

## Certificate of Analysis

**Product name:** **Chlorpromazini hydrochloridum**

**Batch number / Weight:** **21L09-B02-216232 / 25 G**

**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder, it decomposes on exposure to air and light	Conform		
Identification A	acc to Ph.Eur.	Conform		
Identification C	acc to Ph.Eur.	Conform		
pH	3,5 - 4,5	4,34		
Impurity F	<=0,15	<0,15	%	
Related substances	Conform	Conform		
Impurity B	<=0,3	<0,05	%	
Impurity C	<=0,3	<0,05	%	
Impurity D	<=0,3	<0,05	%	
Impurity A	<=0,15	<0,05	%	
Impurity E	<=0,15	<0,05	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=1,0	<0,05	%	
Loss on drying	<= 0,5	0,17	%	
Sulphated ash	<= 0,1	0,10	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Chlorpromazine hydrochloride	99,0 - 101,0	100,5	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
Agnieszka Pszczółka  
Qualified Person

31-03-2022

Expiration: 30-04-2026

Conclusion: APPROVED

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