BI@SPECTRA

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

Manufacturing Date: / Manufacturing Site:	CATE C URA GRADI C4250- CW. 112.09 g / : 100 Majes Packaging SPECIFIC to Slip! \leq 100	20-00367 Amy Y OF ANALY CIL E / UC4250 g/mol. ~ CAS#45-22 Retest Da stic Way, Bangor g Site: 100 Majestic	<u>1 v.1.0 :</u> <u>7 encho :</u> 7 SIS -8 / 18013	: Supersed : Managen / ngor PA, TFf	1800 I KESULT Intly Yellow Powder
Reason for Revision: See Revision History in ensur. CERTIFIC. BIO PHARMA (LOT: UC C4H4N2O2 ~ F. Manufacturing Date: / Manufacturing Site: Packaging Date: / ANALYSIS ANALYSIS Appearance and Color White to Assay (dried basis) Chlorides	CATE C URA GRADI C4250- CW. 112.09 g / : 100 Majes Packaging SPECIFIC to Slip! \leq 100	OF ANALY CIL E / UC4250 g/mol. \land CAS# 6-22 Retest Da stic Way, Bangor g Site: 100 Majestic ON Yellow Pow	/SIS -8 / 18013 Ba	/ ngor PA, TFr	180 I KESULT Intly Yellow Powder
CERTIFIC. BIO PHARMA (LOT: UC C4H4N2O2 & F. Manufacturing Date: / Manufacturing Date: / Manufacturing Site: Packaging Date: / Packaging Date: / ANALYSIS Appearance and Color White to Assay (dried basis) Chlorides	CATE C URA GRADI C4250- CW. 112.09 g / : 100 Majes Packaging SPECIFIC to Slip! \leq 100	CIL E / UC4250 g/mol. ^ CAS# 6-22 Retest Da stic Way, Bangor g Site: 100 Majestic	-8 / 18013 Ba	TF	CESULT ntly Yellow Powder
BIO PHARMA LDT: UC C4H4N2O2 ~ F. Manufacturing Date: / Manufacturing Site: Packaging Date: / / ANALYSIS Appearance and Color White to Assay (dried basis) Chlorides	URAC GRADI C4250- C.W. 112.09 g / 100 Majes Packaging SPECIFIC to Slig! \leq 100	CIL E / UC4250 g/mol. ^ CAS# 6-22 Retest Da stic Way, Bangor g Site: 100 Majestic	-8 / 18013 Ba	TF	CESULT ntly Yellow Powder
LOT: UC C4H4N2O2 * F. Manufacturing Date: / Manufacturing Site: Packaging Date: / / ANALYSIS Appearance and Color White to Assay (dried basis) Chlorides	GRADI C4250- CW. 112.09 g / 100 Majes Packaging SPECIFIC So Slight 2 4 100	E / UC4250 g/mol. ~ CAS#45-22 Retest Da stic Way, Bangor g Site: 100 Majestic C ON Yellow Pow	-8 / 18013 Ba:	TF	CESULT ntly Yellow Powder
LOT: UC C4H4N2O2 * F. Manufacturing Date: / Manufacturing Site: Packaging Date: / / ANALYSIS Appearance and Color White to Assay (dried basis) Chlorides	C4250- 7.W. 112.09 g / 100 Majes Packaging SPECIFIC SPECIFIC SO Slight 2 < 100	g/mol. \checkmark CAS#25-22 Retest Da stic Way, Bangor g Site: 100 Majestic C ON Yellow Pow	-8 / 18013 Ba:	TF	CESULT ntly Yellow Powder
C4H4N2O2 × F. Manufacturing Date: / Manufacturing Site: Packaging Date: / / ANALYSIS Appearance and Color White to Assay (dried basis) Chlorides	5.W. 112.09 g / 100 Majes Packaging SPECIFIC to Slip ≤ 100	g/mol. \land CAS#46-22 Retest Da stic Way, Bangor g Site: 100 Majestic C ON Yellow Pow	/ 18013 Ba	TF	CESULT ntly Yellow Powder
Manufacturing Date: / Manufacturing Site: Packaging Date: / Packaging Date: / / ANALYSIS Appearance and Color White to Assay (dried basis) Chlorides Chlorides Chlorides	/ 100 Majes Packaging SPECIFIC to Slight \$ 100	Retest Da stic Way, Bangor g Site: 100 Majestic ON Yellow Pow	/ 18013 Ba	TF	CESULT ntly Yellow Powder
Manufacturing Site: Packaging Date: / ANALYSIS Appearance and Color White to Assay (dried basis) Chlorides Chlorides	Packaging SPECIFIC to Slip 2 < 100	stic Way, Bangor g Site: 100 Majestic ON Yellow Pow	Ba	TF	CESULT ntly Yellow Powder
Packaging Date: / / ANALYSIS Appearance and Color White to Assay (dried basis) Chlorides Chlorides Chlorides	Packaging SPECIFIC to Slip 2 < 100	g Site: 100 Majestic ON Yellow Pow	Ba	TF	CESULT ntly Yellow Powder
Appearance and ColorWhite toAssay (dried basis)Chlorides	to Slip' ≥ ≤ 100 g	Yellow Pow	White		ntly Yellow Powder
Assay (dried basis) Chlorides	≥ ≤ 100 <u>;</u>		White		•
Chlorides					o /
					%
Endotovin content	3EI	P.		≤ 1	00 ppm
Endotoxin content		U/g			EU/g
Heavy Metals	\leq .	om		≤ 2	20 ppm
Identification (IR)	isses			Passes Test	
Loss on Drying	0.50%		%		
Melting Point	Cooc I u	rget 335°C)	\geq 300 °C		
Reaction		Test	Passes Test		
Residue on Ignition	≤ 0.1	0%			%
Solubility	Passes	Test	Passes Test		
Sulfates	$\leq 400 \text{ ppm}$		≤ 400 ppm		
ТАМС	$\leq 100 \text{ C}$	CFU/g		≤	CFU/g
COMPARY OF ORIGIN: U.S.					
<u>T METHOD POLICE</u> : N: 16-001314					
<u>I</u> NDP <u>A</u> Matern represented by this Cer	tificante ef	6 A	1. f	~ ~ ~ ~ ~ ~	
max ared in accor nee with the IPEC-P					
represented by this Cellicate of Analysis is not					
Drug Product or Hennold Item.					
		- · ··	.1		
Prepared by: Dat	te:	Job Ti	tle:		<u> </u>
Reviewed by: Dat	te:	Job Ti	tle:		

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