

Certificate of Analysis

Product name: **Natrii cyclamas**
Batch number / Weight: **21K15-B07-230245 / 100 G**
Analysed according to: **Ph.Eur.11.1**
Number of analysis / Inspection Code **21K15-B07 / INS-21-6017**
Reference Code / No.: **V01401 / CA452/20**

Tests	Requirement	Result	Unit	Standard remark
Appearance	or colourless crystals	Conform		
Identification A	(Almost) white, crystalline powder	Conform		
Identification E	Conform	Conform		
Appearance of solution	Conform	Conform	%	
pH	Clear / colourless	Conform		
Absorbance	5,5 - 7,5	6,81		
Impurity A	$\leq 0,10$	0,010		
Impurities B, C and D	$\leq 0,1$	Conform	%	
Sulphates	$\leq 1 / 10 / 1$	Conform	ppm	
Loss on drying	$\leq 0,1$	$< 0,1$	%	
Residual solvents	$\leq 1,0$	0,03	%	
Metallic residues	CPMP/ICH/82 260/06	Conform		Data producer
Assay Sodium cyclamate	CHMP/ICH/353369/2013	Conform		Data producer
TSE/BSE-statement:	98,5 - 101,0	100,49	%m/m	
	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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:
Dominika Soltysik
Qualified Person

14-06-2023

Expiration: 01-10-2025

Conclusion: APPROVED

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