

Certificate of Analysis

Product name: **Pseudoephedrini hydrochloridum**

Batch number / Weight: **21J18-B02-219316 / 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	+61,7	°	
Related substances	Conform	Conform		
Impurity A	≤1,0	0,0	%	
Any other impurity	≤0,5	0,0	%	
Sum of impurities other than A	≤1,0	0,0	%	
Loss on drying	≤0,5	0,1	%	
Sulphated ash	≤0,1	0,0	%	
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	99,4	%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

25-02-2022

Expiration: 31-10-2025

Conclusion: APPROVED

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