BIOSPECTRA
Bulk cGMP Fine Chemical Manufacturer

EXCIPIENT
ICH Q7 GMP MANUFACTURED PRODUCT

HEPES

BET*, GMP

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

HEPE-3320

BIO EXCIPIENT GRADE

ANALYSIS		SPECIFICATIONS
Absorbance (0.1M)	250 nm	< = 0.0500 a.u.
	260 nm	< = 0.0500 a.u.
	280 nm	< = 0.0800 a.u.
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	260 nm	< = 0.0500 a.u.
	280 nm	< = 0.0800 a.u.
Appearance and Color		White Crystals
Assay, Dried Basis		> = 99.5%
Chloride		< = 50 ppm
Endotoxin		< = 5 EU/g
Enzymes	DNase	None Detected
	RNase	None Detected
	Protease	None Detected
Identification, IR		Conforms to Reference Standard
Insoluble Matter		< = 0.01%
Loss on Drying		< = 0.5%
Microbial Content	TAMC	< = 100 CFU/g
	TYMC	< = 100 CFU/g
pH (5%)		5.0 – 6.5
pKa		7.45 – 7.65
Residue on Ignition		< = 0.1%
Solubility	Solubility (5%)	Passes Test
	Solubility (0.05M)	Passes Test
Sulfate		< = 50 ppm
Trace Metals	Arsenic (As)	< = 5 ppm
	Copper (Cu)	< = 5 ppm
	Iron (Fe)	< = 5 ppm
	Lead (Pb)	< = 1 ppm

*Bioburden and Endotoxin Tested

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

General Product Overview

HEPES is a zwitterionic buffer used to maintain pH of media used in cell cultures. It is one of Good's 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.

Industry Application

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

Key Product Features

- The manufacturing of HEPES, HEPE-3320 is performed at BioSpectra's Bangor and Stroudsburg, PA facilities.
- Appears as 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

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