BioKyowa Inc.
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BIOKYOWA

CERTIFICATE OF ANALYSIS

835

PRODUCT:	L-GLUTAMINE
LOT NUMBER:	GM-PL-13864
QUANTITY:	7,900 KG
DATE OF MANUFACTURE:	May-26-2013
DATE OF ANALYSIS:	Jun-03-2013
RETEST DATE:	May-26-2016

TEST	METHOD*	SPECIFICATION	RESULT
APPEARANCE	Visual	White crystalline powder	White crystalline powder
IDENTIFICATION	USP	CONFORMS	CONFORMS
STATE OF SOLUTION	%T430nm	NLT 98.0%	99.3%
pH	USP	4.0 - 6.0	5.2
SPECIFIC ROTATION (AT 20°C)	USP	+6.3 to +7.3°	+6.7
CHLORIDE	USP	NMT 0.020%	NMT 0.020%
SULFATE	USP	NMT 0.020%	NMT 0.020%
IRON	USP	NMT 10 PPM	NMT 10 PPM
HEAVY METALS	USP	NMT 5 PPM	NMT 5 PPM
LEAD	USP	NMT 5 PPM	NMT 5 PPM
ARSENIC	JP	NMT 1 PPM	NMT 1 PPM
FOREIGN AMINO ACIDS**	USP	NMT 0.5%	NMT 0.5%
LOSS ON DRYING	USP	NMT 0.20%	0.00%
RESIDUE ON IGNITION	USP	NMT 0.10%	0.08%
ASSAY (DRIED BASIS)	USP	99.0 - 101.0%	99.7%
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	NEG

We hereby certify that the commodity described above meets the monograph requirements of the current USP, JP, and FCC; and meets the requirements of residual solvents in those pharmacopoeias. *METHOD-USP including cross-validation. ** 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: Brendan O'Shaughnessy Jun-04-2013

Brendan O'Shaughnessy, Quality Manager

30330-00/01, 30350-00/01