

Certificate of Analysis

Productname: Chlorphenamini maleas
Number of analysis/Inspection Code: 3 / KEUR-181097B
Batchnumber: 19C26-B01-367385
Reference code / No.: 4254 / SLL/C/0119017
Analysed according to: PH.EUR 9.7

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	130 - 135	134	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Identification C	-0,10 - +0,10	Conform	°	Optical rotation
Appearance of solution	Conform / colour <=BY6	Conform		10% <i>m/V</i>
Optical rotation	-0,10 - +0,10	0,00	°	
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	<0,05	%	
Impurity B	<=0,1	<0,05	%	
Impurity C	<=0,1	<0,05	%	
Impurity D	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Loss on drying	<=0,5	0,3	%	4 h 105 °C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Chlorphenamine maleate	98,0 - 101,0	99,0	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

03/12/20

Expiration: 12-2023

Conclusion: APPROVED

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