

# BIOSPECTRA

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

Effective Date:	12-Apr-2024	12-Apr-2027	: Date of Next Review
Prepared By:	Taylor Yurick	BSI-COA-0028 v.4.0	: Supersedes
QA/QC Approval:	Shana Geffken	Jessica DeMaio	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### MOPS

### BIO EXCIPIENT GRADE / MOPS-3220-01

### LOT: MOPS-S01-1024-0234

 $C_7H_{15}NO_4S$  \* F.W. 209.26 g/mol. \* CAS# 1132-61-2

Manufacturing Date: 05/22/24 Retest Date: 05/31/26

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 10/18/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance (0.1 M)	250 nm	0.020 a.u. max.	0.002 a.u.
	260 nm	0.020 a.u. max.	0.002 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.	0.1%	
pH (1% solution)	3.0 – 4.5	4.3 @ 23.3 °C	
pH (2.5M)	2.5 – 4.5	3.6 @ 25.4 °C	
pK <sub>a</sub>	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%	

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ANALYSIS	SPECIFICATION	TEST RESULT	
Trace Metals	Arsenic (As)	5 ppm max.	< 0.45 ppm
	Copper (Cu)	5 ppm max.	< 0.15 ppm
	Iron (Fe)	5 ppm max.	< 0.30 ppm
	Lead (Pb)	5 ppm max.	< 1.0 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0008

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: Anil McCall Date: 10/18/24 Job Title: QA Tech III

Reviewed by: James Bligh Date: 10/22/24 Job Title: QA Supervisor