

Certificate of Analysis

Productname: Acetylcysteinum apyrogeen
Number of analysis/Inspection Code: 1 / KEUR-180073B
Batchnumber: 19A23-B03-367349
Reference code / No.: 2285 / 1100001383
Analysed according to: PH.EUR9.7+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or Colourless crystals	Conform Conform		
Identification A	+21,0 - +27,0	Conform		Specific optical rotation
Identification C	Conform	Conform		IR-spectrum
Appearance of solution	Clear / colourless	Conform		5% <i>m/V</i>
pH	2,0 - 2,8	2,2		1% <i>m/V</i>
Specific optical rotation	+21,0 - +27,0	+22,1		Phosphatebuffer pH 7.0, dried
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	<0,05	%	
Impurity B	<=0,2	0,4	%	
Impurity C	<=0,3	<0,05	%	
Impurity D	<=0,15	<0,05	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=0,5	0,4	%	
Zinc	<=10	Conform	ppm	
Loss on drying	<=1,0	0,1	%	3 h 70°C vacuum
Sulphated ash	<=0,2	0,2	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Acetylcysteine	98,5 - 101,0	99,6	% <i>m/m</i>	Dried
Endotoxins	<=5	Conform	IU / g	LAL-test
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
 dr. M.J. Vincenten - van Maanen
 Pharmacist - Qualified Person

02/03/20

Expiration: 12-2023

Conclusion: APPROVED

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