

Certificate of Analysis

Product name: Chlorphenamini maleas

Batch number / Weight: 21J01-B03-232308 / 10 G

Analysed according to: Ph.Eur.11.2

Number of analysis / Inspection Code 21J01-B03 / INS-22-0806

Reference Code / No.: V01853 / SLL/C/0721103

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	130 - 135	134,1	°C	
Identification B	Conform	Conform		
Identification C	-0,10 - +0,10	Conform	°	
Appearance of solution	Conform / colour <=BY6	Conform		
Optical rotation	-0,10 - +0,10	+0,008	°	
Related substances	Conform	Conform		
Impurity A	<=0,2	<0,05	%	
Impurity B	<=0,1	<0,05	%	
Impurity C	<=0,1	<0,05	%	
Impurity D	<=0,1	0,00	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,00	%	
Loss on drying	<=0,5	0,00	%	
Sulphated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Chlorphenamine maleate	98,0 - 101,0	100,22	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:
Dominika Soltysik
Qualified Person

28-11-2023

Expiration: 31-05-2026

Conclusion: APPROVED

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