

Certificate of Analysis

Product name: Phenylephrini hydrochloridum
Batch number / Weight: 21G17-B08-213220 / 5 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 hydrochloride	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:
 Agnieszka Pszczółka
 Qualified Person

06-12-2021

Expiration: 08-12-2023

Conclusion: APPROVED

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