

BIOSPECTRA

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

Effective Date:	15-Mar-2019	15-Mar-2022	: Date of Next Review
Prepared By:	Amy Yenko	18-002529 v.4.0	: Supersedes
QA/QC Approval:	Jenna Miller	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

SODIUM DECANOATE

CERTIFICATE OF ANALYSIS

BIO EXCIPIENT GRADE / ND3220 – G500

LOT: ND3220-005-1218

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

Manufacturing Date: 10/11/2018 Retest Date: 10/31/2020

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 10/15/2018

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)	95.0% – 105.0%	102.67%
Identification (IR)	Matches the reference	Matches the reference
Loss on Drying	3.0% max.	1.8866%
pH (10%)	9.0 – 11.0	10.52 @ 24.0 °C
Single Impurities (GC)	≤1.0%	≤1.0%
Total Impurities (GC)	≤3.0%	≤3.0%
Sodium	Passes Test	Passes Test
Solubility in Water	Passes Test	Passes Test
Water (KF)	≤5.0%	2.28%

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 18-002419

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured Excipient for use in further Manufacturing. 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 to be present at the specified limits. Class 3 solvent Ethanol is likely to be present at levels <5000ppm.

Prepared by: H. Beum Date: 11/8/19

Reviewed by: Cob Date: 11/8/19