



Shanghai Kyowa Amino Acid CO.,Ltd.

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CERTIFICATE OF ANALYSIS

7583
N/07

Commodity: L-LYSINE MONOHYDROCHLORIDE
Lot No.: 16031244 -
Manufacturing date: Apr-19-2016 -
Analysis date: Apr-19-2016
Relest date: Apr-19-2019 -


SPECIFICATION	ACCEPTANCE CRITERIA	RESULT
APPEARANCE	WHITE POWDER	WHITE POWDER
IDENTIFICATION BY IR	PASS TEST	PASS TEST
STATE OF SOLUTION (T%)	NOT LESS THAN 98.0%	NOT LESS THAN 98.0%
pH	5.0 ~ 6.0	5.7
SPECIFIC ROTATION (AT 20°C)	+ 20.7 ~ + 21.5°	+21.4°
(AT 25°C)	+ 20.4 ~ + 21.4°	+21.2°
AMMONIUM (NH ₄)	NOT MORE THAN 0.020%	NOT MORE THAN 0.020%
CHLORIDE CONTENT	19.1 ~ 19.5%	19.4%
SULFATE (SO ₄)	NOT MORE THAN 0.020%	NOT MORE THAN 0.020%
IRON (Fe)	NOT MORE THAN 10ppm	NOT MORE THAN 10ppm
HEAVY METALS (as Pb)	NOT MORE THAN 5ppm	NOT MORE THAN 5ppm
ARSENIC (As ₂ O ₃)	NOT MORE THAN 1ppm	NOT MORE THAN 1ppm
LOSS ON DRYING	NOT MORE THAN 0.40%	0.05%
RESIDUE ON IGNITION	NOT MORE THAN 0.10%	0.03%
RELATED SUBSTANCES		
UNSPECIFIED IMPURITY	NOT MORE THAN 0.2%	NOT DETECTED
TOTAL IMPURITIES	NOT MORE THAN 1.0%	NOT DETECTED
ASSAY (DRY BASIS)	99.0 ~ 101.0%	100.1%

We hereby certify that the commodity described above is tested in according with CP, however, meets quality requirements of the current JP, EP and USP monographs, including EP and USP requirements for residual solvent and microbiology (non-sterile substance for pharmaceutical use).

No animal origin raw materials/additives are used throughout the manufacturing process.

Made in China.

The undersigned affirms that contents mentioned above are truly reported in accordance with the analysis by Quality Control Department.


Lu Yazhou

Date of issue: May-18-2016

QA Manager