BIOSPECTRA

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

Effective Date:	01-Mar-2021	01-Mar-2024	: Date of Next Review
Prepared By:	Jared L Lobb	16-001185 v.5.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

HEPES

BIO EXCIPIENT GRADE / NEW CODE HEPE-3220-25

(HISTORICAL CODE HE3220-K025)

LOT: HEPE-0121-00192

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

Manufacturing Date: 11/30/21 Retest Date: 11/30/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 12/7/21

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (0.1M)	250 nm	0.0500 a.u. max.	0.0104 a.u.
	260 nm	0.0500 a.u. max.	0.0058 a.u.
	280 nm	0.0800 a.u. max.	0.0052 a.u.
Absorbance (0.05M)	250 nm	0.0500 a.u. max.	0.0059 a.u.
	260 nm	0.0500 a.u. max.	0.0038 a.u.
	280 nm	0.0800 a.u. max.	0.0034 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay, Dried Basis		99.5% min.	100.0%
Chloride		0.005% max.	< 0.005%
Endotoxins		≤ 5 EU/g	<1 EU/g
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	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.	0.1%
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%
Trace Metals	Arsenic (As)	5 ppm max.	< 5 ppm
	Copper (Cu)	5 ppm max.	< 5 ppm
	Iron (Fe)	5 ppm max.	< 5 ppm
	Lead (Pb)	5 ppm max.	< 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: _____ Date: 12/21/21 Job Title: QA Specialist

Reviewed by: _____ Date: 12/21/21 Job Title: QA Manager

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