

Certificate of Analysis

Productname: Phenylephrini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-184605B
Batchnumber: 20D01-F06-370683
Reference code / No.: 3283 / PEH-200305
Analysed according to: PH.EUR10.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	-43 - -47	Conform	°	Specific optical rotation
Identification C	Conform	Conform		IR-spectrum
Identification E	Conform	Conform		Chloride
Appearance of solution	Clear and colourless	Conform		2%m/V
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-43 - -47	-47	°	2%m/V; dried
Related substances	Conform	Conform		HPLC
Impurity C	<=0,1	n.d.	%	
Impurity E	<=0,1	<0,05	%	
Unspecified impurities	<=0,10 each	<0,05	%	
Total impurities	<=0,2	<0,05	%	
Sulphates	<=500	Conform	ppm	
Loss on drying	<=1,0	0,2	%	105 °C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Phenylephrine hydrochloride	98,5 - 101,0	100,7	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
 Paul Hofman
 Pharmacist - Qualified Person

07/30/20

Expiration: 01-2023

Conclusion: APPROVED

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