

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

|                      |                                |                 |                       |
|----------------------|--------------------------------|-----------------|-----------------------|
| Effective Date:      | 28-Sep-2020                    | 28-Sep-2023     | : Date of Next Review |
| Prepared By:         | Amy Hosein                     | 16-001185 v.4.1 | : Supersedes          |
| QA/QC Approval:      | Carissa McCollan               | Amy Yenko       | : Management Approval |
| Reason for Revision: | See Revision History in ensur. |                 |                       |

## CERTIFICATE OF ANALYSIS

### HEPES

### BIO EXCIPIENT GRADE / HE3220-K025

### LOT: HE3220-040-1120

$C_8H_{13}N_2O_4S$  \* F.W. 238.30 g/mol. \* CAS# 7365-45-9  
 Manufacturing Date: 9/5/20      Retest Date: 9/30/22  
 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013  
 Packaging Date: 11/12/20  
 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS              | SPECIFICATION    | TEST RESULT      |               |
|-----------------------|------------------|------------------|---------------|
| Absorbance<br>(0.1M)  | 250 nm           | 0.0500 a.u. max. | 0.0200 a.u.   |
|                       | 260 nm           | 0.0500 a.u. max. | 0.0156 a.u.   |
|                       | 280 nm           | 0.0800 a.u. max. | 0.0137 a.u.   |
| Absorbance<br>(0.05M) | 250 nm           | 0.0500 a.u. max. | 0.0076 a.u.   |
|                       | 260 nm           | 0.0500 a.u. max. | 0.0051 a.u.   |
|                       | 280 nm           | 0.0800 a.u. max. | 0.0050 a.u.   |
| Appearance and Color  | White / Crystals | White / Crystals |               |
| Assay, Dried Basis    | 99.5% min.       | 100.1%           |               |
| 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.        | <0.5%            |               |
| Microbial Content     | TAMC             | ≤ 100 CFU/g      | <10 CFU/g     |
|                       | TYMC             | ≤ 100 CFU/g      | <10 CFU/g     |
| pH (5% Soln)          | 5.0 – 6.5        | 5.2              |               |
| pK <sub>a</sub>       | 7.45 – 7.65      | 7.54             |               |

| 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: Jaron Hughes Date: 11/30/20 Job Title: QA Specialist

Reviewed by: Car Date: 11/30/20 Job Title: QA Supervisor