BIOSPECTRA

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

Effective Date:	23-Jun-2017	23-Jun-2020	: Date of Next Review
Prepared By:	Jamie Storm	16-000073 v2.0	: Supersedes
QA/QC Approval:	Crystal Hamelburg	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

HEPES

CERTIFICATE OF ANALYSIS

BIO PHARMA GRADE / HE4220 – K001

LOT: HE4220-027-0719

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

Manufacture Date: 6/14/2019 Retest Date: 6/30/2021

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 7/17/2019

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (0.1M)	250 nm	0.0500 a.u. max.	0.0083 a.u.
	260 nm	0.0500 a.u. max.	0.0040 a.u.
	280 nm	0.0800 a.u. max.	0.0031 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay, Dried Basis		99.5% min.	100.40%
Chloride		0.005% max.	<0.005%
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.	<0.0015%
Loss on Drying		0.5% max.	0.1256%
pH (5% Soln)		5.0 – 6.5	5.27 @ 23.2 °C
pK_a		7.45 – 7.65	7.51
Residue on Ignition		0.1% max.	<0.0299%
Solubility (5%)		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.

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TEST METHOD REFERENCE: DCN: 16-001305

RESIDUAL SOLVENTS: BioSpectra certifies that the HEPES manufactured at BioSpectra comply with the requirements of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents. There are no Class 1, 2, 3 or other solvents used or produced in the manufacturing or purification of HEPES.

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: IPEC Compliant GMP Manufactured Chemical, for use in further Manufacturing or as a Reagent for Laboratory and Research. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Prepared by: _____ Date: 7/24/19

Reviewed by: _____ Date: 7/24/19

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