

Certificate of Analysis

Productname: Diphenhydramini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-179371B
Batchnumber: 18K28-B02-364320
Reference code / No.: 4254 / SLL/DPH/1118079
Analysed according to: PH.EUR 9.5

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification C	Conform	Conform		IR-spectrum
Identification D	White	Conform		Chloride
Appearance of solution	Clear /colour <=BY6	Conform		5% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	0,1	%	
Any other impurity	<=0,3	0,1	%	
Total impurities	<=1,0	0,2	%	
Loss on drying	<=0,5	0,2	%	105°C
Sulphated ash	<= 0,1	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Diphenhydramine hydrochloride	99,0 - 101,0	100,5	% <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:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

01/08/20

Expiration: 10-2023

Conclusion: APPROVED

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