BIOSPECTRA

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

Effective Date:	29-Aug-2025		29-Aug-2028	: Date of Next Review
Prepared By:	Carissa Albert		BSI-COA-0330 v.1.2	: Supersedes
QA/QC Approval:	Hannah Kuchmas		Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in MasterControl.			

CERTIFICATE OF ANALYSIS
DEXTRAN POWDER, MW 10,000
BIO EXCIPIENT GRADE / D010-3201
LOT: D010-L10-0725-0008

$(C_6H_{10}O_5)n$ ⅄ M.W. 10000 ⅄ CAS# 9004-54-0
Manufacture Date: 07/11/25   Retest Date: 07/31/26
Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Appearance and Color		White to Slightly Off-White Powder	Passes Test
Chloride		< = 1 %	< 1 %
Cold Water Solubility (1%)		Passes Test	Passes Test
Absorbance (10%)	375nm	< = 0.20 OD Unit	0.01 OD unit
Heavy Metals (Pb)		< = 20 ppm	< 0.15 ppm
Intrinsic Viscosity (1%), 37°C		0.08 – 0.11	0.09
Loss on Drying		< = 7.0 %	4.9 %
pH (10%)		4.5 – 7.0	5.8
Residue on Ignition		< = 2.0 %	0.1 %
Specific Rotation (2%), 20°C		> = + 148°	+186 °

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0139

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

VALIDATION STATEMENT: Material represented by this Certificate of Analysis is a sample of the material that was manufactured during an ongoing prospective validation.

SHELF LIFE: BioSpectra's Stability Testing Program is ongoing to further support the retest date.

Prepared by: _Danil McCall_ Date: _9/12/25_ Job Title: _QA Tech III_

Reviewed by: _Can Albert_ Date: _9/12/25_ Job Title: _Senior Quality Manager_