

# BIOSPECTRA

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

Effective Date:	19-Dec-2023	19-Dec-2026	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Carissa Albert	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

## CERTIFICATE OF ANALYSIS

### MES HYDRATE

### GMP, LOW BIOBURDEN, LOW ENDOTOXIN EXCIPIENT GRADE

### BIO EXCIPIENT GRADE / MESH-3250-01

### LOT: MESH-0123-00003

$C_6H_{13}NO_4S \cdot xH_2O$  \* F.W. 195.24 g/mol. (anhydrous basis) \* CAS# 1266615-59-1

Manufacturing Date: 06/20/23    Retest Date: 06/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 12/18/23    Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance	260 nm	≤ 0.04 a.u.	< 0.04 a.u.
(0.1M in Water)	280 nm	≤ 0.02 a.u.	< 0.02 a.u.
Appearance		White Powder	White Powder
Assay (anhydrous basis)		≥ 99.5%	100.2%
Cytotoxicity		Passes Test	Not Tested
Endotoxin		≤ 50 EU/g	< 25 EU/g
	DNase, Exonuclease Detection	Passes Test	Passes Test
Enzymes	NICKase, Endonuclease Detection	Passes Test	Passes Test
	RNase Detection	Passes Test	Passes Test
	Protease Detection	Passes Test	Passes Test
Identification (IR)		Passes Test	Passes Test
pH 1% in Water		3.5 - 4.1	3.8
Solubility 0.1M in Water		Clear and Colorless	Clear and Colorless
Total Aerobic Microbial Count		≤ 100 CFU/g	< 10 CFU/g
Total Yeast and Mold		≤ 100 CFU/g	< 10 CFU/g

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Trace Elements	Aluminum (Al)	≤ 5.0 ppm	< 1.5 ppm
	Antimony (Sb)	≤ 5.0 ppm	< 1.5 ppm
	Arsenic (As)	≤ 3.0 ppm	< 0.45 ppm
	Barium (Ba)	≤ 5.0 ppm	< 1.5 ppm
	Bismuth (Bi)	≤ 5.0 ppm	< 1.5 ppm
	Cadmium (Cd)	≤ 5.0 ppm	< 0.06 ppm
	Calcium (Ca)	≤ 20.0 ppm	< 15 ppm
	Chromium (Cr)	≤ 5.0 ppm	< 1.5 ppm
	Cobalt (Co)	≤ 5.0 ppm	< 0.15 ppm
	Copper (Cu)	≤ 5.0 ppm	< 1.5 ppm
	Iron (Fe)	≤ 5.0 ppm	< 1.5 ppm
	Lead (Pb)	≤ 5.0 ppm	< 0.15 ppm
	Lithium (Li)	≤ 5.0 ppm	< 1.5 ppm
	Manganese (Mn)	≤ 5.0 ppm	< 1.5 ppm
	Magnesium (Mg)	≤ 5.0 ppm	< 1.5 ppm
	Molybdenum (Mo)	≤ 5.0 ppm	< 1.5 ppm
	Nickel (Ni)	≤ 5.0 ppm	< 0.60 ppm
Sodium (Na)	≤ 20.0 ppm	< 6.0 ppm	
Zinc (Zn)	≤ 5.0 ppm	< 1.5 ppm	
Water (by Karl Fischer)	5.0 - 8.9%	8.8%	

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0009

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.

RESIDUAL SOLVENTS 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: M. Anafu Date: 12/21/23 Job Title: QA Mater. Disp. Tech. III

Reviewed by: Jamie Bugh Date: 12/27/23 Job Title: QA Mater. Disp. Supervisor