Certificate of Analysis

Product name: **Acetylcysteinum apyrogeen**

Batch number / Weight: **23H16-B01-231631 / 25 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23H16-B01 / INS-23-6819**

Reference Code / No.: **V01407 / 1100064520**

Tests	Requirement	Result	Unit	Standard remark
Protocol number		1819/S/0823		
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification A	+21,0 - +27,0	+23,7		
Identification C	Conform	Conform		
Appearance of solution	Clear/ colourless	Conform		
Specific optical rotation	+21,0 - +27,0	+23,7		
Related substances	Conform	Conform		
Impurity B	<=0,2	0,00	%	
Impurity C	<=0,3	<0,05	%	
Impurity D	<=0,15	<0,05	%	
Any other impurity	<=0,10	0,000	%	
Total impurities	<=0,5	0,00	%	
Zinc	<=10	<3	ppm	
Loss on drying	<=1,0	0,03	%	
Sulphated ash	<=0,2	0,00	%	
Assay	98,5 - 101,0	100,58	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Endotoxins	<=5	<5	IU / g	
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 FAPL, ElSpol, CBMiA, Eurofins

Release:
Dominika Sołtysik
Qualified Person

18-10-2023

Expiration: 31-01-2028

Conclusion: APPROVED

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