



Certificate of Analysis

Productname: Phenylephrini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-116880B
Batchnumber: 14H13-B02-302215 ✓
Reference code / No.: 3283 / PEH-140714C
Analysed according to: PH.EUR 8.2



Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or white crystals	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% <i>m</i> /V
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-43 - -47	-46	°	2% <i>m</i> /V; dried
Related substances	Conform	Conform		HPLC
Impurity C	<=0,1	<0,1	%	
Impurity E	<=0,1	<0,05	%	
Unspecified impurities	<=0,10 each	<0,10	%	
Total impurities	<=0,2	<0,2	%	
Sulphates	<=500	Conform	ppm	
Loss on drying	<=1,0	0,1	%	105 °C
Sulphated ash	<=0,1	0,0	%	
Residual solvents	CPMP/ICH/283/95	Conform		
Assay Phenylephrine hydrochloride	98,5 - 101,0	100,4	% <i>m</i> /m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

01/12/15

Expiration: 07-2017 ✓

Conclusion: APPROVED

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