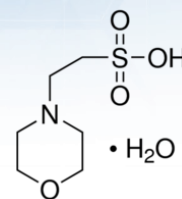


MES, Monohydrate, Low PVS, GMP Excipient Grade

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES/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:

$C_6H_{13}NO_4 \cdot H_2O$

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_a @ 20°C: 6.1

BIO EXCIPIENT GRADE | Product Code: MESM-3222 | Previously: ME3222

$C_6H_{13}NO_4 \cdot H_2O$ · F.W. 213.25 g/mol. · CAS# 145224-94-8



ANALYSIS		SPECIFICATIONS
Absorbance (1M)	260 nm	0.1000 a.u. max.
	280 nm	0.1000 a.u. max.
Appearance and Color		White Crystalline Powder
Assay		99.5% min.
Chloride		0.005% max.
Color (1M, Alkaline)		Colorless
Enzymes	DNase	None Detected
	RNase	None Detected
	Protease	None Detected
Heavy Metals (as Pb)		2 ppm max.
Identification (IR)		Conforms to Reference
Loss on Drying @ 130°C		7 -10%
pH (5% solution)		3.1 – 3.5
pH (1.0M)		2.7 – 3.7
pH (0.5M)		2.5 – 4.5
pK _a		5.9 – 6.3
Turbidimetry/PVS Limit Test		≤ 1 ppm
Residue on Ignition		0.05% max.
Solubility		Passes Test
Sulfate		0.005% max.

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



ANALYSIS		SPECIFICATIONS
Trace Elements	Arsenic (As)	2 ppm max.
	Copper (Cu)	2 ppm max.
	Iron (Fe)	2 ppm max.
	Lead (Pb)	2 ppm max.
Water (by Karl Fischer)		7.9 – 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	✓

✓ 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 Bio Excipient Grade MES, Monohydrate MESM-3222 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-3222 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-3222 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.