



米克 (武汉) 生物科技有限公司

Mike(Wuhan) Biotechnology Co.,Ltd

## Certificate of Analysis -Alpha Lipoic Acid

CAS:1077-28-7

Batch Number: MK-ALA-221020

Batch Quantity: 2000kg

Manufacture Date: Oct.20th,2022

Analysis Date:Oct.24th,2022 Certificate Date:Oct.24th,2022

Shelf life 2 years when properly stored.

Storage: store in a cool dry place in well closed/sealed containers. Protect from light.

Test Item	Analysis Specification	Result
Appearance	Light yellow powder	Confirms
Identification	The retention time of the peak for alpha	Confirms
Specific optical rotation	-1.0°~+1.0°	0.6°
Melting point	60-62°C	61°C
Loss on drying	0.2% max.	0.19%
Bulk density	≥0.60 g/ml	Confirms
Polymer content	2% max.	Confirms
6-8-epitriethiooctanoic acid	0.2% max.	Non detectable
Heavy metals	≤10ppm	Confirms
Chloride	≤0.07%	Confirms
Limit of polymer content	≤2.0%	Confirms
Residual of Cyclohexane	≤500ppm	Confirms
Residual of Ethyl Acetate	≤250ppm	Confirms
Residual of Toluene	≤20ppm	Confirms
Assay	99.0~101.0%	99.20%

**This Product meets current European Pharmacopeia Requirements.**

### Additional Tests carried out in Addition to European Pharmacopeia requirements

Test	Specification	Results
Heavy metals –by atomic absorption		
1) Total heavy metals	≤10ppm	0.12ppm
2) Arsenic (As)	≤0.5ppm	0.01ppm
3) Cadmium (Cd)	≤1ppm	0.03ppm
4) Lead (Pb)	≤2ppm	0.05ppm
5) Mercury (Hg)	≤0.5ppm	0.03ppm
Microbiological Tests		
1) Total Plate count	≤100cfu/g	0.1cfu/g
2) Total Yeast and Mould	≤10cfu/g	0.1cfu/g
3) E. Coli in 10g	Absent	Complies
4) Salmonella in 10g	Absent	Complies
5) Staphylococcus in 10g	Absent	Complies

**Conclusion:** This product conforms to the enterprise standard .

