



武汉远大弘元股份有限公司  
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NO.1 INDUSTRIAL PARK, GEDIAN ECONOMY DEVELOPMENT ZONE, YICHANG CITY, HUBEI, CHINA

质 检



WUBC

C E R T I F I C A T E O F A N A L Y S I S C103-2005038-1

产品名称: N-乙酰-L-半胱氨酸(非动物源/素食) 批 号 Lot No: C103-202005309F

Product: N-ACETYL-L-CYSTEINE (NON ANIMAL SOURCE/VEGAN) CAS No: (616-91-1)

批 量 Quantity: 25KGS X40 报告日期 Report Date: MAY 15, 2020

Item 项目	Specification 标准(EP9 & USP39)	Result 检测结果
Characters	A White ,crystalline powder or Colourless crystals	符合 Conforms
Solubility	Freely soluble in water and in alcohol,practically insoluble in methylene chloride	符合 Conforms
鉴别 Identification	Specific rotation [ $\alpha$ ] <sub>D</sub> <sup>20</sup>	+21.0 to +27.0° (on dried basis)
	熔 点 Melting point	104°C to 110°C
	红外光谱 Infrared Spectrum	符合标准 Compares to standard
	相关物质 Related substances	The chromatograms obtained with sample and standard are compared.The retention time and size of the principal peak in the chromatograms should be the same
	鉴别反应 Identification reaction	显现深紫色 A dark violet colour develops
溶解状况 appearance of solution	样品溶液澄清无色 Solution S is clear and colourless	符合 Conforms
酸度 pH	2.0 to 2.8	2.2
锌 Zinc	不得大于 Not more than 10 ppm	<10 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 3ppm	<3 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 1.0%	0.11%
灼烧残渣 Residue on ignition(sulfated)	不得大于 Not more than 0.2%	0.05%
相关物质 related substances	L-Cystine $\leq 0.5\%$	<0.05%
	L-Cysteine $\leq 0.5\%$	<0.05%
	N,N'-diacetyl-L-cystine $\leq 0.5\%$	<0.05%
	N S-Diacetyl-L-Cysteine $\leq 0.5\%$	<0.05%
	The Biggest Non Identified Impurity $\leq 0.5\%$	<0.05%
	Sum of Impurities $\leq 0.5\%$	0.05%
含 量 Assay (on dried substance)	98.0 to 101.0 %	99.5%
残留溶剂 Residual Solvents	Meet the requirements	Meet the requirements
颗粒度 Particle Size	100% pass 20Mesh	Conforms
Bulk Density(Tap Density) 紧密度	0.75-0.85g/ml	0.82g/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 EP9& USP39 标准检验,结果符合规定。 Conclusion: Agree with the specification EP9 & USP39.

备注: Remarks: Vegan/Non Animal Source. Origin: D,L-2-amino-  $\Delta$  2-thiazoline-4-carboxylic acid (ATC)

STORAGE CONDITIONS: PRESERVE IN TIGHT CONTAINERS AT CONTROLLED ROOM TEMPERATURE

Manu. Date: MAY 08, 2020

Expire Date: APR 30, 2023

检验报告员:

复核人:

质检部负责人:

Inspector:

Auditor:

Chief of QC:

赵敏

胡明

赵红敏