

METAPHARMACEUTICAL

N DE LOTE:

武 汉 远 大 股 份 有 限 公 司

WUHAN

WUHAN GRAND HOYO CO., LTD. QUALITY CONTROL
武汉远大弘元股份有限公司
检验专用章(3)
仅供检验使用,其他无效

CO., LTD.

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

质 检 单 CERTIFICATE OF ANALYSIS N-Acetyl-L-Cysteine C103-2110515F-1

产品名称: N-乙酰-L-半胱氨酸 (非动物源/素食)		批 号 Lot No: C103-202110515F
Product: N-ACETYL-L-CYSTEINE (NON-ANIMAL SOURCE/VEGAN)		CAS No: (616-91-1)
批 量 Quantity: 1000KGS		报告日期 Report Date: OCT 19, 2021
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 present), 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	Conforms
比旋度 Specific optical rotation[α] _D ²⁰	+21.0 to +27.0° (dried substance)	+22.5°
相关物质 related substances	杂质 B Impurity B L-半胱氨酸 L-Cysteine ≤0.2%	<0.05%
	杂质 C Impurity C N, N-Diacetyl-L-Cystine ≤0.3%	<0.05%
	杂质 D Impurity D N S-Diacetyl-L-Cysteine ≤0.15%	0.06%
	其他杂质 Unspecified impurities	杂质 A Impurity A L-Cystine ≤0.10% <0.05%
	其他未知杂质 Any other impurity ≤0.10%	<0.05%
总杂质 Total	≤0.5%	0.14%
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%	0.05%
含 量 Assay	98.5 ~ 101.0 % (dried substance)	99.7%
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	0.84g/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: OCT 14, 2021

Expire Date: SEP 26, 2024

检验报告员:

复核人:

质检部负责人:

Inspector:

Auditor:

Chief of QC: