



东北制药集团股份有限公司

NORTHEAST PHARMACEUTICAL GROUP CO., LTD

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CERTIFICATE OF ANALYSIS
ACETYL L-CARNITINE HCL

BATCH NUMBER	DY0542200023	MANUFACTURE DATE	May.24.2022
BATCH SIZE	1000kg	TEST DATE OF APPLICATION	May.24.2022
QUANTITY	40Cartons	RETEST DATE	May.23.2024
Analysis Items		Specifications	Analysis Results
1.	Characteristics	White crystalline powder	White crystalline powder
2.	Identification	IR:Complies	Complies
3.	Specific Rotation	-26° ~ -29°	-28°
4.	Acidity (pH)	2.3 ~ 2.6	2.4
5.	Loss on Drying	≤0.5%	0.17%
6.	Residue on Ignition	≤0.5%	0.02%
7.	Heavy Metals	≤0.001%	< 0.001%
8.	Cyanide	Meets the Requirements	Meets the Requirements
9.	Arsenic	≤0.0001%	< 0.0001%
10.	Assay	98.5% ~ 101.0%	99.7%
11.	The total aerobic microbial count(TAMC)	≤10 ³ cfu/g	< 10cfu/g
12.	The total combined yeasts and moulds count(TYMC)	≤10 ² cfu/g	< 10cfu/g
13.	Escherichia coli	Not detected /g	Not detected
14.	Staphylococcus aureus	Not detected /g	Not detected
15.	Salmonella	Not detected /10 g	Not detected

We, Northeast Pharmaceutical Group Co. , Ltd., certify that this batch of ACETYL L-CARNITINE HCL meets the requirements of Inhouse Standards.

Supervisor

路阳 2022.06.02

Final Batch Disposition

Approved

By:

唐桂茹

2022年6月2日

