

Certificate of Analysis

Productname: **Diphenhydramini hydrochloridum**
Number of analysis/Inspection Code: 1 / KEUR-186760B
Batchnumber: **20G03-F08-374370**
Reference code / No.: 4254 / SLL/DPH/0620064
Analysed according to: **PH.EUR10.2**

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%m/V
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	0,1	%	
Loss on drying	<=0,5	0,2	%	105 °C
Sulphated ash	<= 0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Diphenhydramine hydrochloride	99,0 - 101,0	100,3	%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

11/02/20

Expiration: 05-2025

Conclusion: APPROVED

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