

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

Effective Date:	27-May-2021	27-May-2024	: Date of Next Review
Prepared By:	Jess DeMaio	Not Applicable	: Supersedes
QA/QC Approval:	Emily Gibbons	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

## <sup>1</sup>CERTIFICATE OF ANALYSIS

### HEPES

### ANALYTICAL SUMMARY

### BIO EXCIPIENT GRADE / NEW CODE HEPE-3251-25

### (HISTORICAL CODE HE3251-K025)

### LOT: HEPE-0123-00103

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

Manufacturing Date: 8/11/23 Retest Date: 8/31/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 8/17/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	250 nm	0.0500 a.u. max.	0.0389 a.u.
	260 nm	0.0500 a.u. max.	0.0126 a.u.
	280 nm	0.0500 a.u. max.	0.0092 a.u.
Absorbance (0.05M)	250 nm	0.0500 a.u. max.	0.0035 a.u.
	260 nm	0.0500 a.u. max.	0.0013 a.u.
	280 nm	0.0500 a.u. max.	0.0008 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay, Dried Basis		99.5% min.	100.5%
Chloride		0.005% max.	< 0.005%
Endotoxin		≤ 5 EU/g	<1 EU/g
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	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

ANALYSIS		SPECIFICATION	TEST RESULT
	pK <sub>a</sub>	7.45 – 7.65	7.58
	Residue on Ignition	0.1% max.	<0.1%
	Solubility (1%)	Passes Test	Passes Test
	Solubility (0.05M)	Passes Test	Passes Test
	Sulfate	0.005% max.	<0.005%
	Arsenic (As)	5 ppm max.	<0.45 ppm
Trace Metals	Copper (Cu)	5 ppm max.	<1.5 ppm
	Iron (Fe)	5 ppm max.	<1.5 ppm
	Lead (Pb)	5 ppm max.	<0.15 ppm
	Water (Karl Fischer)	≤ 0.5%	0.4%

COUNTRY OF ORIGIN: U.S.A.

<sup>1</sup>CERTIFICATE OF ANALYSIS ANALYTICAL SUMMARY: This Certificate of Analysis serves as an analytical summary of the results. Method Development Test results are reported and may be generated from a non-validated method. The results will serve as proof of analysis capability.

Prepared by: Anil McCall Date: 9/7/23 Job Title: QA Support Tech

Reviewed by: Jon Singh Date: 9/7/23 Job Title: QA Mater. Disp. Supervisor