

## Certificate of Analysis

**Product name:** **Clonidini hydrochloridum**

**Batch number / Weight:** **22B22-B03-225799 / 500 MG**

**Analysed according to:** **Ph. Eur. 10.8**

**Number of analysis / Inspection Code** **22B22-B03-221021 / INS-22-6429**

**Reference Code / No.:** **V01504 / 21015379**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear / $\leq Y7$	Conform		
pH	4,0 - 5,0	4,42		
Related substances	Conform	Conform		
Unspecified impurities	$\leq 0,10$	nd	%	
Total impurities	$\leq 0,2$	0,00	%	
Loss on drying	$\leq 0,5$	0,08	%	
Sulphated ash	$\leq 0,1$	0,0049	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	98,5 - 101,0	99,90	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:  
Ewelina Gadzinowska  
Qualified Person

08-11-2022

Expiration: 20-11-2024

Conclusion: APPROVED

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