BIOSPECTRA

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

Effective Date:	27-Nov-2018		27-Nov-2021	: Date of Next Review
Prepared By:	Crystal Hamelburg		18-002529 v.2.0	: 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 – K003

LOT: ND3220-003-1018

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

Manufacture Date: 10/04/2018

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 10/09/2018

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)	97.0% – 103.0%	101.74%
Identification (IR)	Passes Test	Passes Test
Loss on Drying	3.0% max.	2.1195%
pH (10%)	9.0 – 11.0	10.63 @ 25.7 °C
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%	2.16%

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 and storage of this product, there is no potential for any of the residual solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 to be present at the specified limits; furthermore, if tested this product would comply with USP/NF requirements.

Prepared by: _____ Date: 11/28/18

Reviewed by: _____ Date: 11/28/18