



武汉远大弘元股份有限公司

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### SPECIFICATIONS OF N-ACETYL-L-CYSTEINE

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Product Name: N-Acetyl-L-Cysteine (Acetylcysteine)

CAS NO.: 616-91-1

Molecular formula: C<sub>5</sub>H<sub>9</sub>NO<sub>3</sub>S

Molecular weight: 163.20

Item	Specification (EP10.3&USP39)	
Characters	White or almost white, crystalline powder or colourless crystals, freely soluble in water and in ethanol, practically insoluble in methylene chloride.	
Identification	Specific rotation [α] <sub>D</sub> <sup>20</sup>	+21.0 to +27.0° (on dried basis)
	Infrared Spectrum	It complies with the spectrum obtained with Acetylcysteine CRS.
	Related substances	The chromatography obtained with sample and standard are compared. The retention time and size of the principal peak in the chromatography should be the same
	Melting point	104 °C ~ 110°C
	Identification reaction	A dark violet colour develops
Appearance of solution	Solution S is clear and colourless	
pH	2.0 ~2.8	
Zn	≤ 10ppm	
Heavy Metals(Pb)	≤ 10ppm	
Lead	≤ 3ppm	
Arsenic	≤ 1ppm	
Cadmium	≤ 1ppm	
Mercury	≤ 0.1ppm	
Related substances	By Liquid chromatography L-Cystine: ≤0.2% N, N'-diacetyl-L-Cystine: ≤0.3% N,S'-diacetyl-L-Cysteine: ≤0.15% Impurity A: ≤ 0.10% Unspecified impurities: ≤ 0.10% Total impurities: ≤ 0.5%	
Loss on drying	Not more than 1.0%	
Sulphated ash	Not more than 0.2%	
Residual Solvents	Meet the requirements	
Particle size	100% pass 20 mesh	
Density	Tapped Density: 0.75-0.85g/ml	
Microbiology	Total Plate count less than 1000cfu/g Yeast & molds less than 100cfu/g Salmonella Negative/25g E Coli Negative/25g Staphylococcus Negative/25g	
Assay	98.5 to 101.0 % (Dried substance)	

Conclusion: Agree with the specification EP10.3&USP39

Storage: Preserve in tight containers at controlled room temperature.

Shelf life: Recommend 3 years.

