



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

Effective Date:	4-Feb-2025	4-Feb-2028	: Date of Next Review
Prepared By:	Taylor Yurick	BSI-COA-0287 v.1.1	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: 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

LOT: MESH-E02-1025-0007

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

Manufacturing Date: 06/16/25 Retest Date: 06/30/27

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (0.1M in Water)	260 nm	≤ 0.04 a.u.	< 0.04 a.u.
	280 nm	≤ 0.02 a.u.	< 0.02 a.u.
Appearance		White Powder	White Powder
Assay (anhydrous basis)		$\geq 99.5\%$	100.2%
Cytotoxicity (50% Concentration)		Passes Test	Passes Test
Endotoxin		≤ 50 EU/g	< 25 EU/g
Enzymes	DNase, Exonuclease Detection	Passes Test	Passes Test
	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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ANALYSIS	SPECIFICATION	TEST RESULT
Aluminum (Al)	≤ 5.0 ppm	< 1.5 ppm
Antimony (Sb)	≤ 5.0 ppm	< 2.7 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
Trace Elements 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	< 4.5 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%	8.6 %

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0123

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: *David McCall* Date: 10/22/25 Job Title: QA Tech III

Reviewed by: *Janet Blythe* Date: 10/22/25 Job Title: QA Supervisor