

# BIOSPECTRA

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

Effective Date:	20-Jan-2025	20-Jan-2028	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### DEXTRAN SULFATE SODIUM SALT, MW 8000

### BIOTECH, LBLE, GMP

### BIO PHARMA GRADE / DXSE-4252

### LOT: DXSE-0123-00020

(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 g/mol. \* CAS# 9011-18-1

Manufacture Date: 11/13/23 Retest Date: 7/31/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance (Color)	Off White to Light Yellow	Off White to Light Yellow
Appearance (Form)	Powder	Powder
Chloride Content	≤ 1000 ppm	< 1000 ppm
Clarity (20% solution) Absorbance at 360nm	≤ 0.9 OD unit	< 0.9 OD unit
Enzymes	DNase Endo/Nickase	Passes Test
	DNase Exonuclease	Passes Test
	Protease	Passes Test
Free Inorganic Sulfate	≤ 0.2 %	< 0.2 %
Glucose	35 – 48 %	37 %
Identification (Colorimetric)	Passes Test	Passes test
Insoluble Iron	≤ 2.0 %	< 0.00045 %
Loss on Drying	≤ 10.0 %	3.9 %
Microbial Content	≤ 10 CFU/g	< 10 CFU/g
pH (1% solution)	5.0 - 7.5	7.1
Residue on Ignition	35 – 50 %	42 %
Residual Pyridine	≤ 2.0 %	< 2.0 %
Specific Rotation 20°C	+75° - +105°	+85°
Total Sulfur Content	17.0% – 20.0%	17.3 %
Viscosity (In 1.0M NaCl at 25°C)	0.018 - 0.032	0.028

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0091

INTENDED USE: 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: Shirley McCall Date: 1/31/25 Job Title: QA Tech III

Reviewed by: Car Albert Date: 2/3/25 Job Title: Senior Quality Manager