DCN: BSI-COA-0150 v.4.1

BIOSPECTRA

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

Effective Date:	14-Apr-2022	14-Apr-2025	: Date of Next Review
Prepared By:	Emily Gibbons	BSI-COA-0150 v.4.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

UREA

BIO EXCIPIENT GRADE / NEW CODE UREA-3221-

LOT: UREA- -

CH_4N_2O ⅄ F.W. 60.06 g/mol. ⅄ CAS# 57-13-6

Manufacture Date: / / Retest Date: / /

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

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

Meets or Exceeds USP / EP / JP Specifications

USP REQUIREMENTS

ANALYSIS	SPECIFICATION	TEST RESULT
Assay	98.0-102.0%	%
Identification A (IR)	Passes Test	Passes Test
Identification B (HPLC)	Retention Time Corresponds to Standard	Passes Test
Alcohol-Insoluble Matter	0.04% maximum	%
Urea RCA	NMT 0.1%	%
Organic Impurities Any Individual Unspecified Impurity	NMT 0.1%	%
Total Impurities	NMT 2.0%	%
Residue on Ignition (Sulfated Ash)	0.1% maximum	%

EP REQUIREMENTS

ANALYSIS	SPECIFICATION	TEST RESULT
Assay (dried substance)	98.5-101.5%	%
Appearance of Solution	Clear and Colorless	
Alkalinity	Passes Test	Passes Test
Ammonium	500 ppm maximum	ppm
Biuret	0.1% maximum	%
Heavy Metals	10 ppm maximum	ppm
Identification A	132-135°C	- °C
Identification B (IR)	Passes Test	Passes Test
Identification C	Passes Test	Passes Test
Identification D	Passes Test	Passes Test
Loss on Drying	1.0% maximum	%
Sulfated Ash (Residue on Ignition)	0.1% maximum	%

JP REQUIREMENTS		
ANALYSIS	SPECIFICATION	TEST RESULT
Assay	99.0% minimum	%
Chloride	0.007% maximum	%
Ethanol-insoluble substances	0.04% maximum	%
Heavy Metals	20 ppm maximum	ppm
Identification 1	Reddish Purple Color Develops	Reddish Purple Color Develops
Identification 2	White, Crystalline Precipitate is Formed	White, Crystalline Precipitate is Formed
Melting Point	132.5-134.5°C	- °C
Residue on Ignition (Sulfated Ash)	0.1% maximum	%
Sulfate	0.010% maximum	%

ADDITIONAL ANALYSES		
ANALYSIS	SPECIFICATION	TEST RESULT
Appearance	White Crystalline Powder	White Crystalline Powder
Assay	99.0-100.5%	%
Assay (Dried Basis)	99.0-101.0%	%
Elemental Impurities	Complies with USP <232><233>	Complies with USP <232><233>
Residual Solvents	Complies with USP <467>	Complies with USP <467>

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0006

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

RESIDUAL SOLVENTS STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1,2,3, or 4.

Prepared by: _____ Date: _____ Job Title: _____

Reviewed by: _____ Date: _____ Job Title: _____