

BIOSPECTRA

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

Effective Date:	16-Apr-2021	16-Apr-2024	: Date of Next Review
Prepared By:	Shana Geffken	16-001170 v.3.0	: Supersedes
QA/QC Approval:	Jess DeMaio	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

MOPS

BIO EXCIPIENT GRADE / NEW CODE MOPS-3220-50

(HISTORICAL CODE MP3220-K050)

LOT: MOPS-0222-00312

C₇H₁₅NO₄S · Δ F.W. 209.26 g/mol. Δ CAS# 1132-61-2

Manufacturing Date: 10/04/22 Retest Date: 10/31/24

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 10/16/22 Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance (0.1 M)	250 nm	0.020 a.u. max.	0.003 a.u.
	260 nm	0.020 a.u. max.	0.003 a.u.
	280 nm	0.020 a.u. max.	0.002 a.u.
Appearance and Color	White / Crystals	White / Crystals	
Assay	99.5% min.	100.2%	
Chloride	0.005% max	<0.005%	
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Identification (IR)	Passes Test	Passes Test	
Karl Fischer Water	0.1% max.	<0.1%	
Loss on Drying	1.0% max.	<1.0%	
pH (1% solution)	3.0 – 4.5	4.2 @ 23.1 °C	
pH (2.5M)	2.5 – 4.5	3.5 @ 25.1 °C	
pK _a	7.0 – 7.5	7.2	
Residue on Ignition	0.1% max.	<0.1%	
Solubility (5%)	Passes Test	Passes Test	
Sulfate	0.005% max.	<0.005%	
Trace Metals	Arsenic (As)	5 ppm max.	<0.45 ppm
	Copper (Cu)	5 ppm max.	<0.90 ppm
	Iron (Fe)	5 ppm max.	<0.90 ppm
	Lead (Pb)	5 ppm max.	<0.15 ppm

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000498

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.

OVI 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: *Kristina Castillo* Date: 11/10/22 Job Title: QA Technician

Reviewed by: *Jill A* Date: 11/10/22 Job Title: QA Supervisor