

SHANGHAI KYOWA AMINO ACID CO., LTD.
NO. 158, XINTUAN ROAD, QINGPU INDUSTRIAL ZONE, SHANGHAI, P.R.CHINA

CERTIFICATE OF ANALYSIS

Commodity: L-LYSINE MONOHYDROCHLORIDE
Lot No.: 13101108
Manufacturing date: Oct-25-2013
Analysis date: Oct-25-2013
Retest date: Oct-25-2016

7583

SPECIFICATION	ACCEPTANCE CRITERIA	RESULT
APPEARANCE	WHITE POWDER	WHITE POWDER
IDENTIFICATION BY IR	PASS TEST	PASS TEST
STATE OF SOLUTION (7%)	NOT LESS THAN 98.0%	NOT LESS THAN 98.0%
pH	5.0 ~ 6.0	5.6
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%	0.03%
RESIDUE ON IGNITION	NOT MORE THAN 0.10%	0.02%
FOREIGN AMINO ACIDS	NOT MORE THAN 0.5% (TLC, 50µg)	NOT MORE THAN 0.5% (TLC, 50µg)
ASSAY (DRY BASIS)	99.0 ~ 101.0%	100.0%

We hereby certify that the commodity described above is tested in accordance with CP, however, meets quality requirements of the current JP, EP, USP and FCC 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.

Lijinhua

QA Manager





Spett.le

METAPHARMACEUTICAL IND S.L.
D.ssa Miriam Miguel Sala
C/Josep Plà, n° 163, 2° 5ª
08020 Barcelona

Fiorenzuola, 14 lug. '14

Oggetto: Tracciabilità lotti

In riferimento alla Vs. richiesta confermiamo la corrispondenza dei seguenti lotti:

LISINA-L MONOCLORIDRATO Ph.Eur.
Lotto K7583005

cod. 007583
Lotto fornitore 13101108
D.ssa Miriam Miguel Sala
C/Josep Plà, n° 163, 2° 5ª
08020 Barcelona

Restando a disposizione per eventuali chiarimenti porgiamo distinti saluti.

A.C.E.F. S.p.A.

C.Q.

cod. 007583
Lotto fornitore 13101108
D.ssa Miriam Miguel Sala
C/Josep Plà, n° 163, 2° 5ª
08020 Barcelona

porgiamo distinti saluti.

A.C.E.F. S.p.A.

Lotto fornitore 13101108
C/Josep Plà, n° 163, 2° 5ª
08020 Barcelona

porgiamo distinti saluti.