



东北制药集团股份有限公司

NORTHEAST PHARMACEUTICAL GROUP CO., LTD

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CERTIFICATE OF ANALYSIS
LEVOCARNITINE (L-CARNITINE BASE) EP

BATCH NUMBER	DY0172200205	MANUFACTURE DATE	Jun.3.2022
BATCH SIZE	1000kg	TEST DATE OF APPLICATION	Jun.21.2022
QUANTITY	40Drums	RETEST DATE	Jun.2.2024
Analysis Items		Specifications	Analysis Results
1.	Characteristics	White or almost white,crystalline powder or colourless crystals, hygroscopic	White crystalline powder,hygroscopic
2.	Identification	IR Absorption: the spectrum obtained with the substance to be examined correspond with the spectrum obtained with the RS.	Complied
3.	Specific Rotation (on anhydrous substance)	-32.0° ~ -29.0°	-31.2°
4.	Acidity or Alkalinity (pH)	6.5 ~ 8.5	7.6
5.	Assay (anhydrous substance)	98.0% ~ 102.0%	99.7%
6.	Water Content	≤1.0%	0.17%
7.	Related Substances	Impurity A≤0.3% Any others≤0.10% Total Impurities other than impurity A≤0.5%	0.01% < 0.02% < 0.02%
8.	Sulphated Ash	≤0.1%	0.02%
9.	Chloride	≤200ppm	< 200ppm
10.	Sulphates	≤300ppm	< 300ppm
11.	Clarity of Solution	Clear	Clear
12.	Color of Solution	Colorless	Colorless

We, **Northeast Pharmaceutical Group Co. , Ltd.**, certify that this batch of **L-Carnitine Base** meets the requirements of **EP10.1**

Supervisor

Final Batch Disposition

Approved

By:

