

HEPES, FREE ACID

BLE, GMP, EXCIPIENT

CAS #: 7365-45-9

 Formula: $C_8H_{18}N_2O_4S$

F.W.: 238.30 g/mol

HEPE-3250
Bio EXCIPIENT GRADE

ANALYSIS	SPECIFICATIONS
Absorbance (0.1M)	≤ 0.0500 a.u.
	≤ 0.0500 a.u.
	≤ 0.0800 a.u.
Appearance and Color	White Crystals
Appearance of Solution (1%)	Passes Test
Assay, Dried Basis	> = 99.5%
Chloride	≤ 50 ppm
Endotoxin	≤ 5 EU/g
Enzymes	DNase – Exonuclease
	None Detected
	DNase – Endonuclease
	None Detected
Identification, IR	None Detected
	Conforms to Reference Standard
Identification, HPLC	Conforms to Reference Standard
Insoluble Matter	≤ 0.01%
Loss on Drying	≤ 0.2%
Microbial Content	TAMC
	≤ 100 CFU/g
	TYMC
	≤ 50 CFU/g
	Bile tolerant Gram negative Bacteria
	Absent/g
	Candida albicans
	Absent/g
Escherichia coli	Absent/g
	Pseudomonas aeruginosa
Salmonella species	Absent/g
	Absent/10g
Staphylococcus aureus	Absent/g
	Absent/g
pH (5%)	5.0 – 6.5
pH (1%)	4.7 – 5.3
pK _a	7.45 – 7.65
Residue on Ignition	≤ 0.10%

ANALYSIS	SPECIFICATIONS
Residual Solvents	Methanol
Solubility (5%)	Passes Test
Sulfate	≤ 50 ppm
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 Overview

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 pKa value similar to its pH value, making it an ideal buffer for pH maintenance. A known limitation is its interference with the Folin protein assay. This buffer can form radicals, so it is not suitable for redox studies. HEPES is a Good's buffer because it has low UV absorptivity, minimal reactivity, stable pH and is soluble in water.

Refer to page 2 for additional product details.

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Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

Key Product Features

- The manufacturing of HEPES, HEPE-3250 is performed at BioSpectra's Bangor and Stroudsburg, PA facilities.
- Appears as a white crystals
- Manufactured in accordance with ICH Q7
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives
- Is not subject to genetic modification
- Synonyms: N-(2-Hydroxyethyl) Piperazine-N'-2-Ethanesulfonic Acid, 4-(2-Hydroxyethyl); Piperazine-1-Ethanesulfonic Acid

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

10kg, 25kg and 50kg pails

Click here to view SDS, CoAs and other supporting regulatory documents on our website.

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