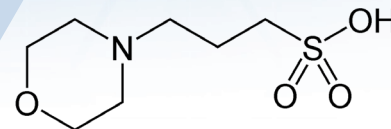


MOPS, Free Acid, GMP Excipient Grade

INTENDED FOR USE AS AN EXCIPIENT

MOPS is a zwitterionic buffer used as a running buffer for denaturing gel electrophoresis and as a buffering agent in many biological and biochemical applications. MOPS interferes with the Folin protein assay and partially decomposes when autoclaved in the presence of glucose. MOPS can be used as a Good's buffer because it has low UV absorptivity, minimal reactivity, stable pH and is soluble in water.

Lead Time: 3-6 months
Minimum Order Quantity: 250kg



CAS #: 1132-61-2
Molecular Formula: C₇H₁₅NO₄S
Solubility in Water (g/L): 980
F.W.: 209.26 g/mol
pH @ 20°C: 3.0 - 4.5
Useful pH: 6.5 - 7.9
pK_a @ 20°C: 7.2

BIO EXCIPIENT GRADE | Product Code: MOPS-3220 | Previously: MP3220


C₇H₁₅NO₄S • F.W. 209.26 g/mol. • CAS# 1132-61-2



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

| ANALYSIS | | SPECIFICATIONS |
|----------------------|--------------|--------------------|
| Absorbance (0.1M) | 250 nm | 0.020 a.u. maximum |
| | 260 nm | 0.020 a.u. maximum |
| | 280 nm | 0.020 a.u. maximum |
| Appearance and Color | | White / Crystals |
| Assay | | 99.5% minimum |
| Chloride | | 0.005% maximum |
| Enzymes | DNase | None Detected |
| | RNase | None Detected |
| | Protease | None Detected |
| Identification (IR) | | Passes Test |
| Karl Fischer Water | | 0.1% maximum |
| Loss on Drying | | 1.0% maximum |
| pH (1% solution) | | 3.0-4.5 |
| pH (2.5M) | | 2.5-4.5 |
| pKa | | 7.0-7.5 |
| Residue on Ignition | | 0.1% maximum |
| Solubility (5%) | | Passes Test |
| Sulfate | | 0.005% maximum |
| Trace Metals | Arsenic (As) | 5 ppm maximum |
| | Copper (Cu) | 5 ppm maximum |
| | Iron (Fe) | 5 ppm maximum |
| | Lead (Pb) | 5 ppm maximum |



|  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 MOPS MOPS-3220 is performed at BioSpectra's Stroudsburg, PA facility and is conducted in a dedicated processing area using only dedicated equipment.
- MOPS is a White Crystalline product.
- Molecular Formula: $C_7H_{15}NO_4S$
- Molecular Weight: 209.26 g/mol.
- CAS Number: 1132-61-2.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all MOPS MOPS-3220 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- MOPS manufactured at BioSpectra and any raw materials used in the manufacture of MOPS at BioSpectra are not subject to genetic modification.
- Synonyms: 3-(N-Morpholino)propanesulfonic acid, 4-Morpholinepropanesulfonic acid.

GMP Compliance:

Bio Excipient Grade MOPS, Free Acid MOPS-3220 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of MOPS, Free Acid is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

The recommended retest period for MOPS 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.