

# BIOSPECTRA

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

|                      |  |                   |                       |
|----------------------|--|-------------------|-----------------------|
| Effective Date:      | 20-Jul-2023                            | 20-Jul-2026       | : Date of Next Review |
| Prepared By:         | Virginia Pena                          | BSI-COA-0185v.1.1 | : Supersedes          |
| QA/QC Approval:      | Carissa Albert                         | Dora Meissner     | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. |                   |                       |

## CERTIFICATE OF ANALYSIS

### DEXTRAN SULFATE SODIUM SALT, 8000MW

### BIO PHARMA GRADE / DXSE-4250-15

### LOT: DXSE-0123-00023

(C<sub>6</sub>H<sub>7</sub>Na<sub>3</sub>O<sub>14</sub>S<sub>3</sub>)<sub>n</sub> \* M.W. 8000 \* CAS# 9011-18-1  
 Manufacture Date: 10/16/23 Retest Date: 06/30/25  
 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013  
 Packaging Date: 11/06/23  
 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS   | SPECIFICATION                    | TEST RESULT                      |
|--|----------------------------------|----------------------------------|
| Appearance                                       | Off white to light yellow powder | Off white to light yellow powder |
| Clarity (20% solution) Absorbance at 360nm       | ≤ 0.9 OD unit                    | < 0.9 OD unit                    |
| Chloride   | ≤ 1000 ppm                       | < 1000 ppm                       |
| Endotoxin  | ≤ 0.012EU/mg                     | < 0.005 EU/mg                    |
| Free Sulfate                                     | ≤ 0.2%                           | < 0.2%                           |
| Glucose  | 35 - 48%                         | 37%                              |
| Identification (Colorimetric)                    | Passes Test                      | Passes Test                      |
| Insoluble Iron                                   | ≤ 2%                             | 0.00045%                         |
| Loss on Drying                                   | ≤ 10%                            | 4%                               |
| Manganese (as reported)                          | ≤ 1 ppm                          | 0.066 ppm                        |
| pH (1% solution)                                 | 5.0 - 7.5                        | 7.0                              |
| Residue on Ignition                              | 35 - 50%                         | 42%                              |
| Pyridine   | ≤ 2%                             | < 2%                             |
| Specific Rotation [α] <sub>D</sub> <sup>20</sup> | +75° - +105°                     | +84°                             |
| Specific Viscosity (In 1.0M NaCl at 25°C)        | 0.018 - 0.032                    | 0.029                            |
| Total Bioburden                                  | ≤ 100 CFU/g                      | < 10 CFU/g                       |
| Sulfur   | 17 - 20%                         | 19 %                             |

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0091

INTENDED USE: Once the Validation Study is complete, Material represented by this Certificate of Analysis is suitable for use as a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

SHELF LIFE: The retest date is assigned based on the industry standard for Dextran Sulfate Sodium Salt 8000MW. BioSpectra's Stability Testing Program is ongoing to further support the retest date.

Prepared by: Anil McCall Date: 11/8/24 Job Title: QA Tech III

Reviewed by: Carolee Date: 11/8/24 Job Title: Senior Quality Manager