

BIOSPECTRA

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

Effective Date:	7-Apr-2025	7-Apr-2028	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0119 v.8.2	: Supersedes
QA/QC Approval:	Krista Rehrig	Amy Yenko	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

SODIUM DECANOATE

BIO EXCIPIENT GRADE / NDEC-3201

LOT: NDEC-G13-0225-0001

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

Manufacturing Date: 11/20/24 Retest Date: 11/30/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

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%	100.7%
Elemental Impurities		Complies with USP <232>	Complies with USP <232>
Endotoxin		≤ 20.0 EU/g	< 20.0 EU/g
Identification (IR)		Matches the reference	Matches the reference
Impurities (GC)	Single Impurities	≤ 1.0%	≤ 0.2%
	Sodium Octanoate (Octanoic Acid)	Report	0.04%
	Sodium Nonanoate (Nonanoic Acid)	Report	0.05%
	Total Impurities	≤ 3.0%	≤ 0.2%
Iron		Report	< 1.5 ppm
Loss on Drying		5.0% max.	2.6%
Microbial Content	TAMC	≤ 100 CFU/g	< 100 CFU/g
	TYMC	≤ 100 CFU/g	< 100 CFU/g
pH (10%)		9.0 – 11.0	10.1
Residual Solvents (GC)	Ethanol	Conforms to USP <467> Ethanol ≤5000ppm	≤ 5000 ppm
Sodium Quantification		Report	11.13%
Solubility in Water		Passes Test	Passes Test
Water (KF)		≤5.0%	2.6%

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0029

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: Dan McCall Date: 7/21/25 Job Title: QA Tech III

Reviewed by: Car Allert Date: 7/21/25 Job Title: Senior Quality Manager