

Certificate of Analysis

Productname: **Guaifenesinum**
Number of analysis/Inspection Code: 1 / KEUR-186327B
Batchnumber: **20B10-F04-370896**
Reference code / No.: 2217 / 19GF10790
Analysed according to: **PH.EUR10.0**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / colourless	Conform		2%/v
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		HPLC
Impurity C, D	<=0,1	<0,03	%	
Impurity B	<=0,5	0,1	%	
Any other impurity	<=0,5	<0,03	%	
Total impurities	<=0,7	0,1	%	
Chlorides and monochlorhydrins	<=250	Conform	ppm	
Loss on drying	<=0,5	0,1	%	3 h 60°C in vacuo
Sulphated ash	<=0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Guaifenesin	98,0 - 102,0	100,2	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
Paul Hofman
Pharmacist - Qualified Person

10/14/20

Expiration: 10-2024

Conclusion: APPROVED

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