# **Excipient**

**ICH-Q7 GMP Manufactured Product** 

# 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

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<sub>a</sub> @ 20°C: 7.2

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

C<sub>2</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	
рКа		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 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	<b>√</b>
Customized Manufacturing Schedule	✓
Custom Regulatory Packet Accelerated Stability	<b>V</b>
Video Conference access to BioSpectra Sites	<b>→</b>
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 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<sub>7</sub>H<sub>15</sub>NO<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-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.

