

MES Hydrate, LBLE*, GMP, Excipient Grade

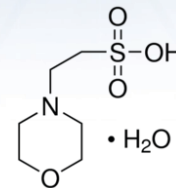
*Low Bioburden, Low Endotoxin

INTENDED FOR USE AS AN EXCIPIENT

MES Hydrate is a zwitterionic buffer that is not absorbed through cell membranes and is virtually transparent in UV light. MES is a buffering agent used in many biological and biochemical applications. It is also used as a running buffer for denaturing gel electrophoresis. The characteristics of low UV absorptivity, minimal reactivity, stable pH and solubility in water allow MES Hydrate Excipient to be used as a Good's buffer.

Lead Time (If No Stock): 3-6 months

Minimum Order Quantity: 250kg



CAS #: 1266615-59-1

Molecular Formula:



F.W.: 195.25 g/mol

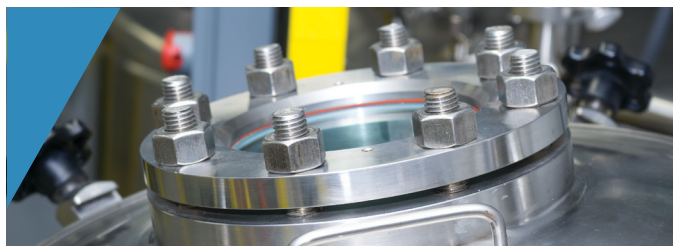
BIO EXCIPIENT GRADE | Product Code: MESH-3250

$C_6H_{13}NO_4S \cdot H_2O$ · F.W. 195.25 g/mol. · CAS# 1266615-59-1




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

ANALYSIS		SPECIFICATIONS
Absorbance (0.1M) in Water	A260	≤ 0.04 a.u.
	A280	≤ 0.02 a.u.
Appearance		White Powder
Assay (anhydrous basis)		≥ 99.5%
Cytotoxicity		Passes Test
Endotoxin		≤ 50 EU/g
Enzymes	DNase, Exonuclease Detection	Passes Test
	NICKase, Endonuclease Detection	Passes Test
	RNase Detection	Passes Test
	Protease Detection	Passes Test
Identification (IR)		Passes Test
pH 1% in Water		3.5 – 4.1
Solubility 0.1M in H ₂ O		Clear and Colorless
Total Aerobic Microbial Count		≤ 100 CFU/g
Total Yeast and Mold		≤ 100 CFU/g
Water (by Karl Fischer)		5.0 – 8.9%



ANALYSIS	SPECIFICATIONS	
Trace Elements	Aluminum (Al)	≤ 5.0 ppm
	Antimony (Sb)	≤ 5.0 ppm
	Arsenic (As)	≤ 3.0 ppm
	Barium (Ba)	≤ 5.0 ppm
	Bismuth (Bi)	≤ 5.0 ppm
	Cadmium (Cd)	≤ 5.0 ppm
	Calcium (Ca)	≤ 20.0 ppm
	Chromium (Cr)	≤ 5.0 ppm
	Cobalt (Co)	≤ 5.0 ppm
	Copper (Cu)	≤ 5.0 ppm
	Iron (Fe)	≤ 5.0 ppm
	Lead (Pb)	≤ 5.0 ppm
	Lithium (Li)	≤ 5.0 ppm
	Manganese (Mn)	≤ 5.0 ppm
	Magnesium (Mg)	≤ 5.0 ppm
	Molybdenum (Mo)	≤ 5.0 ppm
	Nickel (Ni)	≤ 5.0 ppm
	Sodium (Na)	≤ 20.0 ppm
	Zinc (Zn)	≤ 5.0 ppm

 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	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
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	✓



General Product Description:

- The manufacturing of Bio Excipient Grade MES, Hydrate MESH-3250 is performed at BioSpectra's Bangor, PA facility.
- MES is a White Crystalline product.
- Molecular Formula: $C_6H_{13}NO_4S \cdot H_2O$
- Molecular Weight: 195.25 g/mol.
- CAS Number: 1266615-59-1.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all MES, Hydrate MESH-3250 manufactured at BioSpectra and its raw materials are completely synthetic and are not derived from or come in contact with animal parts, products, and/or byproducts.
- Synonyms: 2-(N-Morpholino)ethanesulfonic acid, 4-Morpholineethanesulfonic acid monohydrate.

GMP Compliance:

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

Retest Date:

The recommended retest period for MES, Hydrate 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.