

BIOSPECTRA

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

Effective Date:	4-Oct-2021	4-Oct-2024	: Date of Next Review
Prepared By:	Danielle Gathagan	Not Applicable	: Supersedes
QA/QC Approval:	Jess DeMaio	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

HEPES

BIO EXCIPIENT GRADE / NEW CODE HEPE-3220-20

(HISTORICAL CODE HE4220-K020)

LOT: HEPE-0121-00141

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

Manufacturing Date: 7/29/21 Retest Date: 7/31/23

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 9/18/21

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance (0.1M)	250 nm	0.0500 a.u. max.	0.0052 a.u.
	260 nm	0.0500 a.u. max.	0.0009 a.u.
	280 nm	0.0800 a.u. max.	0.0008 a.u.
Absorbance (0.05M)	250 nm	0.0500 a.u. max.	0.0039 a.u.
	260 nm	0.0500 a.u. max.	0.0017 a.u.
	280 nm	0.0800 a.u. max.	0.0014 a.u.
Appearance and Color	White / Crystals	White / Crystals	
Assay, Dried Basis	99.5% min.	100.3%	
Chloride	0.005% max.	< 0.005%	
Endotoxins	≤ 5 EU/g	<1 EU/g	
	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
Enzymes	Protease	None Detected	None Detected
	Heavy Metals	1 ppm max.	< 1 ppm
Identification (IR)	Passes Test	Passes Test	
Insoluble Matter	0.01% max.	<0.01%	
Loss on Drying	0.5% max.	0.2%	
Microbial Content	TAMC	≤ 100 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
pH (5% Soln)	5.0 – 6.5	5.3	
pK _a	7.45 – 7.65	7.52	

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ANALYSIS	SPECIFICATION	TEST RESULT
Residue on Ignition	0.1% max.	<0.1%
Solubility (5%)	Passes Test	Passes Test
Solubility (0.05M)	Passes Test	Passes Test
Sulfate	0.005% max.	< 0.005%
	Arsenic (As)	< 5 ppm
Trace Metals	Copper (Cu)	< 5 ppm
	Iron (Fe)	< 5 ppm
	Lead (Pb)	< 5 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-001305

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: M. Shafer Date: 10/8/21 Job Title: QA Tech. I

Reviewed by: C. W. Date: 10/8/21 Job Title: QA Manager