

非開示情報

Certificate of Analysis

Product name	Alpha Lipoic Acid	CAS No.	1077-28-7
Batch No.	非開示情報	Source	Production Plant
Quantity	500.70g	非開示情報	STP-8026/01.02
Manufacturing date	2024.02	Manufacturing date	2024.03.02
Test date	2024.02	Test date	2026.02.25

Test items	Results	Method
Appearance	Slightly yellow crystal powder	Conforms Organoleptic
Solubility	Meets the requirements	Conforms Organoleptic
Identification	Meets the requirements	Conforms IR
		Conforms HPLC
Loss on drying	≤ 0.20%	0.10% USP
Specific rotation	- 1.0~+1.0°	+0.1° USP
Melting point	60.0~62.0°C	60.6~61.8°C USP
Residue on ignition	≤ 0.10%	0.04% USP
Heavy metals	≤ 10 ppm	Conforms USP
Lead	≤ 3 ppm	< 3 ppm USP
Arsenic	≤ 1 ppm	< 1 ppm USP
Cadmium	≤ 1 ppm	< 1 ppm USP
Mercury	≤ 0.1 ppm	< 0.1 ppm USP
Limit of polymer content	Meets the requirements	Conforms TLC
Residual solvents	Ethyl acetate ≤ 500 ppm	95 ppm GC
	Cyclohexane ≤ 3880 ppm	529 ppm GC
	Toluene ≤ 20 ppm	3 ppm GC
Related substance	Single impurity ≤ 0.1%	0.06% HPLC
	Total impurities ≤ 2.0%	0.12% HPLC
Assay	99.0~101.0% on the dried basis	99.5% HPLC
Total aerobic bacteria	≤ 1000 cfu/g	< 10 cfu/g USP
Mold & yeast	≤ 100 cfu/g	< 10 cfu/g USP
E.coli	Absence/g	ND USP
Staphylococcus aureus	Absence/g	ND USP
Salmonella	Absence/10g	ND USP
Particle size	100% through 20 mesh	Conforms USP
Loose bulk density	Report result	0.43 g/mL USP
Conclusion	Conforms 合格	

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