DCN: 16-001172 v.2.1

BI SPECTR A

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

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

MOPS

CERTIFICATE OF ANALYSIS

BIO PHARMA GRADE / MP4220-G100

LOT: MP4220-010-0819

Manufacturing Date: 7/2/2019

Retest Date: 7/31/2021 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	0.0058a.u.
Absorbance (0.1M)	260 nm	0.020 a.u. maximum	0.0048 a.u.
	280 nm	0.020 a.u. maximum	0.0043 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.5% minimum	99.82%
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	0.08%
Loss on Drying		1.0% maximum	0.0459%
pH (1% solution)		3.0-4.5	4.26 @ 23.2 °C
pH (2.5M)		2.5-4.5	3.58 @ 23.5 °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%
Trace Metals	Arsenic (As)	5 ppm maximum	< 5 ppm
	Copper (Cu)	5 ppm maximum	< 5 ppm
	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. Breuns	_Date:	8128/19