

BIOSPECTRA

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

Effective Date:	22-Jan-2025	22-Jan-2028	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

HEPES

BIOTECH, LBLE, GMP

BIO PHARMA GRADE / HEPE-4250

LOT: HEPE-0124-00084

C₈H₁₈N₂O₄S * F.W. 238.30 g/mol. * CAS# 7365-45-9

Manufacturing Date: 8/3/24 Retest Date: 8/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (0.1M)	250 nm	≤ 0.0500 a.u.	0.0073 a.u.
	260 nm	≤ 0.0500 a.u.	0.0030 a.u.
	280 nm	≤ 0.0800 a.u.	0.0023 a.u.
Absorbance (0.05M)	250 nm	≤ 0.0500 a.u.	0.0040 a.u.
	260 nm	≤ 0.0500 a.u.	0.0018 a.u.
	280 nm	≤ 0.0800 a.u.	0.0013 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay, Dried Basis		≥ 99.5 %	100.4 %
Chloride		≤ 50 ppm	< 50 ppm
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		≤ 1 ppm	< 1 ppm
Identification, IR		Conforms to Reference Standard	Conforms to Reference Standard
Insoluble Matter		≤ 0.01 %	< 0.01 %
Loss on Drying		≤ 0.5 %	< 0.5 %
Microbial Content	TAMC	≤ 100 CFU/g	< 10 CFU/g
	TYMC	≤ 100 CFU/g	< 10 CFU/g
pH (5% solution)		5.0 – 6.5	5.3
pK _a		7.45 – 7.65	7.52
Residue on Ignition		≤ 0.1 %	< 0.1 %
Solubility (5%)		Passes Test	Passes Test


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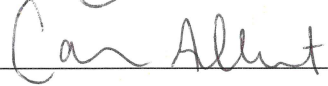
ANALYSIS	SPECIFICATION	TEST RESULT
Solubility (0.05M)	Passes Test	Passes Test
Sulfate	≤ 50 ppm	< 50 ppm
Arsenic (As)	≤ 5 ppm	< 0.45 ppm
Aluminum (Al)	≤ 5 ppm	< 1.5 ppm
Bismuth (Bi)	≤ 5 ppm	< 3.0 ppm
Calcium (Ca)	≤ 10 ppm	< 0.60 ppm
Copper (Cu)	≤ 5 ppm	< 0.15 ppm
Trace Metals		
Iron (Fe)	≤ 5 ppm	< 0.30 ppm
Lead (Pb)	≤ 5 ppm	< 0.30 ppm
Lithium (Li)	≤ 5 ppm	< 1.5 ppm
Molybdenum (Mo)	≤ 5 ppm	< 3.0 ppm
Nickel (Ni)	≤ 5 ppm	< 0.75 ppm
Potassium (K)	≤ 50 ppm	< 15 ppm
Water, KF	≤ 0.1 %	0.1 %

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0070

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. 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: 2/3/25 Job Title: QA Technician 1

Reviewed by:  Date: ~~2/2~~ 2/5/25 Job Title: Senior Quality Manager
incorrect date
CKA 2/5/25