

BioKyowa Inc.
 PO Box 1550
 Cape Girardeau, MO 63702
 Phone: (573) 335-4849
 Fax: (573) 335-1466



CERTIFICATE OF ANALYSIS

PRODUCT: L-GLUTAMINE
LOT NUMBER: GM-PL-18519
DATE OF MANUFACTURE: Feb-09-2018
DATE OF ANALYSIS: Feb-21-2018
RETEST DATE: Feb-09-2021

TEST	METHOD*	SPECIFICATION	RESULT
APPEARANCE	Visual	White crystalline powder	White Crystalline Powder
IDENTIFICATION	USP	Conforms	CONFORMS
STATE OF SOLUTION	%T430nm	NLT 98.0%	99.5%
pH	USP	4.0 - 6.0	4.8
SPECIFIC ROTATION (AT 20°C)	USP	+6.3 to +7.3°	+6.4
CHLORIDE	USP	NMT 0.020%	NMT 0.020%
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**	USP	NMT 0.5%	NMT 0.5%
LOSS ON DRYING	USP	NMT 0.20%	0.01%
RESIDUE ON IGNITION	USP	NMT 0.10%	0.05%
ASSAY (DRIED BASIS)	USP	99.0 - 101.0%	99.9%
TOTAL COUNT (CFU)	USP	NMT 1,000/g	NMT 1,000/g
YEASTS AND MOLDS (CFU)	USP	NMT 100/g	NMT 100/g
COLIFORM	USP	NEG/g	NEG/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 in those pharmacopoeias. *METHOD-USP and FCC include cross validation with internal method. ** Foreign Amino Acids 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.

ORIGINAL

ANALYSIS APPROVED BY / DATE:

30330-00/01/03, 30350-00

Linda Withrow

Linda Withrow, Quality Assurance

May-09-2018