

BioKyowa Inc.

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**CERTIFICATE OF ANALYSIS**

GIC: 1060400037050

PRODUCT: L-Glutamine

LOT NUMBER: GM-PL-24136

DATE OF MANUFACTURE: Nov/21/2024

DATE OF ANALYSIS: Dec/17/2024

RETEST DATE: Nov/21/2027

TEST	Method*	SPECIFICATION	RESULT
Appearance	Visual	White Crystalline Powder	White Crystalline Powder
Identification	USP	Conforms	Conforms
State of Solution	%T430nm	NLT 98.0%	99.0%
pH	USP	Between 4.0 and 6.0	5.1
Specific Rotation (at 20°C)	USP	Between +6.3 and +7.3	+6.8
Chloride	USP	NMT 0.020%	NMT 0.017%
Sulfate	USP	NMT 0.020%	NMT 0.020%
Iron	USP	NMT 10 PPM	NMT 10 PPM
Arsenic	USP	NMT 1.4 PPM	NMT 0.1 PPM
Cadmium	USP	NMT 0.5 PPM	NMT 0.1 PPM
Lead	USP	NMT 0.5 PPM	NMT 0.1 PPM
Mercury	USP	NMT 0.2 PPM	NMT 0.1 PPM
Foreign Amino Acids (TLC)**	USP	NMT 0.5%	NMT 0.4%
Loss on Drying	USP	NMT 0.20%	0.09%
Residue on Ignition	USP	NMT 0.10%	0.07%
Assay (Dried Basis)	USP	Between 99.0 and 101.0%	99.7%
Microbial Total Count	USP	NMT 1000 cfu/g	NMT 100 cfu/g
Microbial Count - Yeasts and Molds	USP	NMT 100 cfu/g	NMT 50 cfu/g
Microbial Count - Coliform	USP	Negative cfu/g	Negative cfu/g
Insoluble Foreign Matter	FCC	Conforms	Conforms

We hereby certify that the commodity described above meets the monograph requirements of the current USP and FCC; and meets the requirements of residual solvents on those pharmacopoeias. *METHOD-USP and FCC include cross validation with internal method. **Foreign Amino Acid Testing - Meets requirements for Related Compounds as required by USP, and Ninhydrin-positive substances as required by EP. Made in USA by fermentation using a non-pathogenic microbe, and without animal origin raw materials. Intended use for our product is as raw material or ingredient for further processing. Our product is not intended for API usage.

ORIGINAL

ANALYSIS APPROVED BY/DATE:

Gabe Seabaugh Feb-26-2025

Quality Assurance