BIOSPECTRA

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

Effective Date:	1-Mar-2021		1-Mar-2024	: Date of Next Review
Prepared By:	Jaron Hughes		18-002783 v.7.1	: 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 / NEW CODE NDEC-3201-03
(HISTORICAL CODE ND3201-K003)
LOT: NDEC-0121-00012

$C_{10}H_{19}NaO_2$ ⚊ F.W. 194.25 g/mol. ⚊ CAS# 1002-62-6
Manufacturing Date: 5/28/21   Retest Date: 11/30/23
Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
Packaging Date: 6/19/21 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)		95.0% – 105.0%	99.6%
Elemental Impurities		Complies with USP <232>	Complies with USP <232>
Identification (IR)		Matches the reference	Matches the reference
Impurities (GC)	Single Impurities	≤ 1.0%	≤ 1.0%
	Sodium Octanoate (Octanoic Acid)	Report	None Detected
	Sodium Nonanoate (Nonanoic Acid)	Report	None Detected
	Total Impurities	≤ 3.0%	≤ 3.0%
Iron		Report	<2.49 ppm
Loss on Drying		5.0% max.	2.5%
pH (10%)		9.0 – 11.0	9.9
Residual Solvents (GC)	Ethanol	Conforms to USP <467> Ethanol ≤5000ppm	≤ 5000 ppm
Sodium Quantification		Report	11.93%
Solubility in Water		Passes Test	Passes Test
Water (KF)		≤5.0%	2.5%

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.

Prepared by: _Jason Hughes_ Date: _8/23/21_ Job Title: _QA Specialist_

Reviewed by: _____ Date: _8/23/21_ Job Title: _QA Manager_