

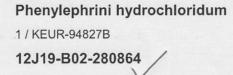
Certificate of Analysis

Productname: Number of analysis/Inspection Code:

Batchnumber:

Reference code / No.:

Analysed according to:



PH.EUR 7.5

Minar	MADENT d.o.o. ikova ul. 6 Jaribor
	FUJS DRAGO
	prejema: <u>4.7.201</u>
Pregledal	MAROLT Robert, mag. farm., spec.
Datum	pregleda: 40.7. 813

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or white crystals	Conform		
Identification A	-4347	Conform	o	Specific optical rotation
Identification C	Conform	Conform		IR-spectrum
Identification E	White	Conform		Chloride
Appearance of solution	Clear and colourless	Conform		2%m/V
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-4347	-45,6	0	2%m/V; 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	%m/m	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

17-04-13

Expiration: 10-2015

Conclusion: APPROVED

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