

Certificate of Analysis

Product name: Acetylcysteinum
Batch number / Weight: 19E09-B02-217107 / 25 G
Analysed according to: Ph.Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
pH	2,0 - 2,8	2,2		
Specific optical rotation	+21,0 - +27,0	+23,3	°	
Related substances	Conform	Conform		
Impurity A	<=0,5	0,0	%	
Impurity B	<=0,5	<0,05	%	
Impurity C	<=0,5	0,1	%	
Impurity D	<=0,5	0,0	%	
Any other impurity	<=0,5	0,0	%	
Total impurities	<=0,5	0,1	%	
Zinc	<=10,0	<2	ppm	
Loss on drying	<=1,0	0,0	%	
Sulphated ash	<=0,2	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Acetylcystein	98,0 - 101,0	100,2	%m/m	
Total aerobic microbial count (TAMC)	<=100	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10	Conform	CFU/g	
Endotoxins	Conform	Conform	IU / mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

24-11-2021

Expiration: 31-01-2024

Conclusion: APPROVED

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