

武汉德洛透大弘元股份有限公司

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WUHAN

GRAND

HOYO

CO., LTD.

NO.1 INDUSTRIAL PARK, GEDIAN ECONOMY DEVELOPMENT ZONE, E'ZHOU CITY, HUBEI, CHINA

质 检 单

CERTIFICATE OF ANALYSIS N-Acetyl-L-Cysteine

C103-202302516F-1

产品名称: N-乙酰-L-半胱氨酸 (非动物源/素食)		批 号 Lot No: C103-202302516F
Product: N-ACETYL-L-CYSTEINE (NON-ANIMAL SOURCE/VEGAN)		CAS No: (616-91-1)
批 量 Quantity: 1000KGS		报告日期 Report Date: FEB 17, 2023
检测项目 Test Item	检测标准 Specification (EP10.3&USP39)	检测结果 Result
性状 Characters	白色结晶性粉末或无色结,易溶于水和 96%酒精, 几乎不溶于二氯甲烷。A almost white crystalline powder or Colourless crystals, freely soluble in water and in alcohol(96 percent), practically insoluble in methylene chloride	符合 Conforms
鉴别 Identification	Test A (Specific Optical rotation)	符合 Conforms
	Test (IR)	符合 Conforms
溶液外观 Appearance of solution		澄清无色 Clear and colourless
比旋度 Specific optical rotation[α] _D ²⁰		+21.0 to +27.0° (dried substance)
相关物质 related substances	杂质 B ImpurityB L-半胱氨酸 L-Cysteine ≤0.2%	<0.05%
	杂质 C ImpurityC N, N-Diacetyl-L-Cystine ≤0.3%	<0.10%
	杂质 D ImpurityD N S-Diacetyl-L-Cysteine ≤0.15%	<0.05%
	其他杂质 Unspecified impurities	杂质 A Impurity A L-Cystine ≤0.10%
		其他未知杂质 Any other impurity ≤0.10%
	总杂质 Total ≤0.5%	0.09%
酸度 pH	2.0 to 2.8	2.2
锌 Zinc	不得大于 Not more than 5ppm	<5 ppm
重 金 属 Heavy metals(Pb)	不得大于 Not more than 10ppm	<10 ppm
铅 Lead	不得大于 Not more than 2ppm	<2 ppm
砷 Arsenic	不得大于 Not more than 1ppm	<1 ppm
镉 Cadmium	不得大于 Not more than 1ppm	<1 ppm
汞 Mercury	不得大于 Not more than 0.1ppm	<0.1 ppm
干燥失重 Loss on Drying	不得大于 Not more than 0.5%	0.09%
炽灼残渣 Residue on ignition	不得大于 Not more than 0.2%	0.10%
含 量 Assay	98.5 ~ 101.0 % (dried substance)	99.5%
颗粒度 Particle Size	100% pass 20Mesh	Conforms
残留溶剂 Residual Solvents	Meet the requirements	Meet the requirements
Tapped Density 紧密度	0.75-0.85g/ml	0.85g/ml
Total Plate Count	< 1000cfu/g	Conforms
Yeast & molds	< 100cfu/g	Conforms
Salmonella	Negative/25g	Conforms
E Coli	Negative/25g	Conforms
Staphylococcus	Negative/25g	Conforms

结论: 本品按 EP10.3&USP39 质量标准检验, 结果符合规定。Conclusion: Agree with the specification of EP10.3&USP39.

备注: Remarks: Vegan/Non Animal Source.

Origin: D,L-2-amino-Δ 2-thiazoline-4-carboxylic acid (ATC)

STORAGE CONDITIONS: PRESERVE IN TIGHT CONTAINERS AT CONTROLLED ROOM TEMPERATURE

Manu. Date: FEB 12, 2023

Expire Date: JAN 18, 2026

检验报告员: 陈彩虹

复核人: 赵敏

质检部负责人: 张博

Inspector:

Auditor:

Chief of QC: