

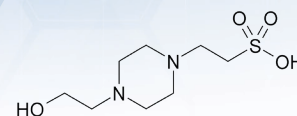
HEPES Free Acid, GMP, Excipient Grade

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-3320

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




ANALYSIS		SPECIFICATIONS
Absorbance (0.1M)	250 nm	0.0500 a.u. max.
	260 nm	0.0500 a.u. max.
	280 nm	0.0800 a.u. max.
Absorbance (0.05M)	250 nm	0.0500 a.u. max.
	260 nm	0.0500 a.u. max.
	280 nm	0.0800 a.u. max.
Appearance and Color		White / Crystals
Assay, Dried Basis		99.5% min.
Chloride		0.005% max.
Endotoxin		≤ 5 EU/g
Enzymes	DNase	None Detected
	RNase	None Detected
	Protease	None Detected
Heavy Metals		1 ppm max.
Identification (IR)		Passes Test
Insoluble Matter		0.01% max.
Loss on Drying		0.5% max.
Microbial Content	TAMC	≤ 100CFU/g
	TYMC	≤ 100CFU/g
pH (5% Soln)		5.0 - 6.5
pK_a		7.45 - 7.65
Residue on Ignition		0.1% max.
Solubility (5%)		Passes Test
Solubility (0.05M)		Passes Test
Sulfate		0.005% max.

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



Quality Assurance / Regulatory Support / Quality Control

ANALYSIS		SPECIFICATIONS
Trace Metals	Arsenic (As)	5 ppm max.
	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.

 Key Compliance Attributes of BioSpectra Grades	
	Bio Excipient Grade ICH-Q7 Compliant Manufactured
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Excipient Grade: Intended for use as ICH-Q7 Compliant Excipient

LBLE: LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).
LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.



General Product Description:

- The manufacturing of HEPES HEPE-3320 is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of HEPE-3320 is cleaned in accordance with BioSpectra's Cleaning Validation 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-3320 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-3320 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.

Package Sizes:

10kg, 25kg and 50kg pails.