

## Certificate of Analysis

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

**Batch number / Weight:** **21L23-B03-217431 / 50 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	$\leq 1,0$	0,051	%	
Any other impurity	$\leq 0,5$	0,00	%	
Sum of impurities other than A	$\leq 1,0$	0,05	%	
Loss on drying	$\leq 0,5$	0,08	%	
Sulphated ash	$\leq 0,1$	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

12-04-2022

Expiration: 30-09-2026

Conclusion: APPROVED

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