

Certificate of Analysis

Product name: **Bromhexini hydrochloridum**

Batch number / Weight: **21J12-B12-222296 / 10 G**

Analysed according to: **Ph. Eur. 10.8**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / $\leq Y_6$	Conform		
Related substances	Conform	Conform		
Impurity C	$\leq 0,15$	0,00	%	
Any other impurity	$\leq 0,10$	0,06	%	
Total impurities	$\leq 0,2$	0,1	%	
Loss on drying	$\leq 1,0$	0,1	%	
Sulphated ash	$\leq 0,1$	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,0 - 102,0	99,2	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

18-08-2022

Expiration: 30-11-2025

Conclusion: APPROVED

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