

BIOSPECTRA

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

Effective Date:	27-Apr-2020	27-Apr-2023	: Date of Next Review
Prepared By:	Kyle Snyder	19-002807 v.1.1	: Supersedes
QA/QC Approval:	Carissa McCollian	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

SODIUM DECANOATE

BIO EXCIPIENT GRADE / ND3320 – K005

LOT: ND3320-004-0121

$C_{10}H_{19}NaO_2$ * F.W. 194.25 g/mol. * CAS# 1002-62-6

Manufacturing Date: 1/24/20 Retest Date: 7/31/22

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 1/12/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance	White to off-white powder	White to off-white powder
Assay (Dried basis)	97.0% – 103.0%	99.9%
Identification (IR)	Passes Test	Passes Test
Loss on Drying (LOD)	3.0% max.	2.1%
pH (10%)	9.0 – 11.0	9.7
Single Impurities (GC)	≤ 1.0%	<1.0%
Sodium	Passes Test	Passes Test
Solubility in Water	Passes Test	Passes Test
Water (KF)	1.5% – 3.0%	2.2%

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 18-002419

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.

RESIDUAL SOLVENT STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

Prepared by: *Jason Hughes* Date: 1/18/21 Job Title: QA Specialist

Reviewed by: *C. M.* Date: 1/18/21 Job Title: QA Supervisor