

## Certificate of Analysis

**Product name:** **Pseudoephedrini hydrochloridum**

**Batch number / Weight:** **21L23-B03-213224 / 250 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification A	+61,0 - +62,5	Conform		
Identification B	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear / colourless	Conform		
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	+61,0 - +62,5	+61,8		
Related substances	Conform	Conform		
Impurity A	<=1,0	0,051	%	
Any other impurity	<=0,5	0,00	%	
Sum of impurities other than A	<=1,0	0,05	%	
Loss on drying	<=0,5	0,08	%	
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 Pseudoephedrine hydroch	99,0 - 101,0	100,44	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
Ewelina Gadzinowska  
Qualified Person

28-03-2022

Expiration: 30-09-2026

Conclusion: APPROVED

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