DCN: 16-001172 v.2.1

BI SPECTRA

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

Effective Date:	23-Jun-2017	23-Jun-2020	: Date of Next Review
Prepared By:	Jamie Storm	16-001172 v.2.0	: Supersedes
QA/QC Approval:	Crystal Hamelburg	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

MOPS

CERTIFICATE OF ANALYSIS

BIO PHARMA GRADE / MP4220-G100

LOT: MP4220-011-0819

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 8/20/2019 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Analysis		SPECIFICATION	TEST RESULT	
	250 nm	0.020 a.u. maximum	0.0064a.u.	
Absorbance (0.1M)	260 nm	0.020 a.u. maximum	0.0055 a.u.	
	280 nm	0.020 a.u. maximum	0.0050 a.u.	
Appearance and Color		White / Crystals	White / Crystals	
Assay		99.5% minimum	99.83%	
Chloride		0.005% maximum	<0.005%	
	DNase	None Detected	None Detected	
Enzymes	RNase	None Detected	None Detected	
	Protease	None Detected	None Detected	
Identification (IR)		Passes Test	Passes Test	
Karl Fischer Water		0.1% maximum	0.07%	
Loss on Drying		1.0% maximum	0.0265%	
pH (1% solution)		3.0-4.5	4.24 @ 23.1 °C	
pH (2.5M)		2.5-4.5	3.56 @ 23.2 °C	
pK_a		7.0-7.5	7.1	
Residue on Ignition		0.1% maximum	<0.0300%	
Solubility (5%)		Passes Test	Passes Test	
Sulfate		0.005% maximum	<0.005%	
	Arsenic (As)	5 ppm maximum	< 5 ppm	
	Copper (Cu)	5 ppm maximum	< 5 ppm	
Trace Metals	Iron (Fe)	5 ppm maximum	< 5 ppm	
	Lead (Pb)	5 ppm maximum	< 5 ppm	

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000498

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INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: IPEC Compliant GMP Manufactured Chemical for use in further manufacturing or as a reagent for Laboratory and Research. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, 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 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: _	8/28/19
Reviewed by: H. B. em	Date: _	8128119