



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-L10-0625-0005

(C₆H₁₀O₅)_n ★ M.W. 10000 ★ CAS# 9004-54-0

Manufacture Date: 06/30/25 Retest Date: 06/30/26

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	0.02 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 %	4.4 %
pH (10%)	4.5 – 7.0	6.1
Residue on Ignition	< = 2.0 %	< 2.0 %
Specific Rotation (2%), 20°C	> = + 148°	+187 °

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: Amel McAll Date: 9/12/25 Job Title: QA Tech III

Reviewed by: Car Alut Date: 9/12/25 Job Title: Senior Quality Manager