

Certificate of Analysis

Product name: **Phenylephrini hydrochloridum**

Batch number / Weight: **21F15-B10-217251 / 10 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	-43 - -47	Conform	°	
Identification C	Conform	Conform		
Identification E	Conform	Conform	%	
Appearance of solution	Clear and colourless	Conform		
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-43 - -47	-46	°	
Related substances	Conform	Conform		
Impurity C	<=0,1	0,00	%	
Impurity E	<=0,1	0,00	%	
Unspecified impurities	<=0,10 each	<0,05	%	
Total impurities	<=0,2	<0,05	%	
Sulphates	<=500	Conform	ppm	
Loss on drying	<=1,0	0,2	%	
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 Phenylephrine hydrochlori	98,5 - 101,0	100,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

03-02-2022

Expiration: 08-12-2023

Conclusion: APPROVED

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