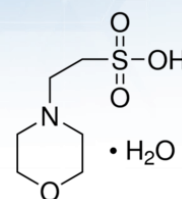


MES, Monohydrate, GMP Grade

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES

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 to be used as a Good's buffer.



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_a @ 20°C: 6.1

BIO PHARMA GRADE | Product Code: MESM-4220 | Previously: ME4220


$C_6H_{13}NO_4S \cdot H_2O$ · 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 / Crystals |
| Assay | | 99.0% min. |
| Chloride | | 0.005% max. |
| Color (1M, Alkaline) | | Colorless |
| Enzymes | DNase | None Detected |
| | RNase | None Detected |
| | Protease | None Detected |
| Heavy Metals | | 2 ppm max. |
| Identification (IR) | | Passes Test |
| Loss on Drying @ 130°C | | 7 -10% |
| pH (5% Soln.) | | 3.0 – 3.5 |
| pH (0.5M) | | 2.5 – 4.5 |
| pK _a | | 5.9 – 6.3 |
| Residue on Ignition | | 0.05% max. |
| Solubility (5%) | | Passes Test |
| Sulfate | | 0.005% max. |
| Trace Elements | Arsenic (As) | 5 ppm max. |
| | Copper (Cu) | 5 ppm max. |
| | Iron (Fe) | 5 ppm max. |
| | Lead (Pb) | 5 ppm max. |

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



|  Key Compliance Attributes of BioSpectra Grades | Bio Pharma Grade IPEC GMP 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 | ✓ |



General Product Description:

- The manufacturing of Bio Pharma Grade MES, Monohydrate MESM-4220 is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of Bio Pharma 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-4220 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 Pharma Grade MES, Monohydrate MESM-4220 is suitable for use as a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. This grade of MES, Monohydrate is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, 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 Pharma Grade: Intended for use as IPEC cGMP Compliant Chemical

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.