

## Certificate of Analysis

**Product name:** **Promethazini hydrochloridum**  
**Batch number / Weight:** **20B17-B06-200921 / 10 G**  
**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or faintly yellowish, crystalline powder	Conform		
Identification	Conform	Conform		
Melting point	about 222	223	°C	
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification D	Conform	Conform		
pH	4,0 - 5,0	4,23		
Related substances	Conform	Conform		
Impurity B	<=0,8	0,33	%	
Impurity C	<=0,2	0,12	%	
Impurity A	<=0,1	<0,05	%	
Impurity D	<=0,1	0,00	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=1,2	0,50	%	
Loss on drying	<=0,5	0,20	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Promethazine hydrochloride	99,0 - 101,0	100,62	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
Dorota Sutkowska  
Qualified Person

24-08-2020

Expiration: 31-10-2024

Conclusion: APPROVED

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