

BIOSPECTRA

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

Effective Date:	26-Mar-2025	26-Mar-2028	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0273 v.1.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

MES HYDRATE

BIO EXCIPIENT GRADE / MESH-3201

LOT: MESH-E02-0225-0002

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

Manufacturing Date: 02/21/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance (Color)	White	White
Appearance (Form)	Crystalline Powder	Crystalline Powder
Solubility (Color)	Colorless	Colorless
Solubility (Turbidity) 20g plus 80mL of H ₂ O	Clear	Clear
Infrared Spectrum	Conforms to Structure	Conforms to Structure
Water (by Karl Fischer)	≤ 9%	9%
A290 UV Absorbance 20% w/w	≤ 0.05 a.u.	< 0.05 a.u.
Silver (Ag)		
Arsenic (As)		
Bismuth (Bi)		
Cadmium (Cd)		
Copper (Cu)		
Trace Metals (ICP-MS)	Sum ≤ 5 ppm	< 5 ppm
Mercury (Hg)		
Molybdenum (Mo)		
Lead (Pb)		
Antimony (Sb)		
Tin (Sn)		
pH (0.5M in H ₂ O)	2.5 – 4.0	3.3
pH (1.0M in H ₂ O)	2.7 – 3.7	3.2
Titration with NaOH (anhydrous)	≥ 99.5%	100.3 %
Impurity PVS Limit Test	≤ 1 ppm	< 1 ppm

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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 SOLVENT 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: Amil McCall Date: 3/28/25 Job Title: QA Tech III

Reviewed by: Car Allert Date: 3/28/25 Job Title: Senior Quality Manager