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)

For Injection Use

BATCH NUMBER	DY0172200312	**MANUFACTURE DATE**	Sep.6.2022
BATCH SIZE	1000kg	**TEST DATE OF APPLICATION**	Sep.6.2022
QUANTITY	40Drums	**RETEST DATE**	Sep.5.2024

	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.	Clarity of Solution	Clear	Clear
4.	Color of Solution	Colorless	Colorless
5.	Specific Rotation	-32.0°～ -29.0°	-31.0°
6.	Assay (anhydrous substance)	98.0%～102.0%	99.5%
7.	Acidity or Alkalinity （pH)	6.5～8.5	7.5
8.	Sulphated Ash	≤0.1%	0.05%
9.	Chloride	≤200ppm	＜200ppm
10.	Sulphates	≤300ppm	＜300ppm
11.	Water Content	≤1.0%	0.16%
12.	Related Substance	Impurity A≤0.3% Any other impurity:≤0.10% Total Impurities other than impurity A≤0.5%	0.01% ＜0.02% ＜0.02%
13.	Residual Solvents	Acetone≤5000ppm Ethanol≤5000ppm Methanol≤3000ppm	24ppm 365ppm Not detected
14.	Total aerobic microbial count	≤10^3cfu/g	＜10cfu/g
15.	Yeasts and Moulds	≤10^2cfu/g	＜10cfu/g
16.	Salmonella	Not detected/10g	Not detected
17.	Escherichia coli	Not detected/g	Not detected
18.	Staphylococcus aureus	Not detected/g	Not detected
19.	Bacterial endotoxin	＜0.1EU/mg	＜0.1EU/mg

We, **Northeast Pharmaceutical Group Co., Ltd.**, certify that this batch of **LEVOCARNITINE (L-CARNITINE BASE)** meets the requirements of **Inhouse standard.**

Supervisor 路阳 2022.09.15
Final Batch Disposition

Approved **By:** 康桂茹

2022年9月15日

EN3066003114