

Certificate of Analysis

Product name: **Acetylcysteinum apyrogen**
Batch number / Weight: **21H03-B09-218127 / 500 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification A	+21,0 - +27,0	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear/ colourless	Conform		
Specific optical rotation	+21,0 - +27,0	+22,8		
Related substances	Conform	Conform		
Impurity B	<=0,2	<0,05	%	
Impurity C	<=0,3	<0,05	%	
Impurity D	<=0,15	<0,05	%	
Any other impurity	<=0,10	0,07	%	
Total impurities	<=0,5	0,07	%	
Zinc	<=10	Conform	ppm	
Loss on drying	<=1,0	0,05	%	
Sulphated ash	<=0,2	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,5 - 101,0	99,3	%m/m	
Endotoxins	<=5	<5	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Agnieszka Pszczółka
 Qualified Person

30-03-2022

Expiration: 31-05-2026

Conclusion: APPROVED

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