

HEPES Free Acid, LBLE*, GMP, Excipient Grade

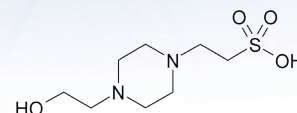
*Low Bioburden, Low Endotoxin

INTENDED FOR USE AS AN EXCIPIENT

HEPES is a zwitterionic buffer used to maintain pH of media used in cell cultures. It is one of Good's twelve buffers that has a pK_a value similar to its pH value making it an ideal buffer for pH maintenance. It has only one restriction, it interferes with the Folin protein assay. This buffer can form radicals so it is not suitable for redox studies. HEPES is used as a Good's buffer because it has low UV absorptivity, minimal reactivity, stable pH and is soluble in water.

Lead Time: 3-6 months

Minimum Order Quantity: 250kg



CAS #: 7365-45-9

Molecular Formula: $C_8H_{18}N_2O_4S$

Solubility in Water (g/L): 400

F.W.: 238.30 g/mol

pH @ 20°C: 5.0 - 6.5

Useful pH: 6.8 - 8.2

pK_a @ 20°C: 7.55

BIO EXCIPIENT GRADE | Product Code: HEPE-3250 | Previously: HE3250

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



These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

| ANALYSIS | | SPECIFICATIONS |
|-----------------------------------|---------------------------------|------------------|
| Absorbance (0.1M) | 250 nm | ≤ 0.0500 a.u. |
| | 260 nm | ≤ 0.0500 a.u. |
| | 280 nm | ≤ 0.0800 a.u. |
| Appearance and Color | | White / Crystals |
| Appearance of Solution (1% Water) | | Conforms |
| Assay, Dried Basis | | 99.5% min. |
| Chloride | | ≤ 50 ppm |
| Endotoxins | | ≤ 5 EU/g |
| Enzymes | DNases (Exo- and endonucleases) | None Detected |
| | RNase | None Detected |
| | Protease | None Detected |
| Heavy Metals (as Pb) | | ≤ 1 ppm |
| Identification (IR) | | Passes Test |
| Identification (TLC) | | Conforms |
| Insoluble Matter | | ≤ 0.01% |
| Loss on Drying (105°C) | | ≤ 0.2% |
| Methanol | | ≤ 3000 ppm |



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| ANALYSIS | | SPECIFICATIONS |
|----------------------|---|----------------|
| Microbial Content | Bile tolerant Gram negative Bacteria (Absent in 1g) | Conforms |
| | Candida albicans (Absent in 1g) | Conforms |
| | Escherichia coli (Absent in 1g) | Conforms |
| | Pseudomonas aeruginosa (Absent in 1g) | Conforms |
| | Salmonella species (Absent in 10g) | Conforms |
| | Staphylococcus aureus (Absent in 1g) | Conforms |
| | TAMC | ≤ 100 CFU/g |
| | TAMC | ≤ 50 CFU/g |
| pH (5% Soln) | | 5.0 – 6.5 |
| pH (1% Water) | | 4.7 – 5.3 |
| pK _a | | 7.45 – 7.65 |
| Residue on Ignition | | ≤ 0.1% |
| Solubility (5%) | | Passes Test |
| Sulfate | | ≤ 50 ppm |
| Sulfated Ash (600°C) | | ≤ 0.10% |
| Trace Metals | Arsenic (As) | ≤ 5 ppm |
| | Calcium (Ca) | ≤ 50 ppm |
| | Cadmium (Cd) | ≤ 5 ppm |
| | Cobalt (Co) | ≤ 5 ppm |
| | Copper (Cu) | ≤ 5 ppm |
| | Chromium (Cr) | ≤ 5 ppm |
| | Iron (Fe) | ≤ 5 ppm |
| | Lead (Pb) | ≤ 1 ppm |
| | Magnesium (Mg) | ≤ 10 ppm |
| | Manganese (Mn) | ≤ 5 ppm |
| | Nickel (Ni) | ≤ 5 ppm |
| Potassium (K) | ≤ 50 ppm | |
| | Zinc (Zn) | ≤ 5 ppm |

General Product Description:

- The manufacturing of HEPES, HEPE-3250 is performed at BioSpectra's Bangor and Stroudsburg, PA facilities utilizing multi-use equipment. Equipment used in the manufacturing of HEPE-3250 is cleaned in accordance with BioSpectra's Process Cleaning Validation Master Plan.
- HEPES is a White Crystalline Product.
- Molecular Formula: C₈H₁₈N₂O₄S
- Molecular Weight: 238.30 g/mol.
- CAS Number: 7365-45-9.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all HEPES HEPE-3250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- HEPES manufactured at BioSpectra and any raw materials used in the manufacture of HEPES at BioSpectra are not subject to genetic modification.
- Synonyms: N-(2-Hydroxyethyl)piperazine-N'-2-ethanesulfonic acid, 2-[4-(2-hydroxyethyl)piperazin-1-yl]ethanesulfonic acid.

GMP Compliance:

Bio Excipient Grade HEPES, HEPE-3250 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of HEPES is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

The recommended retest period for HEPES is two years from the date of manufacture.

Storage and Shipping Conditions:

Ship and store in ambient temperature. Store in a clean and dry area. Store in the original container.

Package Sizes:

10kg, 25kg and 50kg pails.

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.