

# BIOSPECTRA

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

|                      |  |                    |                       |
|----------------------|--|--------------------|-----------------------|
| Effective Date:      | 17-Jan-2022                            | 17-Jan-2025        | : Date of Next Review |
| Prepared By:         | Wendy Santay                           | BSI-COA-0214 v.3.0 | : Supersedes          |
| QA/QC Approval:      | Carissa McCollian                      | Amy Yencho         | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. |                    |                       |

## CERTIFICATE OF ANALYSIS

### HEPES

### BIO EXCIPIENT GRADE / NEW CODE HEPE-3251-50

(HISTORICAL CODE HE3251-K050)

LOT: HEPE-0121-00196

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

Manufacturing Date: 12/06/21 Retest Date: 12/31/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 12/13/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS               | SPECIFICATION    | TEST RESULT      |
|------------------------|------------------|------------------|
| Absorbance<br>(1M)     | 250 nm           | 0.0349 a.u.      |
|                        | 260 nm           | 0.0082 a.u.      |
|                        | 280 nm           | 0.0043 a.u.      |
| Absorbance<br>(0.05M)  | 250 nm           | 0.0013 a.u.      |
|                        | 260 nm           | < 0.003 a.u.     |
|                        | 280 nm           | < 0.003 a.u.     |
| Appearance and Color   | White / Crystals | White / Crystals |
| Assay, Dried Basis     | 99.5% min.       | 99.8%            |
| Chloride               | 0.005% max.      | < 0.005%         |
| Endotoxins             | ≤ 5 EU/g         | < 1 EU/g         |
| Enzymes                | DNase            | None Detected    |
|                        | RNase            | None Detected    |
|                        | Protease         | None Detected    |
| Heavy Metals (as Lead) | 1 ppm max.       | < 1 ppm          |
| Identification (IR)    | Passes Test      | Passes Test      |
| Insoluble Matter       | 0.01% max.       | < 0.01%          |
| Microbial Content      | TAMC             | < 10 CFU/g       |
|                        | TYMC             | < 10 CFU/g       |
| pH (1% Soln)           | 4.7 – 5.6        | 5.2              |
| pK <sub>a</sub>        | 7.45 – 7.65      | 7.50             |

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| ANALYSIS                     |              | SPECIFICATION       | TEST RESULT         |
|------------------------------|--------------|---------------------|---------------------|
| Residue on Ignition          |              | 0.1% max.           | < 0.1%              |
| Solubility (1% Soln)         |              | Pass/Clear Solution | Pass/Clear Solution |
| 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             |
| Water Content (Karl Fischer) |              | 0.5% max.           | 0.3%                |

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 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: M. Shafiq Date: 01/17/22 Job Title: QA Tech. I

Reviewed by: C. [Signature] Date: 11/17/22 Job Title: QA Manager