BIOSPECTRA
Premium Pharmaceutical Ingredients

Excipient

ICH-Q7 GMP Manufactured Product

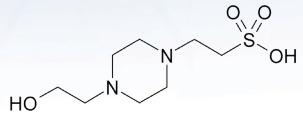
HEPES Free Acid, Low UV, LBLE*, GMP, Excipient Grade

***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-3251 | Previously: HE3251

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

Made in the USA

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

ANALYSIS		SPECIFICATIONS
Absorbance (1M)	250 nm 260 nm 280 nm	0.0500 a.u. max. 0.0500 a.u. max. 0.0500 a.u. max.
Absorbance (0.05M)	250 nm 260 nm 280 nm	0.0500 a.u. max. 0.0500 a.u. max. 0.0500 a.u. max.
Appearance and Color		White / Crystals
Assay, Dried Basis		99.5% min.
Chloride		0.005% max.
Endotoxin		≤ 5 EU/g
Enzymes	DNase RNase Protease	None Detected None Detected None Detected
Heavy Metals (as Lead)		1 ppm max.
Identification (IR)		Passes Test
Insoluble Matter		≤ 0.01% max.
Microbial Content	TAMC TYMC	≤ 50 CFU/g ≤ 50 CFU/g
pH (1% Soln.)		4.7 – 5.6
pK_a		7.45 – 7.65
Residue on Ignition		0.1% max.
Solubility (1% soln.)		Pass / Clear Solution
Solubility (0.05M)		Passes Test

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400

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ANALYSIS	SPECIFICATIONS
Sulfate	0.005% max.
Trace Metals Arsenic (As) Copper (Cu) Iron (Fe) Lead (Pb)	 5 ppm max. 5 ppm max. 5 ppm max. 5 ppm max.
Water Content (Karl Fischer)	0.5% max.

General Product Description:

- The manufacturing of HEPES, HEPE-3251 is performed at BioSpectra's Bangor and Stroudsburg, PA facilities utilizing multi-use equipment. Equipment used in the manufacturing of HEPE-3251 is cleaned in accordance with BioSpectra's Process Cleaning Validation Master Plan.
- HEPES is a White Crystalline Product.
- Molecular Formula: $C_8H_{18}N_2O_4S$
- 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-3251 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-3251 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.