



Certificate of Analysis

Productname: Phenylephrini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-85006B
Batchnumber: 12B29-B07-271332 ✓
Reference code / No.: 2100 / 9002112
Analysed according to: PH.EUR 7.4

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: FUJS/DRAGO Datum prejema: 19.3.2014 Pregledal: MAROLT Robert, mag. farm., spec. Datum pregleda: 21.3.2013
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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> /V
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-43 - -47	-47,0	°	2% <i>m</i> /V; dried
Related substances	Conform	Conform		HPLC
Impurity C, E	<=0,1 each	n.d.	%	
Unspecified impurities	<=0,10 each	n.d.	%	
Total impurities	<=0,2	n.d.	%	
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		Data producer
Assay Phenylephrine hydrochloride	98,5 - 101,0	100,7	% <i>m</i> /m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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

21-06-12

Expiration: 02-2017 ✓

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.