

Certificate of Analysis

Product name: **Acetylcysteinum apyrogen**

Batch number / Weight: **22B07-B19-222289 / 100 G**

Analysed according to: **Ph. Eur. 10**

Number of analysis / Inspection Code **22B07-B19 / INS-22-4183**

Reference Code / No.: **V01407 / 1100044380**

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	+22,9		
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	<0,01	%	
Sulphated ash	<=0,2	0,10	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,5 - 101,0	99,9	%m/m	
Endotoxins	<=5	<5	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)		<10	CFU/g	
Total yeasts and moulds (TYMC)		<10	CFU/g	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, EI Spol, CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

14-09-2022

Expiration: 31-05-2026

Conclusion: APPROVED

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