# BI●SPECTRA

| Effective Date: | 04-APR-2024 | | 04-APR-2027 | : Date of Next Review |
|---|---|---|---|---|
| Prepared By: | Carissa Albert | | BSI-COA-0128 v. 4.0 | : Supersedes |
| QA/QC Approval: | Jaron Hughes | | Wayne Talamonti | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. | | | |

# CERTIFICATE OF ANALYSIS
## D-GALACTOSE, PLANT DERIVED
## BIO EXCIPIENT GRADE / GALP-3251-27
## LOT: GALP-0124-00051

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

Manufacturing Date: 02/29/24      Retest Date: 02/28/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 03/04/24 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% | 0.08% |
| Sulfated Ash | | ≤ 0.1% | <0.1% |
| [2]Water | | ≤ 1.0% | 0.2% |

| 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 | $\leq$ 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]$\leq$ 100 CFU/g | <10 CFU/g |
| TYMC | $\leq$ 100 CFU/g | <10 CFU/g |
| [1]Related Substances — Lactose and 1,6-galactosyl-galactose | $\leq$ 0.6% | <0.05% |
| Galacturonic Acid | $\leq$ 0.6% | <0.05% |
| Dextrose | $\leq$ 0.6% | <0.05% |
| Tagatose | $\leq$ 0.6% | <0.05% |
| Dulcitol | $\leq$ 0.6% | <0.05% |
| Arabinose | $\leq$ 0.6% | 0.08% |
| Any Unspecified Impurity | $\leq$ 0.2% | <0.05% |
| Total Impurities | $\leq$ 1.0% | 0.08% |
| Residue on Ignition | $\leq$ 0.1% | <0.1 % |
| Optical Rotation, Specific Rotation @ 20°C | +78.0° to +81.5° | +80.7° |
| [2]Water | $\leq$ 1.0% | 0.2% |

## 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: BSI-ATM-0026

[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: _Zaire Ragin_ Date: _4/17/24_ Job Title: _QA Tech 1_

Reviewed by: _Jason Hughes_ Date: _4/18/24_ Job Title: _QA Supervisor_