                                         | 0.07%                                                          |
| <sup>1</sup> Related Substances     | Unspecified Impurities    | ≤ 0.3%                                                         | < 0.05%                                                        |
|                                     | Total Impurities          | ≤ 2.0%                                                         | 0.39%                                                          |
| Sulfated Ash                        |                           | ≤ 0.1%                                                         | < 0.1%                                                         |
| <sup>2</sup> Water                  |                           | ≤ 1.0%                                                         | 0.3%                                                           |

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| NF COMPENDIA                               |                                      |                          |
|--------------------------------------------|--------------------------------------|--------------------------|
| ANALYSIS                                   | SPECIFICATION                        | TEST RESULT              |
| <sup>2</sup> Acidity                       | Passes Test                          | Passes Test              |
| <sup>2</sup> Appearance of Solution        | Passes Test                          | Passes Test              |
| <sup>1</sup> Assay, Anhydrous Basis        | 98.0 – 102.0%                        | 99.8%                    |
| Barium                                     | Passes Test                          | Passes Test              |
| <sup>2</sup> Identification A              | Conforms to Reference                | Conforms to Reference    |
| <sup>1</sup> Identification B              | Passes Test                          | Passes Test              |
| <sup>2</sup> Identification C              | Passes Test                          | Passes Test              |
| <sup>1</sup> Limit of Lead                 | ≤ 0.5 ppm                            | < 0.005 ppm              |
| <i>Escherichia coli</i>                    | Absent                               | Absent                   |
| <i>Pseudomonas aeruginosa</i>              | Absent                               | Absent                   |
| <sup>2</sup> Microbial                     | <i>Salmonella species</i>            | Absent                   |
| Content                                    | <i>Staphylococcus aureus</i>         | Absent                   |
|                                            | TAMC                                 | <sup>3</sup> ≤ 100 CFU/g |
|                                            | TYMC                                 | ≤ 100 CFU/g              |
|                                            | Lactose and 1,6-galactosyl-galactose | 0.07%                    |
|                                            | Galacturonic Acid                    | < 0.05%                  |
|                                            | Dextrose                             | < 0.05%                  |
| <sup>1</sup> Related                       | Tagatose                             | < 0.05%                  |
| Substances                                 | Dulcitol                             | < 0.05%                  |
|                                            | Arabinose                            | 0.32%                    |
|                                            | Any Unspecified Impurity             | < 0.05%                  |
|                                            | Total Impurities                     | 0.39%                    |
| Residue on Ignition                        | ≤ 0.1%                               | < 0.1 %                  |
| Optical Rotation, Specific Rotation @ 20°C | +78.0° to +81.5°                     | +80.9°                   |
| <sup>2</sup> Water                         | ≤ 1.0%                               | 0.3%                     |

| ADDITIONAL ANALYSES                          |                 |              |
|----------------------------------------------|-----------------|--------------|
| ANALYSIS                                     | SPECIFICATION   | TEST RESULT  |
| Endotoxins                                   | $\leq 2.5$ EU/g | $< 1.0$ EU/g |
| <sup>1</sup> Glucose                         | $\leq 0.1\%$    | $< 0.05\%$   |
| Aluminum (Al)                                | $\leq 400$ ppb  | $< 25$ ppb   |
| Cadmium (Cd)                                 | $\leq 10$ ppb   | $< 2$ ppb    |
| Cobalt (Co)                                  | $\leq 50$ ppb   | $< 5$ ppb    |
| Chromium (Cr)                                | $\leq 50$ ppb   | $< 50$ ppb   |
| Copper (Cu)                                  | $\leq 25$ ppb   | $< 25$ ppb   |
| Iron (Fe)                                    | $\leq 200$ ppb  | $< 200$ ppb  |
| Trace Metals                                 |                 |              |
| Manganese (Mn)                               | $\leq 25$ ppb   | $< 25$ ppb   |
| Molybdenum (Mo)                              | $\leq 50$ ppb   | $< 50$ ppb   |
| Nickel (Ni)                                  | $\leq 50$ ppb   | $< 20$ ppb   |
| Selenium (Se)                                | $\leq 50$ ppb   | $< 50$ ppb   |
| Vanadium (V)                                 | $\leq 50$ ppb   | $< 10$ ppb   |
| Zinc (Zn)                                    | $\leq 200$ ppb  | $< 200$ ppb  |
| <sup>1</sup> Residual Ethanol                | $\leq 500$ ppm  | $< 100$ ppm  |
| <sup>1</sup> Residual Isopropanol            | $\leq 5000$ ppm | $< 2530$ ppm |
| <sup>1</sup> Residual Methanol               | $\leq 100$ ppm  | $< 50$ ppm   |
| <sup>1</sup> Residual Methyl Isobutyl Ketone | $\leq 500$ ppm  | $< 250$ ppm  |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0026

<sup>1</sup>Alternate Validated Method

<sup>2</sup>Analyses are Harmonized

<sup>3</sup>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: David McCall Date: 9/15/26 Job Title: QA Tech III

Reviewed by: John Rugh Date: 9/15/26 Job Title: QA Supervisor

