

CERTIFICATE OF ANALYSIS

Product Name:	Thioctic acid (Alpha Lipoic Acid)		
CAS No.:	1077-28-7	Ref. Standard:	USP 43
Batch No.:	20220909	Manuf. Date:	Sep. 09 ,2022
Quantity :	100kg	Expiration Date:	Sep. 08 ,2024
Storage Condition:	Store in a well-closed and dry place with constant room temperature and Non-direct sunlight.		

ITEM	METHOD	SPECIFICATION	RESULT
Appearance	Organoleptic	Yellow crystalline granule	Conforms
Identification	FTIR	Positive	Conforms
Physical & Chemical Characteristics			
Particle Size	USP	≥95% through 20 mesh	99.7%
Melting Point	USP	60.0-62.0°C	61.5°C
Specific rotation	USP	-1.0°~+1.0°	+0.13°
Loss on Drying	USP	≤0.2%	0.12%
Residue on Ignition	USP	≤0.1%	0.07%
Bulk density	USP	0.4-0.6g/ml	0.52g/ml
Tapped density	USP	0.5-0.7g/ml	0.66g/ml
Impurity			
Single Impurity	HPLC	≤0.1%	0.04%
Total Impurities	HPLC	≤2.0%	0.39%
Limit of polymer content	TLC	Conforms to standard	Conforms
Residual Solvent			
Cyclohexane	GC	≤3880ppm	Conforms
Ethyl Acetate	GC	≤5000ppm	Conforms
Toluene	GC	≤890ppm	Conforms
Heavy metals			
Lead(Pb)	ICP-MS	≤1.0ppm	Conforms
Arsenic(As)	ICP-MS	≤1.0ppm	Conforms
Cadmium(Cd)	ICP-MS	≤0.2ppm	Conforms
Mercury(Hg)	ICP-MS	≤0.1ppm	Conforms
Microbiological Tests			
Total Plate Count	USP	≤1000cfu/g	Conforms
Yeast & Mold	USP	≤100cfu/g	Conforms
E.Coli.	USP	Negative/10g	Negative
Salmonella	USP	Negative/10g	Negative
Staphylococcus	USP	Negative/10g	Negative
Assay(Dried Basis)	HPLC	98.0%~102.0%	98.57%
Conclusion:	Conform to USP 43 standard.		

Tested by: Tiantian Wang

Approved by: Yulian Liu

