

BIOBUFFER SOLUTIONS

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

Effective Date:	22-Mar-2024	22-Mar-2027	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0293, v.1.0	: Supersedes
QA/QC Approval:	Dora Meissner	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

DEXTRAN SULFATE SODIUM SALT, 8000MW

BIO ULTRA GRADE / DXSE-5201-56.62

LOT: DXSE-0124-00000

 $(C_6H_7Na_3O_{14}S_3)_n$ M.W. 8000 CAS# 9011-18-1

Manufacture Date: 11/06/23 Retest Date: 11/30/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: MM/DD/YY

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
DNase Exonuclease	Pass	Pass
DNase Endo/Nickase	Pass	Pass
Free Inorganic Sulfate	≤ 0.2%	<0.2%
Glucose	35 – 48%	36%
Identification (Colorimetric)	Pass	Pass
Insoluble Iron	≤ 2.0%	<0.00045%
Loss on Drying	≤ 10.0%	4.1%
Microbial Content	≤ 10CFU/g	<10 CFU/g
pH (1% solution)	5.0 - 7.5	7.0
Protease Detection	Pass	Pass
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%	18.1%
UV Absorbance 360nm 20% aqueous	≤ 0.9 Abs UN	<0.9 Abs UN
Viscosity (In 1.0M NaCl at 25°C)	0.018 - 0.032	0.030

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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. The material represented by this Certificate of Analysis is not suitable to be used as an Excipient, 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: Zaivee Ragim Date: 4/10/24 Job Title: QA Tech 1

Reviewed by: Janon Bingham Date: 4/10/24 Job Title: QA Supervisor