

## Certificate of Analysis

**Product name:** **Diphenhydramini hydrochloridum**  
**Batch number / Weight:** **21K29-B04-216253 / 25 G**  
**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification C	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear /colour <=BY6	Conform		
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,5	0,06	%	
Any other impurity	<=0,3	0,07	%	
Total impurities	<=1,0	0,13	%	
Loss on drying	<=0,5	0,07	%	
Sulphated ash	<= 0,1	0,07	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Diphenhydramine hydrochloride	99,0 - 101,0	100,2	%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

24-03-2022

Expiration: 30-09-2026

Conclusion: APPROVED

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