

## **GMP** Buffer

**GMP Manufactured Process Chemical** 

# MOPS, Free Acid, GMP Grade

#### **INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES**

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

N S OH

**CAS #:** 1132-61-2

Molecular Formula:  $C_7H_{15}NO_4S$ 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 @ 20°C: 7.2

BIO PHARMA GRADE | Product Code: MOPS-4220 | Previously: MP4220

C<sub>7</sub>H<sub>45</sub>NO<sub>4</sub>S · 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
	250 nm	0.020 a.u. maximum
Absorbance (0.1M)	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
	DNase	None Detected
Enzymes	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
	Arsenic (As)	5 ppm maximum
Trace Metals	Copper (Cu)	5 ppm maximum
	Iron (Fe)	5 ppm maximum
	Lead (Pb)	5 ppm maximum



## Quality Assurance / Regulatory Support / Quality Control

BIOSPECTRA 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	<b>4</b>
Video Conference access to BioSpectra Sites	<b>Y</b>
Complete access to Product Traceability Access to Supply Chain Information	· ✓

✓ 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.



#### **General Product Description:**

- The manufacturing of Bio Pharma Grade MOPS MOPS-4220 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<sub>7</sub>H<sub>1</sub>ENO<sub>4</sub>S
- 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-4220 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 Pharma Grade MOPS, Free Acid MOPS-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 MOPS, Free Acid is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, 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.

