

Certificate of Analysis

Product name: **Pseudoephedrini hydrochloridum**

Batch number / Weight: **22D07-B01-219931 / 50 G**

Analysed according to: **Ph. Eur.01/2008:1162**

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	+61,9		
Related substances	Conform	Conform		
Impurity A	≤1,0	<0,05	%	
Any other impurity	≤0,5	<0,05	%	
Sum of impurities other than A	≤1,0	0,00	%	
Loss on drying	≤0,5	0,11	%	
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	100,70	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Acetone		<5000	ppm	
Toluene		<890	ppm	

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

26-07-2022

Expiration: 31-12-2026

Conclusion: APPROVED

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