

Certificate of Analysis

Product name: Bromhexini hydrochloridum
Batch number / Weight: 21I06-B06-213365 / 10 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance		Conform		
Identification		Conform		
Identification C		Conform		
Appearance of solution		Conform		
Related substances		Conform		
Impurity C		<0,15	%	
Any other impurity		<0,10	%	
Total impurities	<=0,2	<0,2	%	
Loss on drying	<=1,0	0,0	%	
Sulphated ash	<= 0,1	0,1	%	
Assay		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

24-02-2022

Expiration: 15-07-2024

Conclusion: APPROVED

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