

## MES, Monohydrate, LBLE, GMP Excipient Grade

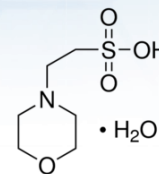
Low Bioburden, Low Endotoxin, GMP Manufactured

### INTENDED FOR USE AS AN EXCIPIENT

MES Monohydrate 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 Monohydrate Excipient to be used as a Good's buffer.

**Lead Time: 3-6 months**

**Minimum Order Quantity: 250kg**



**CAS #:** 145224-94-8

**Molecular Formula:**

$C_6H_{13}NO_4S \cdot H_2O$

**Solubility in Water (g/L):** 310

**F.W.:** 213.25 g/mol

**pH @ 20°C:** 2.5 - 4.5

**Useful pH:** 5.5 - 6.7

**pK<sub>a</sub> @ 20°C:** 6.1

## BIO EXCIPIENT GRADE | Product Code: MESM-3250

$C_6H_{13}NO_4S \cdot H_2O$  · F.W. 213.25 g/mol · CAS# 145224-94-8




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

ANALYSIS		SPECIFICATIONS
Absorbance (1M)	260 nm 280 nm	0.1000 a.u. max. 0.1000 a.u. max.
Appearance and Color		White / Crystals
Assay		≥ 99.5%
Chloride		0.005% max.
Color (1M, Alkaline)		Colorless
Endotoxin		< 50 EU/g
Enzymes	DNase RNase Protease	None Detected None Detected None Detected
Heavy Metals (as Pb)		2 ppm max.
Identification (IR)		Passes Test
Loss on Drying @ 130°C		7 - 9%
pH (5% solution)		3.1 – 3.5
pH (0.5M)		2.5 – 4.0
pK <sub>a</sub>		5.9 – 6.3
Residue on Ignition		0.05% max.
Solubility (5%)		Passes Test
Sulfate		0.005% max.
TAMC		≤ 100 CFU/g
TYMC		≤ 100 CFU/g



ANALYSIS		SPECIFICATIONS
Trace Elements	Cadmium (Cd)	≤ 0.2 ppm
	Lead (Pb)	≤ 0.5 ppm
	Arsenic (As)	≤ 1.5 ppm
	Mercury (Hg)	≤ 0.3 ppm
	Cobalt (Co)	≤ 0.5 ppm
	Vanadium (V)	≤ 1 ppm
	Nickel (Ni)	≤ 2 ppm
	Lithium (Li)	≤ 25 ppm
	Antimony (Sb)	≤ 9 ppm
	Barium (Ba)	≤ 70 ppm
	Molybdenum (Mo)	≤ 150 ppm
	Copper (Cu)	≤ 30 ppm
	Tin (Sn)	≤ 60 ppm
	Chromium (Cr)	≤ 110 ppm
Iron (Fe)	≤ 2 ppm	
Water (by Karl Fischer)		7.8 – 8.9%

 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	✓



## General Product Description:

- The manufacturing of Bio Excipient Grade MES, Monohydrate MESM-3250 is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of Bio Excipient Grade MES, Monohydrate is cleaned in accordance with BioSpectra's Cleaning Validation Plan.
- MES is a White Crystalline product.
- Molecular Formula:  $C_6H_{13}NO_4S \cdot H_2O$
- Molecular Weight: 213.25 g/mol.
- CAS Number: 145224-94-8.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all MES, Monohydrate MESM-3250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- MES, Monohydrate manufactured at BioSpectra and any raw materials used in the manufacture of MES, Monohydrate at BioSpectra are not subject to genetic modification.
- Synonyms: 2-(N-Morpholino)ethanesulfonic acid, 4-Morpholineethanesulfonic acid monohydrate.

## GMP Compliance:

Bio Excipient Grade MES, Monohydrate MESM-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, Monohydrate is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

## Retest Date:

The recommended retest period for MES, Monohydrate 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.

✓ 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.