

## Certificate of Analysis

**Product name:** **Promethazini hydrochloridum**  
**Batch number / Weight:** **19C14-B13-191843 / 10 G**  
**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or faintly yellowish, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification D	Conform	Conform		
pH	4,0 - 5,0	4,4		
Related substances	Conform	Conform		
Impurity B	<=0,8	<0,8	%	
Impurity C	<=0,2	<0,2	%	
Impurity A	<=0,1	<0,05	%	
Impurity D	<=0,1	<0,1	%	
Unspecified impurities	<=0,10	<0,10	%	
Total impurities	<=1,2	<1,2	%	
Loss on drying	<=0,5	0,2	%	
Sulphated ash	<=0,1	Conform	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Promethazine hydrochloride	99,0 - 101,0	100,8	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
 Aleksandra Mazanek  
 Qualified Person

07-09-2019

Expiration: 31-05-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.