

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-0121-00005

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

Manufacturing Date: 04/12/21 Retest Date: 10/31/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 05/01/21 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%	99.4%
Elemental Impurities	Complies with USP <232>	Complies with USP <232>
Identification (IR)	Matches the reference	Matches the reference
Single Impurities	≤ 1.0%	≤ 0.1%
Sodium Octanoate (Octanoic Acid)	Report	<0.001%
Impurities (GC) Sodium Nonanoate (Nonanoic Acid)	Report	<0.001%
Total Impurities	≤ 3.0%	≤ 0.1%
Iron	Report	<2.49 ppm
Loss on Drying	5.0% max.	2.3%
pH (10%)	9.0 – 11.0	9.9
Residual Solvents (GC) Ethanol	Conforms to USP <467> Ethanol ≤5000ppm	≤ 5000 ppm
Sodium Quantification	Report	12.26%
Solubility in Water	Passes Test	Passes Test
Water (KF)	≤5.0%	2.3%

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 18-002419

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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: Willie P. Smith Date: 06/25/21 Job Title: Quality Improvement Manager

Reviewed by: C. Smith Date: 6/25/21 Job Title: QA Manager