BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

Effective Date:	23-Mar-2017	23-Mar-2020	: Date of Next Review
Prepared By:	Jamie Storm	16-001170 v.1.0	: Supersedes
QA/QC Approval:	Nicole Fisher	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

MOPS

CERTIFICATE OF ANALYSIS

BIO EXCIPIENT GRADE / MP3220-G100

LOT: MP3220-001-0317

$C_7H_{15}NO_4S$ · F.W. 209.26 g/mol. · CAS# 1132-61-2

Manufacturing Date: 01/05/2017 Retest Date: 01/31/2019

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360 Packaging Date: 03/20/2017

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (0.1 M)	250 nm	0.020 a.u. max.	0.0047 a.u.
	260 nm	0.020 a.u. max.	0.0041 a.u.
	280 nm	0.020 a.u. max.	0.0042 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.5% min.	99.99%
Chloride		0.005% max	<0.005%
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Identification (IR)		Passes Test	Passes Test
Karl Fischer Water		0.1% max.	0.05%
Loss on Drying		1.0% max.	0.0200%
pH (1% solution)		3.0 – 4.5	4.284 @ 22.00 °C
pH (2.5M)		2.5 – 4.5	3.635 @ 20.50 °C
pK_a		7.0 – 7.5	7.1
Residue on Ignition		0.1% max.	<0.0300%
Solubility		Passes Test	Passes Test
Sulfate		0.005% max.	<0.005%
Trace Metals	Arsenic (As)	5ppm max.	<5 ppm
	Copper (Cu)	5ppm max.	<5 ppm
	Iron (Fe)	5ppm max.	<5 ppm
	Lead (Pb)	5ppm max.	<5 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000498

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured Excipient for use in further Manufacturing. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

OVI STATEMENT: Based on the manufacturing process and the controlled handling and storage of this product, there is no potential for any of the residual solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 to be present at the specified limits; furthermore, if tested this product would comply with USP/NF requirements.

Prepared by: _____ Date: 3/24/17

Reviewed by: _____ Date: 03/24/17