

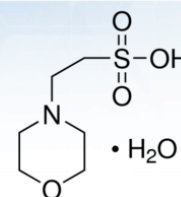
MES, Hydrate, GMP Excipient Grade

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES/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: 3-months

Minimum Order Quantity: 100kg



CAS #: 1266615-59-1

Molecular Formula:



Solubility in Water (g/L): 310

F.W.: 195.24 (anhydrous basis)

pH @ 20°C: 2.5 - 4.5

Useful pH: 5.5 - 6.7

pK_a @ 20°C: 6.1

BIO EXCIPIENT GRADE | Product Code: MESH-3201


$C_6H_{13}NO_4S \cdot xH_2O$ · F.W. 195.24 (anhydrous basis) · CAS# 1266615-59-1



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

| ANALYSIS | SPECIFICATIONS |
|---|-----------------------|
| Appearance (Color) | White |
| Appearance (Form) | Crystalline Powder |
| Solubility (Color) | Colorless |
| Solubility (Turbidity) 20g plus 80ml of H ₂ O | Clear |
| Infrared Spectrum | Conforms to Structure |
| Water (by Karl Fischer) | ≤ 9% |
| A290 UV absorbance 20% W/W | ≤ 0.05 a.u. |
| Trace Metals (ICP-MS), Silver (Ag), Arsenic (As), Bismuth (Bi), Cadmium (Cd), Copper (Cu), Mercury (Hg), Molybdenum (Mo), Lead (Pb), Antimony (Sb), and Tin (Sn) | Sum ≤ 5ppm |
| pH 0.5M in H ₂ O | 2.5 – 4.0 |
| pH 1.0M in H ₂ O | 2.7 – 3.7 |
| Titration with NaOH Anhydrous | ≥ 99.5% |
| Impurity PVS Limit Test | ≤ 1 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 | ✓ |
| 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, Hydrate MESH-3201 is performed at BioSpectra's Bangor, PA facility utilizing multi-use equipment. Equipment used in the manufacturing of Bio Excipient Grade MES, Hydrate is cleaned in accordance with BioSpectra's Cleaning Validation Plan.
- MES, Hydrate is a White Crystalline product.
- Molecular Formula: $C_6H_{13}NO_4S \cdot xH_2O$
- Molecular Weight: 195.24 (anhydrous base).
- 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-3201 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- MES, Hydrate manufactured at BioSpectra and any raw materials used in the manufacture of MES, Hydrate at BioSpectra are not subject to genetic modification.
- Synonyms: 4-Morpholineethanesulfonic acid, 2-(N-Morpholino)ethanesulfonic acid hydrate

GMP Compliance:

Bio Excipient Grade MES, Hydrate MESH-3201 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.

| |
|--|
| ✓ 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. |