Certificate of Analysis

Product	ALPHA LIPOIC	C ACLES PHARMACEUTIA
Batch No.	3F240101	Approval Date 30/01/2024
Mfg. Date	03/01/2024	p. Date 02/01/2026
Quantity	633.50KG	*
Tests	Results	Specifications
Appearance	Complies	Yellow, crystalline powder
Melting point	61.0°C	Should be 60°C-62°C
Optical rotation	0°	Should be -1° - +1°
Identification	Complies	HPLC
	Complies	IR
Polymeric Lipoic Acid	Conforms	NMT 1.0%
Related substances	0.05%	Max Individual Impurity: NMT 0.1%
	0.07%	Total Impurity: NMT 2.0%
Residual Solvents	0.14%	Cyclohexane: NMT 0.388%
	N. D	Ethyl Acetate: NMT 0.5%
	N. D	Toluene: 0.089%
Particle size	Complies	100% through 40 mesh
Loss on drying	0.1%	NMT 0.2%
Residue on ignition	0.05%	NMT 0.1%
Microbial contamination	Conforms	Total plate count: max 1000cfu/g
	Conforms	Yeast and molds: max 100 cfu/g
	Conforms	E.coli: Negative
Assay	99.98%	NLT 99.0% NMT101.0% (calculated on the dried basis)
Conclusion: Conforms to USP43 standard.		