

# 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-4250-10

### LOT: DXSE-0123-00027

 $(C_6H_7Na_3O_{14}S_3)_n$  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: 11/21/23

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	$\leq 0.9$ OD unit	$< 0.9$ OD unit
Chloride	$\leq 1000$ ppm	$< 1000$ ppm
Endotoxin	$\leq 0.012$ EU/mg	$< 0.005$ EU/mg
Free Sulfate	$\leq 0.2\%$	$< 0.2\%$
Glucose	35 - 48%	36%
Identification (Colorimetric)	Passes Test	Passes Test
Insoluble Iron	$\leq 2\%$	$< 0.00045\%$
Loss on Drying	$\leq 10\%$	4%
Manganese (as reported)	$\leq 1$ ppm	0.063 ppm
pH (1% solution)	5.0 - 7.5	7.0
Residue on Ignition	35 - 50%	42%
Pyridine	$\leq 2\%$	$< 2\%$
Specific Rotation $[\alpha]_D^{20}$	$+75^\circ$ to $+105^\circ$	$+85^\circ$
Specific Viscosity (In 1.0M NaCl at 25°C)	0.018 - 0.032	0.030
Total Bioburden	$\leq 100$ CFU/g	$< 10$ CFU/g
Sulfur	17 - 20%	18%

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: M. Arafat Date: 12/04/23 Job Title: QA Mater. Disp. Tech. III

Reviewed by: Jon- Hugh Date: 12/4/23 Job Title: QA Mater. Disp. Supervisor