

## Certificate of Analysis

**Productname:** Clonidini hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-180626B  
**Batchnumber:** 19J08-F01-367577  
**Reference code / No.:** 2382 / 19006484  
**Analysed according to:** PH.EUR 9.8

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification D	White	Conform		Chloride
Appearance of solution	Clear / $\leq Y7$	Conform		5% $m/V$
pH	4,0 - 5,0	4,3		5% $m/V$
Related substances	Conform	Conform		HPLC
Unspecified impurities	$\leq 0,10$	$\leq 0,05$	%	
Total impurities	$\leq 0,2$	$\leq 0,05$	%	
Loss on drying	$\leq 0,5$	0,0	%	105 °C
Sulphated ash	$\leq 0,1$	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Clonidine hydrochloride	98,5 - 101,0	99,5	% $m/m$	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:  
dr. M.J. Vincenten - van Maanen  
Pharmacist - Qualified Person

02/21/20

Expiration: 04-2024

Conclusion: APPROVED

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