

Certificate of Analysis

Product name: Promethazini hydrochloridum
Batch number / Weight: 21E13-B02-215002 / 100 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or faintly yellowish, crystalline powder	Conform		
Melting point	about 222	222,8	°C	
Identification A	Conform	Conform		
Identification D	Conform	Conform		
pH	4,0 - 5,0	4,5		
Related substances	Conform	Conform		
Impurity B	<=0,8	0,24	%	
Impurity C	<=0,2	0,08	%	
Impurity A	<=0,1	<0,05	%	
Impurity D	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,2	0,32	%	
Loss on drying	<=0,5	0,04	%	
Sulphated ash	<=0,1	0,04	%	
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 (dried substance)	99,7	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

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 Qualified Person

15-09-2021

Expiration: 31-01-2026

Conclusion: APPROVED

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