

BIOSPECTRA

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

Effective Date:	10-Jun-2020	10-Jun-2023	: Date of Next Review
Prepared By:	Amy Hosein	20-003115 v.4.1	: Supersedes
QA/QC Approval:	Wendy Santay	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

HEPES

BIO EXCIPIENT GRADE / HE3250 – G500

LOT: HE3250-003-0820

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

Manufacturing Date: 06/17/20 Retest Date: 06/30/22

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 08/26/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
	250nm	≤ 0.0500 a.u.	0.0116 a.u.
Absorbance (0.1M)	260nm	≤ 0.0500 a.u.	0.0066 a.u.
	280nm	≤ 0.0800 a.u.	0.0060 a.u.
Appearance and Color		White / Crystals	White / Crystals
Appearance of Solution (1% water)		Conforms	Conforms
Assay, Dried Basis		$\geq 99.5\%$	100.4%
Chloride		≤ 50 ppm	< 50 ppm
Endotoxins		≤ 5 EU/g	< 1 EU/g
	DNases (Exo-and endonucleases)	None Detected	None Detected
Enzymes	RNases	None Detected	None Detected
	Protease	None Detected	None Detected
Heavy Metals (as Pb)		≤ 1 ppm	< 1 ppm
Identification (IR)		Passes Test	Passes Test
Identification (TLC)		Conforms	Conforms
Insoluble Matter		$\leq 0.01\%$	< 0.01%
Loss on Drying (105°C)		$\leq 0.2\%$	< 0.2%
Methanol		≤ 3000 ppm	< 3000 ppm
	Bile tolerant Gram-negative Bacteria (Absent in 1g)	Conforms	Conforms
Microbial	<i>Candida albicans</i> (Absent in 1g)	Conforms	Conforms
Content	<i>Escherichia coli</i> (Absent in 1g)	Conforms	Conforms
	<i>Pseudomonas aeruginosa</i> (Absent in 1g)	Conforms	Conforms

ANALYSIS	SPECIFICATION	TEST RESULT	
	<i>Salmonella species</i> (Absent in 10g)	Conforms	Conforms
Microbial Content	<i>Staphylococcus aureus</i> (Absent in 1g)	Conforms	Conforms
	TAMC	≤ 100 CFU/g	< 10 CFU/g
	TYMC	≤ 50 CFU/g	< 10 CFU/g
pH (5% Soln)	5.0 – 6.5		5.3
pH (1% Water)	4.7 - 5.3		5.3
pK _a	7.45 – 7.65		7.50
Residue on Ignition	≤ 0.1%		< 0.1%
Solubility (5%)	Passes Test		Passes Test
Sulfate	≤ 50 ppm		< 50 ppm
Sulfated Ash (600°C)	≤ 0.10%		< 0.03%
	Arsenic (As)	≤ 5 ppm	< 5 ppm
	Calcium (Ca)	≤ 50 ppm	< 50 ppm
	Cadmium (Cd)	≤ 5 ppm	< 5 ppm
	Cobalt (Co)	≤ 5 ppm	< 5 ppm
	Copper (Cu)	≤ 5 ppm	< 5 ppm
	Chromium (Cr)	≤ 5 ppm	< 5 ppm
Trace Metals	Iron (Fe)	≤ 5 ppm	< 5 ppm
	Lead (Pb)	≤ 1 ppm	< 1 ppm
	Magnesium (Mg)	≤ 10 ppm	< 10 ppm
	Manganese (Mn)	≤ 5 ppm	< 5 ppm
	Nickel (Ni)	≤ 5 ppm	< 5 ppm
	Potassium (K)	≤ 50 ppm	< 50 ppm
	Zinc (Zn)	≤ 5 ppm	< 5 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-001305

ELEMENTAL IMPURITIES: This product complies with ICHQ3D, USP <232> and USP <233> requirements for Elemental Impurities.

RESIDUAL SOLVENTS: 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.

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.

Prepared by: QAD/ku Date: 10/28/20 Job Title: QA Document Specialist

Reviewed by: Colin Date: 10/28/20 Job Title: QA Supervisor

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