

BIO SPECTRA

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

Effective Date:	17-Jan-2022	17-Jan-2025	: Date of Next Review
Prepared By:	Wendy Santay	BSI-COA-0214 v.3.0	: Supersedes
QA/QC Approval:	Carissa McCollan	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

HEPES

BIO EXCIPIENT GRADE / NEW CODE HEPE-3251-25

(HISTORICAL CODE HE3251-K025)

LOT: HEPE-0123-00045

 $C_8H_{18}N_2O_4S$ * F.W. 238.30 g/mol. * CAS# 7365-45-9

Manufacturing Date: 2/26/23 Retest Date: 2/28/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 3/2/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	250 nm	0.0500 a.u. max.	0.0495 a.u.
	260 nm	0.0500 a.u. max.	0.0229 a.u.
	280 nm	0.0500 a.u. max.	0.0164 a.u.
Absorbance (0.05M)	250 nm	0.0500 a.u. max.	0.0036 a.u.
	260 nm	0.0500 a.u. max.	0.0016 a.u.
	280 nm	0.0500 a.u. max.	0.0011 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay, Dried Basis		99.5% min.	100.1%
Chloride		0.005% max.	< 0.005%
Endotoxins		≤ 5 EU/g	<2 EU/g
	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
Enzymes	Protease	None Detected	None Detected
Heavy Metals (as Lead)		1 ppm max.	< 1 ppm
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		0.01% max.	<0.01%
Microbial Content	TAMC	≤ 50 CFU/g	<10 CFU/g
	TYMC	≤ 50 CFU/g	<10 CFU/g
pH (1% Soln)		4.7 – 5.6	5.3
pK _a		7.45 – 7.65	7.56

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ANALYSIS	SPECIFICATION	TEST RESULT
Residue on Ignition	0.1% max.	<0.1%
Solubility (1% Soln)	Pass/Clear Solution	Pass/Clear Solution
Solubility (0.05M)	Passes Test	Passes Test
Sulfate	0.005% max.	< 0.005%
Trace Metals	Arsenic (As)	< 5 ppm
	Copper (Cu)	< 5 ppm
	Iron (Fe)	< 5 ppm
	Lead (Pb)	< 5 ppm
Water Content (Karl Fischer)	0.5% max.	0.1%

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0070

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: David McCall Date: 5/24/23 Job Title: QA Support Tech

Reviewed by: Jim Singh Date: 5/24/23 Job Title: QA Mater. Disp. Supervisor