



BELOORBAYIR BIOTECH LTD. (unit : bayir chemicals)

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CIN : U73100KA2005PLC035741 Licence No.: KTK/37/54/2019 dated: 01/06/2019

CERTIFICATE OF ANALYSIS

Product Name: LEVOCARNITINE USP			
Batch No. : LCA-25001	Quantity : 1000.0 Kg		
Mfg. Date : January-2025	Expiry Date : December- 2028		
A.R. Number : BCFP25001	Release Date : 03/02/2025		

SL. NO	TEST PARAMETER	SPECIFICATIONS	RESULTS
1	Description	A White crystals or crystalline powder, hygroscopic.	White crystalline powder, hygroscopic
2	Identification (by IR)	The spectrum of the test sample is concordant with that of standard spectrum	Complies
3	Solubility	Freely soluble in water and in hot alcohol. Practically insoluble in acetone, in ether and in benzene.	Complies
4	Assay (on anhydrous basis Levocarnitine)	97.0% to 103.0%	99.6%
5	Residue on ignition	Not more than 0.5%	0.05%
6	Chloride and Sulphate	Not more than 0.4%	<0.4%
7	Enantiomeric Purity	Not more than 0.2% of D-Carnitine	Complies
8	Limit of potassium	Not more than 0.2%	<0.2%
9	Limit of Sodium	Not more than 0.1%	<0.1%
10	Specific optical rotation (on anhydrous basis)	-29.0° to -32.0°	-31.5°
11	pH	5.5 to 9.5	7.2
12	Water content	Not more than 4.0%	1.6%

REMARKS : THE MATERIAL COMPLIES AS PER USP SPECIFICATIONS

Storage : Preserve in tight containers.

Prepared by : *LR*
Date : 03/02/2025

Checked by : *D*
Date : 03/02/2025

Approved by : *fw*
Date : 03/02/2025

Laboratory : No. 84, 13th Cross, 37th Main, 34th Ward, Doddanna Industrial Estate,
Near Peenya 2nd Stage, Bengaluru - 560 091, Karnataka, INDIA