

# BIO SPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

|                      |                                |                 |                       |
|----------------------|--------------------------------|-----------------|-----------------------|
| Effective Date:      | 11-Mar-2021                    | 11-Mar-2021     | : Date of Next Review |
| Prepared By:         | Jared L Lobb                   | 18-002529 v.6.0 | : Supersedes          |
| QA/QC Approval:      | Jaron Hughes                   | Wendy Santay    | : Management Approval |
| Reason for Revision: | See Revision History in ensur. |                 |                       |

## CERTIFICATE OF ANALYSIS

### SODIUM DECANOATE

### BIO EXCIPIENT GRADE / NEW CODE NDEC-3220-01

#### (HISTORICAL CODE ND3220-K001)

#### LOT: NDEC-0122-00005

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

Manufacturing Date: 4/12/21      Retest Date: 4/30/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 3/7/22 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%            | 99.4%                     |
| Identification (IR)    | Passes Test               | Passes Test               |
| Loss on Drying (LOD)   | 3.0% max.                 | 2.3%                      |
| pH (10%)               | 9.0 – 11.0                | 9.9                       |
| Single Impurities (GC) | ≤ 1.0%                    | 0.1%                      |
| Sodium                 | Passes Test               | Passes Test               |
| Solubility in Water    | Passes Test               | Passes Test               |
| Water (KF)             | 1.5% – 3.0%               | 2.3%                      |

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: Jaron Hughes      Date: 3/9/22      Job Title: QA Specialist

Reviewed by: Cur      Date: 3/9/22      Job Title: QA Manager