



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

Effective Date:	22-Jan-2025	22-Jan-2028	: Date of Next Review
Prepared By:	Amy Yench	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-E03-0525-0022

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

Manufacturing Date: 05/03/25

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.
	260 nm	≤ 0.0500 a.u.
	280 nm	≤ 0.0800 a.u.
Absorbance (0.05M)	250 nm	≤ 0.0500 a.u.
	260 nm	≤ 0.0500 a.u.
	280 nm	≤ 0.0800 a.u.
Appearance and Color	White / Crystals	White / Crystals
Assay, Dried Basis	≥ 99.5 %	100.8 %
Chloride	≤ 50 ppm	< 50 ppm
Endotoxin	≤ 5 EU/g	< 1 EU/g
Enzymes	DNase	None Detected
	RNase	None Detected
	Protease	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 %	< 0.1 %
Microbial	TAMC	≤ 100 CFU/g
Content	TYMC	≤ 100 CFU/g
pH (5% solution)	5.0 – 6.5	5.3
pK _a	7.45 – 7.65	7.58
Residue on Ignition	≤ 0.1 %	< 0.1 %
Solubility (5%)	Passes Test	Passes Test

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

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	< 1.5 ppm
Copper (Cu)	≤ 5 ppm	< 0.15 ppm
Trace Metals	Iron (Fe)	< 0.30 ppm
	Lead (Pb)	< 0.30 ppm
	Lithium (Li)	< 1.5 ppm
	Molybdenum (Mo)	< 3.0 ppm
	Nickel (Ni)	< 0.75 ppm
	Potassium (K)	< 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: Anil McCall Date: 7/18/05 Job Title: QA Tech III

Reviewed by: Jon Bryhn Date: 7/18/05 Job Title: QA Supervisor