



Certificate of Analysis

Productname: Phenylephrini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-101068B
Batchnumber: 12J19-B02-286042 ✓
Reference code / No.: 3283 / PEH-120815
Analysed according to: PH.EUR 7.5

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Projek: FUJS DRAGO
EA: H
Datum prijema: 9.12.13
Pregledal: MAROLT Robert, mag. farm., spec.
21 9/9
Datum pregleda: 10.11.2013

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	White	Conform		Chloride
Appearance of solution	Clear and colourless	Conform		2% <i>m</i> / <i>V</i>
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-43 - -47	-45,6	°	2% <i>m</i> / <i>V</i> ; dried
Related substances	Conform	Conform		HPLC
Impurity C, E	<=0,1 each	<0,05	%	
Unspecified impurities	<=0,10 each	<0,05	%	
Total impurities	<=0,2	<0,05	%	
Sulphates	<=500	Conform	ppm	
Loss on drying	<=1,0	0,0	%	105 °C
Sulphated ash	<=0,1	Conform	%	
Residual solvents	CPMP/ICH/283/95	Conform		
Assay Phenylephrine hydrochloride	98,5 - 101,0	100,6	% <i>m</i> / <i>m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Synergy Health.

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

05-11-13

Expiration: 10-2015 ✓

Conclusion: APPROVED

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