

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

Effective Date:	05-Feb-2025	05-Feb-2028	: Date of Next Review
Prepared By:	Taylor Yurick	BSI-COA-0185 v.1.2	: Supersedes
QA/QC Approval:	Jaron Hughes	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## **CERTIFICATE OF ANALYSIS**

## DEXTRAN SULFATE SODIUM SALT, 8000MW BIO PHARMA GRADE / DXSE-4250

LOT: DXSE-G13-0225-0003

(C<sub>6</sub>H<sub>7</sub>Na<sub>3</sub>O<sub>14</sub>S<sub>3</sub>)n → M.W. 8000 → CAS# 9011-18-1

Manufacture Date: 01/09/25 Retest Date: 02/28/27 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 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	0.1 OD unit
Chloride	≤ 1000 ppm	< 1000 ppm
Endotoxin	≤ 0.012EU/mg	< 0.005 EU/mg
Free Sulfate	≤ 0.2%	< 0.2%
Glucose	35 - 48%	36%
Identification (Colorimetric)	Passes Test	Passes Test
Insoluble Iron	≤ 2%	< 0.00045%
Loss on Drying	≤ 10%	3%
Manganese (as reported)	≤ 1 ppm	0.174 ppm
pH (1% solution)	5.0 - 7.5	6.7
Residue on Ignition	35 - 50%	41%
Pyridine	≤ 2%	< 2%
Specific Rotation $[\alpha]_D^{20}$	+75° - +105°	+86°
Specific Viscosity (In 1.0M NaCl at 25°C)	0.018 - 0.032	0.028
Total Bioburden	$\leq 100 \text{ CFU/g}$	< 10 CFU/g
Sulfur	17 - 20%	18 %

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0091

<u>INTENDED USE:</u> 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.

Prepared by: Aud Mcall Date: 2/13/25 Job Title: QA Tech 111

Date: 2/1925 Job Title: OA Supervisor

Reviewed by: