

RAWPHARMA BIZ PVT LTD
18 A Nirant Park
Sola Road Ahmedabad 380061
Gujarat, INDIA

Certificate of Analysis

PRODUCT NAME	Alpha Lipoic Acid
GRADE/USE	USP

Name of Product : Alpha Lipoic Acid USP			
Batch No.	: ALA/004/22	Q.C: A.R. No.	: FP-ALA/004/22
Mfg. Date	: 16-06-2022	Retest Date	: 15-06-2025
Release Date	: 20-06-2022	Quantity	: 200kg

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Description	Yellow crystalline Powder.	Yellow crystalline powder
2.	Solubility	Very Slightly soluble in water , very soluble in Dimethylformamide, freely soluble soluble in methanol.	Complies
3.	Identification		
	A. BY HPLC	The principal peak in the chromatogram obtained with test solution has the same RT as that of the peak in the chromatogram obtained with standard solution, as per assay test.	Complies
	B. By IR	The IR Spectra of Sample Preparation should match with that of WS.	Complies
4.	Chromatographic Impurity (Procedure-1) By HPLC	Single Impurity: NMT 0.1% Total Impurity: NMT 2.0%	0.015% 0.083%
5.	Chromatographic Impurity	(Procedure-1) By TLC	Complies
6.	Melting Point	Between 60.0° C to 62.0 ° C	62° C
7.	Optical Rotation	Between -1.0 ⁰ to + 1.0 ⁰	0.0°
8.	Loss on Drying	Not more than 0.2 % w/w	0.14%w/w
9.	Residue on Ignition	Not more than 0.1 % w/w	0.031%w/w
10.	Untapped Density	Report the result.	0.312 gm/ml
11.	Tapped Density	Report the result.	0.454 gm/ml
12.	Assay (On Dried Basis)	Between 99.0 % and 101.0 % w/w	99.79%
	Additional Test		
13.	Residual Solvent (BY GC)	Toluene: NMT 890ppm	ND
		Cyclohexane: NMT 5000ppm	874.36 ppm
		Ethyl Acetate : NMT 5000ppm	ND