

BIO SPECTRA

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

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|----------------------|--------------------------------|-----------------|-----------------------|
| Effective Date: | 06 Apr 2021 | 06 Apr 2024 | : Date of Next Review |
| Prepared By: | Jared L Lobb | 19-002872 v.3.0 | : Supersedes |
| QA/QC Approval: | Carissa McCollan | Wendy Santay | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

CERTIFICATE OF ANALYSIS

D-GALACTOSE, PLANT DERIVED

BIO EXCIPIENT GRADE / GALP-3251-27

(HISTORICAL CODE GA3251-K025)

LOT: GALP-0123-00080

C₆H₁₂O₆ * F.W. 180.16 g/mol. * CAS# 59-23-4

Manufacturing Date: 8/25/23 Retest Date: 8/31/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 10/20/23 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% | 99.0% |
| 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 |
| | Sum of Impurities A and B | ≤ 1.0% <0.05% |
| ¹ Related Substances | Unspecified Impurities ≤ 0.3% | <0.05% |
| | Total Impurities | ≤ 2.0% 0.10% |
| Sulfated Ash | ≤ 0.1% | <0.1% |
| ² Water | ≤ 1.0% | 0.3% |

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% | 99.0% |
| 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 | ≤ 0.5 ppm | <0.005 ppm |
| | <i>Escherichia coli</i> | Absent |
| | <i>Pseudomonas aeruginosa</i> | Absent |
| ² Microbial | <i>Salmonella species</i> | Absent |
| Content | <i>Staphylococcus aureus</i> | Absent |
| | TAMC | ³ ≤ 100 CFU/g |
| | TYMC | ≤ 100 CFU/g |
| | Lactose and 1,6-galactosyl-galactose | ≤ 0.6% |
| | Galacturonic Acid | ≤ 0.6% |
| | Dextrose | ≤ 0.6% |
| ¹ 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% |
| Optical Rotation, Specific Rotation @ 20°C | +78.0° to +81.5° | +80.7° |
| ² Water | ≤ 1.0% | 0.3% |

ADDITIONAL ANALYSES

| ANALYSIS | SPECIFICATION | TEST RESULT |
|--|---------------|-------------|
| Endotoxins | ≤ 2.5 EU/g | <1.0 EU/g |
| ¹ Glucose | ≤ 0.1% | <0.05% |
| 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 |
| Trace Metals | | |
| 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 | <2510 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: 18-002374

¹Alternate Validated Method

²Analyses are Harmonized

³Specification 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: Amel McLaell Date: 10/31/23 Job Title: QA Tech 1

Reviewed by: John Dwyer Date: 10/31/23 Job Title: QA Mfg. Disp. Supervisor

