

Certificate of Analysis

Product name: Chlorphenamini maleas
Batch number / Weight: 21J01-B03-218856 / 10 G
Analysed according to: Ph. Eur.

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

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

27-04-2022

Expiration: 31-05-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.