

Certificate of Analysis

Product name: **Guaifenesinum**
Batch number / Weight: **20B10-F04-217185 / 250 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		
Impurity C, D	<=0,1	<0,03	%	
Impurity B	<=0,5	0,1	%	
Any other impurity	<=0,05	<0,03	%	
Total impurities	<=0,7	0,1	%	
Chlorides and monochlorhydrines	<=250	Conform	ppm	
Loss on drying	<=0,5	0,1	%	
Sulphated ash	<=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	100,2	%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

10-12-2021

Expiration: 20-10-2024

Conclusion: APPROVED

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