

BIOSPECTRA

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

Effective Date:	15-Apr-2025	15-Apr-2028	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0330 v.1.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Krista Rehrig	: 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-L10-0425-0000

$(C_6H_{10}O_5)_n$ M.W. 10000 CAS# 9004-54-0

Manufacture Date: 04/01/25 Retest Date: 04/30/26

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
Ash Content	$\leq 2.0 \%$	0.03 %
Chloride	$\leq 1 \%$	0.01 %
Cold Water Solubility (1% Solution)	Passes Test	Passes Test
Color of Solution (10%) 375nm	≤ 0.20 OD Units	0.02 OD unit
Heavy Metals (as Pb)	≤ 20 ppm	< 20 ppm
Intrinsic Viscosity (1% solution) @ 37°C	0.08 – 0.11	0.08
Loss on Drying	$\leq 7.0 \%$	4.6 %
pH (10% solution)	4.5 – 7.0	5.4
Specific Rotation (2% Solution) @ 20°C	$\geq +148^\circ$	$+182^\circ$

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.

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

Prepared by: Can Altun Date: 4/16/25 Job Title: Senior Quality Manager

Reviewed by: Jon Bengt Date: 4/16/25 Job Title: QA Supervisor