

Certificate of Analysis

Product name: Promethazini hydrochloridum
Batch number / Weight: 25L22-B03-018198 / 25 g
Analyzed according to: Ph. Eur. 12.1
Number of Analysis / Certificate no.: 25L22-B03 / QO0026232
Reference code / No.: V00724 / HPHCPT068

	Requirement	Result	Unit	Standard remark
Appearance	White or faintly yellowish, crystalline powder	Conform		
Identification	A, D	Conform		
Melting point	about 222	Conform	°C	
pH	4,0 - 5,0	4,42		
Related substances	Conform	Conform		
Impurity B	<=0,8	0,23	%	
Impurity C	<=0,2	0,12	%	
Impurity A	<=0,1	<0,05	%	
Impurity D	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	0,058	%	
Total impurities	<=1,2	0,41	%	
Loss on drying	<=0,5	0,08	%	
Sulfated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	99,0 - 101,0	100,57	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE lab

Release:

19-1-2026
 Ewelina Gadzinowska
 Qualified Person

Expiration: 30-9-2030

Conclusion: APPROVED

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