

Certificate of Analysis

Product name: Bromhexini hydrochloridum
Batch number / Weight: 21D07-B05-217028 / 5 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification C	White	Conform		
Appearance of solution	Clear / $\leq Y_6$	Conform		
Related substances	Conform	Conform		
Impurity C	$< 0,15$	$< 0,15$	%	
Any impurity	$\leq 0,10$	$< 0,10$	%	
Total impurities	$\leq 0,2$	$< 0,2$	%	
Loss on drying	$\leq 1,0$	0,0	%	
Sulphated ash	$\leq 0,1$	0,1	%	
Assay Bromhexine hydrochloride	98,0 - 102,0	101,1	%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

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

23-02-2022

Expiration: 15-07-2024

Conclusion: APPROVED

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