

Certificate of Analysis

Product name: **Promethazini hydrochloridum**

Batch number / Weight: **23I20-B09-233799 / 10 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23I20-B09 / INS-23-8141**

Reference Code / No.: **V00724 / HPHCPR036**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or faintly yellowish, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification D	Conform	Conform		
Melting point	about 222	219,7	°C	
pH	4,0 - 5,0	4,53		
Related substances	Conform	Conform		
Impurity B	<=0,8	0,24	%	
Impurity C	<=0,2	0,2	%	
Impurity A	<=0,1	<0,05	%	
Impurity D	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	0,10	%	
Total impurities	<=1,2	0,55	%	
Loss on drying	<=0,5	0,05	%	
Sulphated ash	<=0,1	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Promethazine hydrochlori	99,0 - 101,0 (dried substance)	100,63	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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 Fagron PL lab

Release:
Dominika Sołtysik
Qualified Person

29-01-2024

Expiration: 30-06-2028

Conclusion: APPROVED

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